

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023

OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 13(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report _____

Commission File Number 001-40377

Valneva SE

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

France

(Jurisdiction of incorporation or organization)

6 rue Alain Bombard

44800 Saint-Herblain, France

(Address of principal executive offices)

Thomas Lingelbach

Chief Executive Officer, Valneva SE

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44800 Saint-Herblain, France

Tel: +33 2 28 07 37 10

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing two ordinary shares, €0.15 nominal value per share	VALN	The Nasdaq Global Select Market
Ordinary shares, €0.15 nominal value per share	*	The Nasdaq Global Select Market*

** Not for trading, but only in connection with the registration of the American Depositary Shares.*

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer’s classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary Shares: 138,912,142 outstanding as of December 31, 2023**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that require a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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INTRODUCTION

Unless otherwise indicated in this Annual Report (this “Annual Report”), “Valneva,” “the company,” “our company,” “we,” “us” and “our” refer to Valneva SE and its consolidated subsidiaries.

“Valneva,” the Valneva logo, “IXIARO,” “JESPECT” “DUKORAL,” “IXCHIQ” and other trademarks or service marks of Valneva SE of any of our business partners appearing in this Annual Report are the property of Valneva, its subsidiaries or its business partners, as applicable. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend to use or display other companies’ trademarks and trade names to imply any relationship with, or endorsement or sponsorship of us by, any other companies.

Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements are presented in euros, and unless otherwise specified, all monetary amounts are in euros. All references in this Annual Report to “\$,” “US\$,” “U.S.\$,” “U.S. dollars,” “dollars” and “USD” mean U.S. dollars and all references to “€” and “euros” mean euros, unless otherwise noted. Throughout this Annual Report, references to ADSs mean American Depositary Shares or ordinary shares represented by such ADSs, as the case may be.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management’s beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report, the words “anticipate,” “believe,” “can,” “could,” “estimate,” “expect,” “intend,” “is designed to,” “may,” “might,” “plan,” “potential,” “predict,” “objective,” “should,” or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- timing and expected outcomes of clinical trials and pre-clinical studies, particularly with respect to the Phase 3 clinical trial of our Lyme disease vaccine candidate VLA15 as well as the ongoing Phase 2 and 3 clinical trials and the planned Phase 4 clinical trials of our approved chikungunya vaccine IXCHIQ;
- the likelihood, timing, and expected outcomes of regulatory filings and approvals, including, in the short-term, potential approval of the chikungunya vaccine candidate VLA1553 in other markets such as Europe, Canada, and Brazil and in the mid-term, potential filings and approvals of VLA15;
- our ability to successfully market IXCHIQ in the United States and other markets where it may be approved;
- our expectations and forecasts for sales of our approved products, particularly IXCHIQ, and estimates of market opportunity for our approved products and vaccine candidates;
- our ability to expand, develop, and advance our pipeline of product candidates;
- our ability to supply a sufficient quantity of our products and product candidates and to safely and effectively scale up our manufacturing capabilities, including at our Almeida manufacturing facility in Scotland;
- expected benefits of our approach to vaccine development, particularly with respect to our vaccine candidates in development;
- the potential safety and effectiveness of our vaccine candidates in development;
- the effects of any pandemics on our sales and operations, including our expectations and assumptions regarding the resumption of travel and the future demand for travel vaccines;
- the effectiveness and profitability of our collaborations and partnerships, our ability to maintain our current collaborations and partnerships and our ability to enter into new collaborations and partnerships;
- our expectations related to future milestone and royalty payments and other revenue under our collaborations and partnerships;
- our ability to meet our obligations under our various collaboration, partnership, and distribution arrangements;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to obtain, maintain, protect and enforce our intellectual property rights and proprietary technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- regulatory developments in the United States, Europe, and other countries, including regulatory developments relating to environmental, social, and governance issues;

- statements regarding future revenue, cash situation, hiring plans, expenses, capital expenditures, capital requirements, and stock performance; and
- other risks and uncertainties, including those listed in the section of this Annual Report titled “Item 3.D—Risk Factors.”

You should refer to the section of this Annual Report titled “Item 3.D—Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this Annual Report.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this Annual Report is generally reliable and is based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the section of this Annual Report titled “Item 3.D—Risk Factors.”

SUMMARY RISK FACTORS

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length in the section below titled “Risk Factors.” These risks include, among others, the following:

- We have incurred and anticipate that we may continue to incur significant operational losses over the next several years and may never achieve or maintain profitability.
- Our future success is substantially dependent on the successful clinical development, regulatory approval, and commercialization of our product candidates in a timely manner. This risk is heightened in the short-term given that we have applied for regulatory approval of our chikungunya vaccine candidate VLA1553 in Europe, Canada, and Brazil and our Lyme disease vaccine candidate is undergoing Phase 3 clinical trials. If we are not able to obtain the regulatory approvals we target, whether as a result of clinical trials results or other factors, we will not be able to commercialize our product candidates according to our plans or at all, and our ability to generate product revenue will be adversely affected. Delays in clinical development may also lead to delays in our expected regulatory and commercial timelines, which could materially impact our business plans and our financial projections.
- Our products are aimed at diseases that largely threaten travelers. If international travel is substantially disrupted, as it was at the height of the COVID-19 pandemic or may be in future due to a similar event, this will significantly adversely affect the sale of these vaccines. Additionally, future outbreaks of disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites, or other business operations, could materially affect our operations globally and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs, or other third parties with whom we conduct business.
- We require ongoing funding to finance our operations. If we are unable to raise capital to complement the Company’s cash when needed, we could be forced to delay, reduce, or terminate certain of our planned investments, including in development programs or other parts of our operations.
- Our future growth depends on continuing to build our pipeline of product candidates. If we are unable to progress existing clinical-stage and pre-clinical stage product candidates or to initiate new clinical or pre-clinical programs, this could have a material impact on our business plans and financial projections.
- We depend upon our existing collaboration partner, Pfizer, and other third parties to advance our business and provide other key services. If we are unable to maintain such existing agreements or enter into additional arrangements as needed, or if such third parties do not provide such services as anticipated, our business could be adversely affected.
- We operate in a highly regulated industry and may fail to comply with applicable regulatory obligations, including after product approval is obtained.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- We rely primarily on our manufacturing facilities and rely in part on third parties’ manufacturing facilities as the source of manufacturing for our products and for certain of our product candidates.
- The terms of our financing arrangements place restrictions on our operating and financial flexibility.
- We may face competition, and our competitors may have significantly greater resources and experience, which may negatively impact our commercial opportunities.
- We are dependent on single source suppliers for some of the components and materials used in our products.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- If we are unable to maintain effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence, and depress the market price of our securities.
- Our information systems and data, and those of third-parties connected to us, are vulnerable to cyber attacks and security breaches which could have a material impact on our operations, reputation, and/or financial results.
- The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States. As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See “Special Note Regarding Forward-Looking Statements” above.

Risks Related to Our Financial Position and Capital Needs

We have incurred and anticipate that we may continue to incur significant operational losses over the next several years and may never achieve or maintain profitability.

We have previously incurred significant net losses. Our net loss was €101.4 million, €143.3 million and €73.4 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated net loss of €551.7 million. We expect to continue to incur significant expenses and we may incur substantial operating losses over the next several years. Since inception, we have devoted a significant amount of our efforts to identifying, researching and conducting pre-clinical and clinical activities of our product candidates, building our manufacturing capabilities, building our commercial and sales infrastructure, organizing and staffing our company, business planning, raising capital, and establishing our intellectual property portfolio. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of our product candidates, including the Phase 4 clinical trials of our approved product IXCHIQ;
- initiate, conduct and complete any ongoing, anticipated, or other future pre-clinical studies and clinical trials, which may be subject to changes in design and cost;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- commercialize any current or future product candidate for which we may obtain or have recently obtained marketing approval, particularly IXCHIQ;
- invest in our manufacturing facilities;
- seek to discover and develop additional product candidates, including via partnerships or asset acquisition;
- maintain, protect and expand our intellectual property portfolio;
- hire additional sales, clinical, regulatory, administrative, and scientific personnel;
- add operational, financial, and management information systems, legal entities, and personnel, including personnel to support our product development and current and future commercialization efforts;

- experience delays or interruptions to pre-clinical studies, clinical trials, our receipt of services from third-party service providers, or our supply chain due to other events, including military conflicts in Ukraine and Israel;
- market and distribute vaccines for new third parties;
- take steps to comply with new regulatory obligations, including those relating to sustainability such as the European Corporate Sustainability Reporting Directive (CSRD), the European Corporate Sustainability Due Diligence Directive (CSDDD), and the climate disclosure rules adopted by the U.S. Securities and Exchange Commission in March 2024; and
- incur ongoing costs associated with operating as a public company on both Euronext Paris and Nasdaq.

Our ability to be profitable in the future will largely depend on our ability to generate sales of our commercial products and to obtain regulatory approval for and commercialize our product candidates. We have historically been substantially dependent on sales of two commercial products, DUKORAL and IXIARO, for revenue. Our chikungunya vaccine IXCHIQ has been approved in the United States but has not yet been approved in Europe or Canada, and we have only recently begun commercial sales of IXCHIQ. We anticipate that if the Phase 3 trial of our Lyme disease vaccine candidate is successful, Pfizer will apply for approval in 2026. Unless and until we obtain the regulatory approvals required to commercialize our product candidates in line with our plans, the likelihood and amount of our future operational losses will depend, in part, on the successful manufacturing and commercialization of our approved products, the pace and amount of our future expenditures, and our ability to obtain funding through milestone or royalty payments under license and collaboration agreements, equity or debt financings, strategic collaborations, and government grants and tax credits. Additionally, our future revenues will depend upon the size of any markets in which our products or product candidates have received approval, and market acceptance, reimbursement from third-party payors, and market share. For example, although we received several regulatory approvals for VLA2001, our vaccine against the SARS-CoV-2 virus causing COVID-19, we were not able to generate sales in our target markets and ultimately discontinued the product. We expect that our main sources of income for the near- and medium-term will be revenue from sales of our approved products and third-party products, revenue from licensing and service agreements, and grants.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve or maintain profitability. If we are required by regulatory authorities to perform studies in addition to those expected (for example, the Phase 4 clinical trials of IXCHIQ which were mandated by the FDA in connection with approval of IXCHIQ in the United States), or if there are any delays in the initiation and completion of our clinical trials, particularly the Phase 3 clinical trial for our Lyme disease vaccine candidate, or any delays in the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

We market our products primarily to travelers to regions where the targeted diseases are endemic. If international travel is substantially disrupted, this will significantly adversely affect the sale of these vaccines.

We market IXCHIQ, DUKORAL and IXIARO primarily to travelers to particular regions. During the COVID-19 pandemic, travel significantly decreased worldwide, and sales of DUKORAL and IXIARO decreased significantly in 2020 and 2021, adversely impacting our financial results. While international travel has resumed significantly, if another disruption causes a substantial decrease in international travel, our revenues will be significantly adversely affected, and we may not be able to finance our operations and continue the development of one or more of our vaccine candidates without additional financing.

Sales of DUKORAL and IXIARO and, in the future, IXCHIQ, may also be impacted by competition from other approved vaccines, as described further in these risk factors and in Item 4 of this Annual Report.

We may require additional funding to finance our operations and achieve our strategic ambitions. If we are unable to raise capital when needed, we could be forced to delay, reduce, or terminate certain of our planned investments, including development programs or other parts of our operations.

As of December 31, 2023, we had total assets of €460.1 million, including cash and cash equivalents of €126.1 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic and rapidly evolving nature of our business. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially viable. To date, we have funded a substantial portion of our operations through sales of equity securities, including our U.S. initial public offering and European private placement in May 2021 and our global offerings in November 2021 and October 2022, as well as an equity subscription agreement with Pfizer in June 2022 for €90.5 (\$95) million. We have also received substantial funding through upfront payments from collaboration and research agreements and the Financing Agreement with Deerfield and OrbiMed, described further below. Additionally, in February 2024, we sold the Priority Review Voucher received in connection with the approval of IXCHIQ for \$103 million. We may need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. We

expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding, and marketing and distribution arrangements, as well as other collaborations, strategic alliances, and licensing arrangements, or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing pre-clinical studies and clinical trials of our product candidates, particularly the Phase 3 clinical trial of our Lyme disease vaccine candidate and the Phase 4 clinical trials of our approved product IXCHIQ;
- the costs, timing, and outcome of regulatory review and approval of our product candidates, including the review of VLA1553 by the European Medicines Agency, Health Canada and Anvisa;
- the scope, progress, results, and costs of pre-clinical development, laboratory testing, and clinical trials of other product candidates that we may pursue, including the cost of acquiring other product candidates;
- our ability to establish and maintain collaboration, license, grant, and other similar arrangements, such as our partnership with Pfizer, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty, or other payments due thereunder;
- the costs and timing of current and future commercialization activities, including product manufacturing, marketing, sales, and distribution, for our current products and any of our product candidates for which we receive marketing approval;
- the revenue received from commercial sales of our products and any product candidates for which we receive marketing approval, and the impact of any future disruptor of international travel on such revenues;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- any expenses needed to attract, hire, and retain skilled personnel;
- the costs of operating as a public company in both France and the United States;
- the extent to which we acquire or in-license other companies' product candidates and technologies; and
- the rate of inflation or other market factors that impact our costs.

Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for our product candidates in development. In addition, our product candidates, if approved, may not achieve commercial success. For example, although we received several regulatory approvals for VLA2001, our vaccine against the SARS-CoV-2 virus causing COVID-19, we were not able to generate sales in our target markets and ultimately discontinued the product. Accordingly, we may need or choose to seek additional financing to achieve our business objectives.

Global financial markets have been negatively impacted as a result of the COVID-19 pandemic and ongoing military conflicts. If these disruptions persist or deepen, or if other global events have a significant impact on the global financial markets, we could experience an inability to access additional capital or an increase in our costs of borrowing, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. Additionally, investors are increasingly using sustainability and ESG criteria to evaluate possible investments, and we cannot guarantee that we will be able to implement effective sustainable practices that will make us attractive for such investors, in a timely fashion or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or altogether terminate certain of our research and development programs or future commercialization efforts, which may adversely affect our business, financial condition, results of operations, and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting on the basis of a report from the Board of Directors. In addition, the French Commercial Code imposes certain limitations on our ability to price certain offerings of our share capital without preferential subscription rights (*droit préférentiel de souscription*), which limitation may prevent us from successfully completing any such offering.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares or the ADSs to decline. The sale of additional equity or convertible securities would dilute our shareholders. We may seek funds through arrangements with collaborative partners or otherwise at an earlier stage of product development than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates at an earlier stage of development or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, prospects, financial condition, and results of operations.

The terms of our financing arrangements place restrictions on our operating and financial flexibility.

In February 2020, we entered into a debt financing agreement, or the Financing Agreement, with Deerfield and OrbiMed. The loans bear interest at 9.95% that, due to the quarterly interest calculation method applied, results in an aggregate annual interest paid of 10.09%. As of December 31, 2023, we had \$200 million (€180.0 million) drawn down in four tranches under the Financing Agreement, including an additional \$100 million (€90.0 million) made available to us in an amendment signed in August 2023. This additional loan will mature in the third quarter of 2028, and repayments begin in the first quarter of 2027. The original loan of \$100 million will mature in the first quarter of 2027, and repayments begin in the first quarter of 2026.

The Financing Agreement contains covenants for minimum revenue and liquidity which are currently set to €115 million and €35 million, respectively. As a result of deferred recognition of revenues and the effects of COVID-19 on product sales, we were previously at risk of not meeting the minimum revenue covenant and have amended these covenants several times since 2020. If our consolidated net revenues (excluding grants) or our liquidity were to fall below the amounts required, this would constitute an event of default that could trigger various consequences. For example, the interest rate on the loans could increase by up to 10 additional interest points if the duration of the default is longer than 15 days, or we could be required to immediately repay the full principal amount of the loans, including all fees and interest associated with repayment.

Compliance with these covenants under the Financing Agreement may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders. For example, if we fail to meet our minimum liquidity covenants and we are unable to raise additional funds or obtain a waiver or other amendment to the Financing Agreement, we may be required to delay, limit, reduce, or terminate certain of our clinical development efforts. In addition, if we were unable to pay the full amount due in case of certain events of default, our lenders could exercise their rights to take possession and dispose of the collateral, which includes substantially all of our intellectual property, securing the Financing Agreement for their benefit. Our business, financial condition, and results of operations could be substantially harmed if this occurs.

Additionally, we announced in February 2022 that Valneva Scotland had received two grants worth up to £20 million (approximately €23.9 million) from Scottish Enterprise, Scotland’s national economic development agency, to support research and development relating to the manufacturing processes of our COVID-19 vaccine and our other vaccine candidates. Following the termination of our COVID-19 vaccine program, in May 2023 we amended the grant relating to this program to reduce the available funding by £0.7 million and to adjust how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. Valneva SE has provided a parent guarantee in connection with these grants, and if we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date. As of the date of this Annual Report, we have received €11.1 million (£9.6 million) of grant funds from Scottish Enterprise.

Risks Related to the Development and Commercialization of Our Product Candidates

Our future success is substantially dependent on the successful clinical development, regulatory approval, and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be adversely affected. Delays in clinical development may also lead to delays in our expected regulatory and commercial timelines, which could materially impact our business plans and our financial projections.

We have invested a significant portion of our time and financial resources in the development of our product candidates. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We may face unforeseen challenges in our product development strategy, and we can provide no assurances that our product candidates will be successful in clinical trials, will ultimately receive regulatory approval from any or all of the agencies from which we seek such approval, and will be commercially successful in their target markets. Generally, failure to develop a vaccine that we can successfully commercialize could result in the total loss of our investment in its development and consequently could have a significant impact on shareholder value.

Our business is particularly dependent on our ability to obtain additional regulatory approvals for IXCHIQ, our chikungunya vaccine, on the timelines we expect. The FDA approved IXCHIQ on November 9, 2023, and review by Health Canada, the EMA and Anvisa (in Brazil) is ongoing. If the decisions of these agencies regarding the approval of IXCHIQ is delayed beyond our expectations or is negative, it would have a significant impact on our business plans and our results of operations. A delay in additional regulatory approvals could occur if, for example, the EMA revokes the accelerated assessment of VLA1553 as a result of our failure to provide requested information according to the EMA’s timelines or for other reasons. In addition, the U.S. Centers for Disease Control’s Advisory Committee for Immunization Practices, or ACIP, issued recommendations relating to vaccination against chikungunya in February 2024. The scope of the recommendation is narrower than the label for IXCHIQ in the United States. There is a high reliance on shared clinical decision-making for IXCHIQ vaccination, and decisions to vaccinate depend on high awareness of risk factors on both the traveler and healthcare practitioner sides. The ACIP recommendation could decrease the demand relative to a broader recommendation for vaccination and could impact IXCHIQ’s commercial success.

While we have obtained regulatory approval in major markets for four of our products, we may not be able to obtain regulatory approval of the product candidates we are currently developing or may seek to develop in the future, at all, in all of the desired markets, for all of the desired labels, or within the timelines expected. Neither we nor any current or future collaborator is permitted to market any product candidates in any geography until we or our collaborators receive

regulatory approval from the applicable regulatory agency. The time required to conduct clinical trials and obtain approval or other marketing authorizations from regulatory authorities is unpredictable, typically takes many years, and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Prior to obtaining approval to commercialize any product candidate in a particular geography, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the applicable regulatory authority, that such product candidate is safe and effective for its intended uses. Results from pre-clinical studies and clinical trials can be interpreted in different ways. Even if we believe that the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the regulatory authorities. Approval by one regulatory authority does not guarantee approval by another regulatory authority, with the same scope or at all, on the basis of the same data. Additionally, regulatory authorities may also require us to conduct additional pre-clinical studies or clinical trials for our product candidates prior to approval or may object to elements of our clinical development program, requiring their alteration. Furthermore, in some jurisdictions such as the EU, initiating Phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and/or the EMA. If we do not obtain such approval, our ability to conduct clinical trials and obtain marketing authorizations may be impaired, and our business may be adversely impacted.

Of the large number of products in development, only a small percentage successfully complete regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approvals or marketing authorizations to market our product candidates, which would significantly harm our business, financial condition, results of operations, and prospects.

Even if we eventually complete clinical testing and receive approval of our product candidates, regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. For example, the FDA's approval of IXCHIQ is conditioned upon our completion of two Phase 4 clinical trials. The timely completion of these trials will require successful coordination with regulatory agencies, who will need to approve the proposed plans, and with local partners. Additionally, execution of the Phase 4 clinical trials will require approval of IXCHIQ in Brazil. Regulatory authorities may also provide approval for a product candidate for a more limited indication or patient population than we originally request and may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay, inhibit, or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, regulations and policies may be added or revised in the EU, the U.S., or other jurisdictions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain regulatory approvals, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we may have obtained.

Successful commercialization of our products depends on numerous factors, some of which may be outside of our control.

Successful commercialization of newly approved products, such as IXCHIQ, will depend on a number of factors, including:

- Developing the commercial organization to support commercialization of the product or entering into partnerships for commercialization in certain geographies;
- Establishing a commercially viable pricing structure;
- Obtaining approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities; and
- Generating knowledge of and demand for our products.

Successful commercialization of any of our products depends on various factors, including continued demand for the product, the ability of us or our third-party manufacturing partners to manufacture sufficient quantities of the product in response to demand, and the cost of the product. For example, we have experienced shortages of IXIARO and DUKORAL relative to the demand, resulting in losses of potential sales.

Additionally, our current marketing strategy includes partnering with third parties for the commercialization of approved products in certain geographies, and we cannot guarantee that we will be able to enter into or maintain such relationships. For example, our partnership with Bavarian Nordic for the distribution of IXIARO and DUKORAL in Germany, one of our key markets, will terminate at the end of 2025.

If we are unable to successfully commercialize our product candidates, including through contracting with third parties, we may not be able to generate sufficient revenue to continue our business.

Success in pre-clinical studies or earlier clinical trials may not be indicative of results in future clinical trials, and we cannot assure you that any ongoing, planned, or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in pre-clinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Pre-clinical and proof-of-concept studies and Phase 1 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results of clinical trials and initial or continued regulatory approval. We cannot guarantee that our ongoing clinical trials will produce data consistent with those of prior trials, nor can we guarantee that positive data from the VLA1553-321 clinical trial in adolescents will result in an expansion of IXCHIQ's approval in the U.S. to allow vaccination of adolescents. There can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols, and the rate of dropout among clinical trial participants. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain or maintain regulatory approval, despite positive results in pre-clinical studies, successful advancement through earlier clinical trials, or initial data that we may publish, which may materially change as clinical trials progress.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. If we conduct clinical trials with a small number of subjects, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of subjects. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we may be unable to design and execute a clinical trial to support regulatory approval, including conditional approval or emergency use authorization for any given current or future product candidate. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving positive results in pre-clinical testing and earlier clinical trials. Data obtained from pre-clinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy or results of audits of clinical trial partners by regulatory authorities during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations, and prospects.

Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials that could delay or prevent the commercialization of our product candidates.

We may not commercialize, market, promote, or sell any product candidate in any geography without obtaining marketing approval from the relevant regulatory authority, and we may never receive such approvals. The time required to obtain approval by any regulatory authority is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, following Pfizer's decision in February 2023 to discontinue approximately half of the participants then enrolled in the Phase 3 trial of our Lyme disease vaccine candidate as a result of violations of Good Clinical Practice, or GCP, at certain trial sites run by a third party, the target for submission of a BLA shifted from 2025 to 2026. Timely completion of the ongoing Phase 3 trial will depend on timely administration of the booster vaccination to participants in the first cohort and of the primary vaccination to participants in the second cohort. Any delays of clinical trials would lead to delays in the regulatory approval process, increase development costs, and could lead to a negative perception of Valneva or the product candidate.

A failure of one or more clinical trials can occur at any stage of testing. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following:

- inability to generate sufficient pre-clinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on the design or implementation of our clinical trials, or any modification thereto;

- regulators or institutional review boards and ethics committees may prevent us or our investigators from commencing a clinical trial or conducting a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays or failures by us or our manufacturing partners to comply with current GCP, good manufacturing practices, cGMP, or other applicable regulations;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for follow-up, or we may fail to recruit suitable subjects to participate in a trial;
- difficulty collaborating with investigators;
- failure by our CROs, partners, other third parties, or us to adhere to clinical trial requirements;
- negative or inconclusive results of clinical trials of our product candidates;
- imposition of a clinical hold by regulatory authorities, as a result of a serious adverse event or concerns with a class of product candidates, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, after review of an investigational new drug application, or IND, or IND amendment, after an application for the authorization of a clinical trial or related amendment, or equivalent application or amendment, or after the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- decisions made by us or requirements imposed by regulators to conduct additional clinical trials or abandon product development programs; or
- disruptions caused by man-made or natural disasters, public health pandemics or epidemics, global instability, or other business interruptions.

In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations, and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, vary, or suspend their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS, or foreign equivalent;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- become subject to product liability litigation; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. The risk of increased development costs is more pronounced for our Lyme disease vaccine candidate given that it is currently in Phase 3 clinical trials. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, need to be restructured, or be completed on schedule, if at all. Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources.

Regulatory authorities have discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product

candidates are promising, such data may not be sufficient to support approval by any regulatory authority. Further, we or our partners, the competent authorities of individual EEA countries, the FDA or other regulatory authorities, or an institutional review board or ethics committee may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current GCP regulations or equivalent regulations in the EEA or other foreign countries, that we are exposing participants to unacceptable health risks, or if the relevant authorities find deficiencies in our INDs or our applications for the authorization of clinical trials, respectively, or in the conduct of these trials. Moreover, we may not be able to file INDs or applications for the authorization of clinical trials to commence additional clinical trials on the timelines we expect because our filing schedule is dependent on further pre-clinical and manufacturing progress. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult, or rendered impossible by multiple factors outside our control.

Identifying and qualifying subjects in a timely manner to participate in our clinical trials is critical to our success. We may encounter difficulties in enrolling subjects in our clinical trials, and such difficulties may delay or prevent development, approval, and commercialization of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of subjects to complete any of our trials. Subject enrollment and retention in clinical trials depends on many factors, including the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing vaccines already in the market, and ongoing clinical trials of competing vaccine candidates for the same indication, the proximity of subjects to clinical sites, and the eligibility criteria for the trial. In addition, enrollment and retention of subjects in clinical trials could be disrupted by man-made or natural disasters, public health events such as pandemics, or other business interruptions. In addition, public perception of a specific clinical trial or of vaccine safety issues may adversely influence willingness of subjects to participate in clinical trials. Additionally, granted emergency use authorizations, or EUAs, may saturate the marketplace prior to our advancement or commercialization, as allowed, for any of the vaccine areas in which we are developing products.

Any negative results we or other study sponsors may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same product candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our current and future clinical trials and, while we enter into agreements governing their services, we will be limited in our ability to ensure their actual performance, including adherence to GCP, and any issues with their performance could have substantial negative effects on our clinical development programs.

The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to successfully develop additional vaccines for other diseases.

A core element of our business strategy, particularly in 2024, is to expand our product pipeline. Following the FDA's approval in November 2023 of the BLA for our chikungunya vaccine and given that the Phase 3 clinical trial of our Lyme disease vaccine candidate is ongoing, we are evaluating the possibilities for the other clinical and preclinical candidates in our pipeline as well as the possibilities for acquiring candidates from third parties or partnering with third parties to co-develop candidates. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development, approved products, or commercial revenue for many reasons, including the following:

- the methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- diseases we may target may cease to be a public health concern;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community, or third-party payors.

We have limited financial, manufacturing, and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and

commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business and shareholder value may be harmed.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their physician. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. If subjects in our clinical trials experience any side effects, and if regulatory authorities determine that such side effects are being caused by our vaccine candidates, they may require additional testing to confirm these determinations.

In addition, it is possible that as we test our product candidates in larger, longer, and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts, and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, financial condition, results of operations, reputation, and prospects.

If the market opportunities for our products and product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our efforts on commercialization of our approved products for prevention of chikungunya, Japanese encephalitis, and cholera. Our estimated market opportunity, pricing estimates, and available coverage and reimbursement may differ significantly from the actual market addressable by our products and product candidates. Our estimates with respect to market opportunity are based on our beliefs, assumptions, and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting, and the number of patients may turn out to be lower than expected. In addition, the disease for which we are developing a product vaccine may cease to be a public health concern. Likewise, the potentially addressable patient population for each of our products or product candidates may be limited or may not be receptive to receiving our vaccines or vaccine candidates, and new patients may become increasingly difficult to identify or access. This may be due in part to reputational challenges that the vaccine industry is facing related to the growing momentum of the anti-vaccine movement in some regions or to a distrust of vaccines against certain diseases or of the adjuvants contained in our vaccines. For example, there has been some negative public perception of Lyme disease vaccines as a result of the Lyme disease vaccine LYMERix, which was marketed by Smith Kline Beecham Biologicals and discontinued due to lack of market access and safety concerns, although its benefit/risk profile was confirmed by an FDA advisory committee even post-approval. If the market opportunities for our products or product candidates are smaller than we estimate, this could have an adverse effect on our business, financial condition, results of operations, and prospects. Similarly, if the estimates and forecasts of investment analysts regarding the market for one of our product candidates differ significantly from the actual addressable market, there could be an impact on Valneva's valuation and on the trading price of our ordinary shares and ADSs.

We may face competition, and our competitors may have significantly greater resources and experience, which may negatively impact our commercial opportunities.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial and technical resources as well as experience and expertise in:

- research and development;
- pre-clinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- management of the organization and the execution of the organization's strategy;
- the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;

- an organization’s intellectual property portfolio;
- the capabilities of an organization throughout the product pipeline, from target identification and validation to discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development, and commercialization activities.

Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd, Sanofi Pasteur, SA, Pfizer Inc. and AstraZeneca, among others, compete in the general vaccine market. In particular, these companies may have greater experience and expertise in: securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products. Smaller or early-stage companies and research institutions also may prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies and research institutions develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. If any of our competitors succeed in obtaining approval from regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, or if the scope of approval for a competing product is broader than an approval granted for our product, our commercial opportunity could be significantly reduced. Mergers and acquisitions, including of specific assets, in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors and in changes to the competitive landscape in regions where we market and distribute our products.

We are aware of companies with competing products or product candidates for Japanese encephalitis (such as Substipharma’s IMOJEV) and cholera (such as Bavarian Nordic’s Vaxchora, which is currently available in the U.S. and a limited number of European markets), each as described further in Item 4 of this Annual Report. If and as these vaccines become available in the markets in which we compete, sales of our vaccines will be adversely affected. Competition is the primary factor affecting our prices outside the United States. We are also aware of companies with active vaccine development programs for Lyme disease and chikungunya. Even if a manufacturer obtains an EUA or regulatory approval for a vaccine, it is likely that competitors will continue to work on new products that could be more efficacious and/or less expensive. Vaccines under development by competitors, including development programs of which we are not aware, may be more effective or further along in the development and regulatory approval process than our vaccine candidates. Even if our vaccine candidates receive EUA or regulatory approval, they may not achieve or maintain significant sales if other, more effective vaccines under development by our competitors are also approved.

In order to compete effectively, we will have to make substantial investments in development, testing, manufacturing, and sales and marketing or partner with one or more established companies in one or more of these areas. We may not be successful in gaining significant market share for any approved product candidate and may not continue to be successful maintaining or gaining market share for our currently marketed products. Our technologies and vaccines also may be rendered obsolete or non-competitive as a result of products introduced by our competitors to the marketplace more rapidly and at a lower cost.

Even if any product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors, government officials, or others in the medical community necessary for commercial success.

Even if any product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors, government officials, and others in the medical community. For example, our COVID-19 vaccine received four marketing approvals but ultimately was not a commercial success due to lack of interest from potential government purchasers. Further, recommendations from regulatory bodies can affect market acceptance of approved products. For example, in the United States, ACIP develops vaccine recommendations for use, as do comparable agencies around the world. ACIP uses working groups that gather, analyze, and prepare scientific information to develop its recommendations, and vaccines that receive a preferred recommendation from ACIP are widely adopted. In February 2024, ACIP issued recommendations relating to vaccination against chikungunya that included recommendations for the use of IXCHIQ that were narrower than IXCHIQ’s label in the United States. This recommendation may decrease the demand for IXCHIQ and impact its commercialization. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue, which would limit the return on our investment and may prevent us from becoming profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative vaccines and therapies;
- the existence of alternative therapies;
- the public perception of new therapies and the reputational challenges that the vaccine industry is facing related to the growing momentum of the anti-vaccine movement in some regions;
- the prevalence and severity of adverse side effects;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the efficacy, safety profile, and potential advantages compared to alternative vaccines and therapies;
- the effectiveness of sales and marketing efforts;

- the cost of the vaccine in relation to alternative vaccines and therapies;
- our ability to offer such product for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- receiving recommendations for use from ACIP and comparable foreign regulatory and advisory bodies;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with medications.

Our efforts to educate physicians, patients, third-party payors, and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complex and distinctive nature of our product candidates. Because we expect sales of our product candidates, if approved, to generate a significant portion of our revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business.

Our current products are, and any future product candidates for which we obtain regulatory approval for will be, subject to ongoing regulatory oversight.

Our currently approved products, and any future products we commercialize, if any, are subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping, applicable product tracking and tracing requirements, and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS or foreign equivalents or contain requirements for potentially costly post-marketing testing, including Phase 4 trials (such as those required for IXCHIQ), and surveillance to monitor the quality, safety, and efficacy of the product. Such regulatory requirements may differ from country to country depending on where we receive regulatory approval. Regulators may also subsequently limit or revise the indicated uses for which the product was originally marketed, which could significantly impact our sales. For example, the agency supervising pharmaceutical products in Canada, which is our principal market for DUKORAL, contacted us in July 2021 to request further information in support of DUKORAL's indications and labeling. While this matter has been resolved, if DUKORAL's indications or labeling were to change significantly in Canada or elsewhere in the future, this could have a significant negative impact on our sales which in turn could result in the product no longer being economically viable.

In addition, biopharmaceutical manufacturers and their facilities are subject to ongoing review and periodic inspections by the competent authorities of individual EEA countries, FDA, or other comparable regulatory authorities for compliance with applicable regulatory requirements, including with cGMP requirements and with commitments made in the application for regulatory approval. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or if a regulatory authority disagrees with the promotion, marketing, or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility, or us. These restrictions could include requesting a recall or requiring withdrawal of the product from the market, suspension of manufacturing, or suspension, variation or withdrawal of the related approval.

If we fail or if a third party fails to comply with applicable regulatory requirements for our products or any of our product candidates that receive regulatory approval in the future, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil, or criminal penalties or monetary fines;
- suspend, vary, or withdraw regulatory approval;
- suspend or vary any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign application for regulatory approval or any supplements thereto submitted by us or our partners;
- restrict the labeling, distribution, marketing, or manufacturing of the product or clinical trial material;
- seize or detain the product or otherwise require the withdrawal of the product from the market or product recalls;
- require conduct of additional post-marketing studies or clinical trials;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations, and prospects.

Regulatory authorities’ policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. In addition, we cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action in any geography where we market a product.

It is difficult to predict how these executive actions, including any executive orders, will be implemented and the extent to which they will affect the regulatory authorities’ ability to exercise their authority. If these executive actions impose constraints on the regulatory authorities’ ability to engage in oversight and implementation activities in the normal course, our business, financial condition, results of operations, and prospects may be negatively impacted.

We may be liable if regulatory enforcement agencies determine we engaged in the off-label promotion of our products, pre-approval promotion of our product candidates, or dissemination of false or misleading labeling, advertising, or promotional materials.

Our promotional activities, materials, and training methods must comply with applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the off-label use of our products or that omit material facts or make false or misleading statements about the safety or efficacy of our products. We are responsible for training our marketing and sales force against promoting our product candidates for off-label use. However, in the United States, the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. Therefore, physicians may use our products off-label if deemed appropriate in their independent medical judgment. Certain other countries also do not restrict or regulate a physician’s choice of treatment within the practice of medicine. A regulatory agency also could conclude that a claim is misleading if it determines that there are inadequate non-clinical and/or clinical data supporting the claim, or if a claim fails to reveal material facts about the safety or efficacy of our products. Additionally, a regulatory agency could claim that we have engaged in pre-approval promotion of a product candidate. Although our policy is to refrain from statements that could be considered off-label promotion of our products, pre-approval promotion of our product candidates, or false or misleading claims, a regulatory agency could disagree with the manner in which we advertise and promote our products or communicate about our product candidates. If a regulatory agency in the United States or certain other countries determines that our promotional activities or advertising materials promote an off-label use or make false or misleading claims, or that our communications about product candidates constitute pre-approval promotion, it could request that we modify our promotional materials, training content, or other communications or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. In the case of a claim of pre-approval promotion, these consequences could result in a delay in the review of any dossiers we have submitted for regulatory review and approval. Equivalent limitations and penalties are provided in the EU, both at the EU level and at the national level in individual EU Member States.

In the United States, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which may lead to costly penalties and may adversely impact our business. Recent court decisions in the United States have impacted FDA’s enforcement activity regarding off-label promotion in light of First Amendment considerations such that companies may share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling; however, there are still significant risks in this area, in part due to the potential for False Claims Act exposure.

In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

If we are unable to maintain and expand our sales and marketing capabilities on our own or with others, we may not be successful in increasing sales of our current products and commercializing future products, if approved.

To increase sales of our current products and third-party products pursuant to distribution agreements, as well as successfully commercialize any product candidate that may result from our development programs, we will need to maintain and continue to build out our sales and marketing capabilities, either on our own or with others. The continued development of our sales and marketing team will be expensive and time-consuming and could delay any product launch. We compete with many companies that currently have extensive, experienced, and well-funded marketing and sales operations to recruit, hire, train, and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train, and retain any of our own marketing and sales personnel. If we are unable to sustain and expand our sales and marketing team, we may be unable to compete successfully against these more established companies. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations.

Our future growth depends, in part, on our ability to penetrate multiple markets, in which we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to continue to commercialize our products and, if approved, our product candidates in markets in Europe, the United States and other countries where we maintain commercialization rights. As we continue to commercialize our products and begin to commercialize our product candidates, if approved, in multiple markets, we are subject to additional risks and uncertainties, including:

- foreign currency exchange rate fluctuations and currency controls;
- economic weakness, including inflation and rising interest rates, or political instability in particular economies and markets;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- the burden of complying with complex and changing regulatory, tax, accounting, and legal requirements, many of which vary between countries;
- different medical practices and customs in multiple countries affecting acceptance of drugs in the marketplace;
- differing payor reimbursement regimes, governmental payors, or patient self-pay systems and price controls;
- tariffs, trade barriers, import or export licensing requirements, or other restrictive actions;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- reduction or loss of protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics; and
- becoming subject to the different, complex, and changing laws, regulations, and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties, and regulations.

In addition, due to the conflict between Russia and Ukraine, the United States, the European Union, and other jurisdictions have imposed various sanctions against Russia and Belarus. The military conflict and the retaliatory measures that have been taken, or could be taken in the future, by the U.S., the European Union, and other jurisdictions against Russia and Belarus have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could adversely affect our business. Other conflicts, such as the ongoing conflict between Israel and Hamas, could cause similar disruption and adversely impact our business. Any or all of these actions, as well as actions such as cyber-attacks by state-sponsored or non-state actors, could disrupt our operations and supply chain and adversely affect our ability to conduct and analyze ongoing and future clinical trials of our product candidates, among other possible consequences. Additionally, concerns about security and any increase in the cost of travel resulting from the rising cost of fuel could impact the travel industry. Any of these results could materially harm our business.

These and other risks associated with international operations may adversely affect our ability to attain or maintain profitable operations. Future sales of our products or our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors, and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, armed conflict, wars, or otherwise, these organizations may defer purchases or may be unable to satisfy their purchasing or reimbursement obligations, which may affect milestone payments or royalties for our products or any of our product candidates that are approved for commercialization in the future. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Our strategic collaborations may require us to relinquish rights to and control over the development and commercialization of our product candidates or to make payments upon achievement of milestone events.

We have in the past and may in the future enter into agreements or engage in strategic collaborations in order to advance our business strategy. For example, in April 2020 we entered into a research collaboration and license agreement with Pfizer in connection with VLA15, our Lyme disease vaccine candidate. Pursuant to this agreement, Pfizer is leading late-stage development of the vaccine candidate, including conducting the ongoing Phase 3 clinical trial, and will have sole control over its commercialization.

In addition, we may in the future explore strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates. We cannot predict what form such strategic collaborations or licenses might take in the future. If we do seek additional strategic collaborations, we are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses that we have deemed important for the development and commercialization of any of our product candidates could delay or limit those processes in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including the following:

- we may be required to undertake the expenditure of substantial operational, financial, and management resources, including expenditure beyond the amount originally agreed;

- we may be required to issue equity securities that would dilute our shareholders' percentage ownership of our company;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may delay or encounter unanticipated problems with clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution, and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted, and maintained in a manner consistent with the best interests of our business;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce, or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

Even if we successfully commercialize any of our vaccine candidates, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement, and healthcare reform, all of which could adversely affect any commercial success of our vaccine candidates.

Market acceptance and sales of any vaccine candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations, and other private health insurers. Therefore, our ability to collect revenue from the commercial sale of our vaccines may depend on our ability, and that of any current or potential future collaboration partners or customers, to obtain adequate levels of approval, coverage, and reimbursement for such products from third-party payors such as:

- government health administration authorities, such as ACIP;
- private health insurers;
- managed care organizations;
- pharmacy benefit management companies; and
- other healthcare related organizations.

Third-party payors decide which therapies they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the

product. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, biological, and vaccine products, or formulary, generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of such product by patients and physicians. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

Third-party payors are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the applicable regulatory authorities, is not used in accordance with cost-effective treatment methods as determined by the third-party payor, or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third parties is the biggest driver of the prices of our products. In the United States, we may be significantly adversely affected if the federal pricing rules change to require a greater discount than the current minimum of 24% compared to non-federal average manufacturer price for products listed on the federal supply schedule.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular product. We cannot be sure that coverage and reimbursement will be available for any vaccine that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any vaccine candidates that we develop.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced pharmaceutical pricing or reimbursement rates for medical products, which could adversely affect our business strategy, operations, and financial results.

For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care organizations, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of various laws, including the ACA, that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on drugs (including vaccines) sold to certain Medicare Part D beneficiaries in the coverage gap (the so-called "donut hole").

Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business in the United States or elsewhere. In addition, we face uncertainties because there are ongoing federal legislative and administrative efforts to repeal, substantially modify, or invalidate some or all of the provisions of the ACA in the United States. We cannot predict the ultimate content, timing, or effect of any healthcare reform legislation or the impact of potential legislation on us. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement, the commercial success of our vaccine products may be greatly hindered, and our financial condition and results of operations may be materially and adversely affected.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers, and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage, and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic, and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is

intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Legislators, policymakers, and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that the COVID-19 pandemic placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Our failure to obtain marketing approval in jurisdictions other than the United States and the European Union would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and the European Union would not assure approval of product candidates in other jurisdictions.

In order to market and sell our product candidates in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals in such jurisdictions and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing aside from that which is required to obtain such approval in the United States and the European Union. The time required to obtain approval may differ from that required to obtain approval from the FDA or regulatory authorities in the European Union. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA approval or approvals from regulatory authorities in the European Union. In addition, some countries outside the United States and the European Union require approval of the sales price of a product before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement, and a product may not be approved for sale in the country until it is also approved for reimbursement. We may not obtain marketing, pricing, or reimbursement approvals outside the United States and the European Union on a timely basis, if at all. Approval by the FDA or regulatory authorities in the European Union does not ensure approval, with the same scope or at all, by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and the European Union does not ensure similar approval by regulatory authorities in other countries or jurisdictions or by the FDA or regulatory authorities in the European Union. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and the European Union do not ensure pricing approvals in those countries or in any other countries where such approvals are required, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities, damage our reputation, and limit commercialization of any product candidate that we may develop as well as continued commercialization of our current products.

We face an inherent risk of product liability exposure related to the sale and use of our products and the testing of our product candidates in clinical trials. Side effects of, or manufacturing defects in, products that we develop could result in injury or even death. For example, our liability could be sought after by subjects participating in the clinical trials in the context of the development of the vaccine candidates tested and unexpected side effects resulting from the administration of these products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by subjects, regulatory authorities, biopharmaceutical companies, and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees, and subcontractors over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy, result in withdrawal of clinical trial participants, result in decreased demand for our products, and may be costly and time-consuming to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities, may be forced to limit or forgo further development or commercialization of the affected products, and may suffer damage to our reputation.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our products or our product candidates.

To date, we have obtained product liability insurance with a coverage amount of €35 million per claim per year. Our product liability insurance will need to be adjusted in connection with the commercial sales of our products and our product

candidates, and may be unavailable in meaningful amounts or at a reasonable cost. Our insurance coverage may not be sufficient to cover any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

In addition, product liability claims relating to our own or similar products may result in increases in insurance premiums or deductibles that may make insurance coverage more costly or prohibitively expensive. Additionally, insurance providers may refuse to provide coverage for a category of related products if one such product is removed from the market for safety reasons. We cannot guarantee that we will be able to maintain product liability insurance coverage for all of our products. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we would incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of our product programs. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Risks Related to Regulatory Compliance

We may fail to obtain regulatory approval for our products on a timely basis or comply with our continuing regulatory obligations after approval is obtained.

Delays in obtaining regulatory approval can be extremely costly in terms of lost sales opportunities, loss of any potential marketing advantage of being early to market, and increased clinical trial costs. The speed with which we begin and complete our pre-clinical studies, clinical trials, and applications for marketing approval will depend on several factors, including the following:

- regulatory agency review and approval of proposed clinical trial protocols;
- approval of clinical trials protocols and informed consent forms by institutional review boards responsible for overseeing the ethical conduct of the trial, or positive ethics committee opinions, as part of the single decision on the authorization of a clinical trial issued by EU Member States including input from the national competent authorities and ethics committee;
- the rate of participant enrollment and retention, which is a function of many factors, including among others the size of the participant population, the proximity of participants to clinical sites, the eligibility criteria for the clinical trial, and the nature of the protocol;
- unfavorable test results or side effects experienced by clinical trial participants;
- analysis of data obtained from pre-clinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit, or prevent regulatory approval or delay, limit, prevent, or result in the suspension, variation, or termination of clinical studies;
- the availability of skilled and experienced staff to conduct and monitor clinical trials and to prepare the appropriate regulatory applications;
- compliance with GCP and other applicable regulations by CROs and personnel conducting a clinical trial; and
- changes in the policies of regulatory authorities for drug or vaccine approval during the period of product development.

We may not be permitted to continue or commence additional clinical trials. Regulatory agencies may require us or our collaborators to delay, restrict, or discontinue clinical trials on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or as a result of non-compliance with applicable regulations such as GCP. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in pre-clinical studies or clinical trials of similar products or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biotechnology and product development industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

In addition, we or our collaborators may be unable to submit applications to regulatory agencies within the timeframe we currently expect. Once submitted, applications must be approved by various regulatory agencies before we or our collaborators can commercialize the product described in the application.

Further, any future regulatory approvals that we receive may be limited in scope. Such limitations would impact the degree to which we can commercialize a product in the relevant territory and could require additional investments of time and resources if we choose to pursue an expansion of the label and indications beyond what may be initially approved.

All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated costs or delays in our clinical trials could delay our ability to generate revenue and harm our financial condition and results of operations.

Accelerated regulatory review and approval procedures do not guarantee faster development, review, or approval or that approval will ultimately be granted.

Regulatory agencies such as the EMA and FDA offer various options for accelerated review and approval of product candidates, such as the EMA's PRIME designation for priority medicines and the FDA's Fast Track designation and accelerated approval pathway. We seek to take advantage of these opportunities in order to facilitate the development, review, and approval processes for our product candidates.

IXCHIQ, or VLA1553 in jurisdictions where it is subject to ongoing regulatory review, has received PRIME designation from the EMA. The PRIME scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options, reviewed under the centralized procedure. PRIME designation does not change the standards for product approval or ensure that the product will receive marketing approval at all or within any particular timeframe. We may seek PRIME designation for other vaccine candidates in the future. If we do seek PRIME designation for our other vaccine candidates, we may not receive it, and even if we receive PRIME designation, we may not experience a faster development process, review, or approval compared to conventional EMA procedures.

VLA15, our candidate against Lyme disease, received Fast Track designation from the FDA. Fast Track designation may be available to help expedite the development or approval process for a drug that is intended for the treatment of a serious or life-threatening condition and that demonstrates the potential to address an unmet medical need for this condition. Fast Track designation does not change the standards for product approval or ensure that the product will receive marketing approval at all or within any particular timeframe. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. Thus, although VLA15 has received Fast Track designation, there is no guarantee that this designation will result in a faster or more successful development or review process or in ultimate approval of this product candidate by the FDA. Additionally, we may also seek Fast Track designation for our other vaccine candidates. If we do seek Fast Track designation for our other vaccine candidates, we may not receive it, and even if we receive Fast Track designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures.

Finally, we received approval for IXCHIQ under the FDA's accelerated approval pathway and may seek such approval for other vaccine candidates in the future. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials, such as the Phase 4 clinical trials that are required for IXCHIQ. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval for a future product candidate, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

The European Union provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial

marketing authorization of the reference product in the European Union. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

We also believe that our product candidates in the EEA should benefit from this data and market exclusivity. As with the U.S., however, if competitors obtain marketing authorization for their biosimilar products, our products may become subject to competition from these biosimilars, with the attendant competitive pressure and consequences.

Our relationships with customers, healthcare providers, and third-party payors are subject, directly or indirectly, to healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors subject us to various fraud and abuse laws and other healthcare laws.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Restrictions under applicable U.S. federal, state, and foreign healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims, including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses, and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf, and their subcontractors that use, disclose, or otherwise process individually identifiable health information;
- the Federal Food Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- similar healthcare laws and regulations in other jurisdictions, such as state anti-kickback and false claims laws, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts. Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These laws may include the French "Bertrand Law", French Ordinance n° 2017-49 of January 19, 2017 and Decree No. 2020-730 of June 15, 2020 relating to benefits offered by persons manufacturing or marketing health products or services, and the UK's Bribery Act 2010, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing, and/or transparency laws applicable to manufacturers or any company providing services related to their products that may be broader in scope than the federal requirements. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations is and will continue to be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, as well as damages, fines, disgorgement, imprisonment, exclusion from participating in U.S. government-funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, and the curtailment or restructuring of our operations.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares and ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing, or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal, or administrative sanctions, including exclusions from U.S. government-funded healthcare programs.

Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations, and prospects.

In the United States, the European Union and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include increasing the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; requiring collection of rebates for drugs paid by Medicaid managed care organizations; requiring manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposing a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implementing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanding the types of entities eligible for the 340B drug discount program; expanding eligibility criteria for Medicaid programs; creating a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and establishing a Center for Medicare Innovation at CMS to test

innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial, and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and through subsequent legislation will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which established a quality payment program, also referred to as the Quality Payment Program. The Quality Payment Program has two tracks, one known as the merit-based incentive payment system for providers in the fee-for service Medicare program, and the advanced alternative payment model for providers in specific care models, such as accountable care organizations. At this time, the full impact to overall physician reimbursement as a result of the introduction of the Medicare Quality Payment Program remains unclear.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs, and review the relationship between pricing and manufacturer patient programs. At the federal level, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively and began in 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented, but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Additionally, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products, and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained, and we may not achieve or sustain profitability. Further, any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In some countries, the proposed pricing for a biopharmaceutical product must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of biopharmaceutical products is subject to government control, and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, refuse to reimburse a product at the price set by the manufacturer, or adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Moreover, in the EEA some countries require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021, the HTA Regulation was adopted, and it entered into force on January 11, 2022. It will apply from 2025.

There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission, and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive will continue to apply on a transitional basis, until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed

to other countries and/or make it harder to seek a marketing authorization for the Company's product candidates on the basis of clinical trials conducted in the United Kingdom.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations, and financial condition.

We are subject to other laws and regulations governing our international operations, including regulations administered by the authorities in the United States, European Union, and United Kingdom, including applicable export control regulations, economic sanctions on countries and persons, and customs requirements and currency exchange regulations, collectively referred to as the trade control laws. Specifically, as a result of the Russian invasion of Ukraine in February 2022, the United States, the European Union, the United Kingdom, and other jurisdictions adopted a series of financial and trade sanctions in relation to Russia and Belarus and Russian and Belarussian listed citizens and entities.

Exports of our products and product candidates must be made in compliance with trade control laws. In some cases, certain licensing, authorization, or reporting requirements may need to be performed. In addition, these laws may restrict or prohibit altogether the supply of certain of our products, product candidates, or services to certain governments, persons, entities, countries, and territories. Changes in our products and product candidates or changes in applicable trade control laws may create delays in the introduction or provision of our products and product candidates in certain jurisdictions, prevent others from using our products and product candidates or, in some cases, prevent the export or import of our products and product candidates to certain countries, governments, or persons altogether. Any limitation on our ability to export or provide our products, product candidates, and services could adversely affect our business, financial condition, and results of operations.

We are also subject to anti-corruption laws of the United States and other applicable jurisdictions. The Foreign Corrupt Practices Act, or FCPA, prohibits companies and their employees, third-party intermediaries, and other associated persons from paying, offering, authorizing payment, or providing anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of a foreign entity in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

French anti-corruption laws also prohibit acts of bribery and influence peddling:

- Article 433-1-1° of the French Criminal Code (bribery of domestic public officials);
- Article 433-1-2° of the French Criminal Code (influence peddling involving domestic public officials);
- Article 434-9 of the French Criminal Code (bribery of domestic judicial staff);
- Article 434-9-1 of the French Criminal Code (influence peddling involving domestic judicial staff);
- Articles 435-1 and 435-3 of the French Criminal Code (bribery of foreign or international public officials);
- Articles 435-7 and 435-9 of the French Criminal Code (bribery of foreign or international judicial staff);
- Articles 435-2, 435-4, 435-8 and 435-10 of the French Criminal Code (active and passive influence peddling involving foreign or international public officials and foreign or international judicial staff);
- Articles 445-1 and 445-2 of the French Criminal Code (bribery of private individuals); and
- French Law n°2016-1691 of December 9th, 2016 on Transparency, the Fight Against Corruption and the Modernization of the Economy (Sapin 2 Law), which provides for numerous new obligations for large companies such as the obligation to draw up and adopt a code of conduct defining and illustrating the different types of behavior to be proscribed as being likely to characterize acts of corruption or influence peddling, to set up an internal warning system designed to enable the collections of reports from employees relating to the existence of conduct or situations contrary to the company's code of conduct, to set up accounting control procedures, whether internal or external, designed to ensure that the books, registers and accounts are not used to conceal acts of

corruption or influence peddling, to set up a disciplinary system for sanctioning company employees in the event of a breach of the company’s code of conduct or a system for monitoring and evaluating the measures implemented.

We are also subject to the UK Bribery Act 2010, which makes it a criminal offense to:

- Offer, promise, or give a financial or other advantage to a person to induce them to perform improperly or reward a person for improper performance (directly or via a third party). A bribe can be of any form, size, or value that would provide the intended recipient with some form of benefit or advantage. Bribes can include money, discounts, vouchers, loans, gifts, hospitality, accommodation, use of assets, preferential treatment, business advantage, and employment opportunities, among others;
- Request, agree to receive or accept a financial or other advantage with the intention of or as reward for improper performance (directly or via a third party);
- Attempt bribery of a foreign public official in order to obtain or retain business or an advantage in the conduct of business, either directly or via a third party;
- As a commercial organization, fail to prevent bribery, as a result of not having adequate procedures in place to prevent a person directly or associated with a company to commit any of the other offenses.

For the purposes of the UK Bribery Act 2010, “foreign public official” means an individual who:

- is an official or agent of a public international organization; or
- exercises a public function:
 - for or on behalf of a country or territory outside the Island (or any subdivision of such a country or territory); or
 - for any public agency or public enterprise of that country or territory (or subdivision).

There is no assurance that we will be effective in ensuring compliance by our employees, representatives, contractors, business partners, and agents with all applicable anti-corruption laws, including the FCPA, the French anti-corruption laws, or other applicable legal requirements, including trade control laws. If we are not in compliance with the FCPA, the French anti-corruption laws, and other anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. Likewise, any investigation of any potential violations of the FCPA, the French anti-corruption laws, other anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations, and financial condition.

As a publicly listed company in France and the United States, we will be subject, and expect to be subject, to new regulations requiring substantial additional disclosure on sustainability and environmental, social, and governance (ESG) matters, including the EU Corporate Sustainability Reporting Directive, the EU Taxonomy Regulation, the EU Corporate Sustainability Due Diligence Directive, and the SEC’s climate rules adopted on March 6, 2024.

On December 14, 2022, the EU adopted Directive 2022/2464/EU, or the Corporate Sustainability Reporting Directive or CSRD. The CSRD introduces new mandatory reporting obligations that will require the publication of audited sustainability information in our Management Report for the year ended December 31, 2024. This information, addressing environmental, social, and governance, or ESG, matters, is set forth in new mandatory European sustainability reporting standards, or ESRS, that will be adopted by the European Commission through secondary legislation.

The First Set of ESRS applicable to EU reporting entities was formally adopted on July 31, 2023. The First Set of ESRS cover general requirements (ESRS 1), general disclosures (ESRS 2), and the following 10 ESG topics:

E1	Climate change
E2	Pollution
E3	Water and marine resources
E4	Biodiversity and ecosystems
E5	Resource and circular economy
S1	Own workforce
S2	Workers in the value chain
S3	Affected communities
S4	Consumers and end-users
G1	Business conduct

The disclosures listed in ESRS 2 are mandatory, even if the entity considers that there are no material impacts, risks, or opportunities. For example, a statement on due diligence, a description of the processes to identify and assess material

impacts, risks, and opportunities and information about the integration of sustainability-related performance in incentive schemes are always required.

Certain disclosures listed in ESRS 2 are mandatory, even if not material. The other disclosures listed in the 10 topical ESRS (ESRS E1-E5, S1-S4 and G1) are only required if “material” impacts, risks, and/or opportunities are identified. “Materiality” under the CSRD must be assessed following the double materiality principle. Double materiality means that the reporting entity should consider both financial materiality (i.e., sustainability matters which generate risks or opportunities that affect, or could reasonably be expected to affect, the Company’s financial position, financial performance, cash flows, access to finance, or cost of capital over the short, medium, or long term) and impact materiality (i.e., the Company’s material actual or potential, positive or negative impacts on people or the environment over the short-, medium-, and long-term). Impacts, risks, and opportunities are material if they satisfy one or both of these materiality tests.

For each topic identified as material, reporting entities will have to include in their reports material sustainability information concerning:

1. their own operations,
2. the operations of their subsidiaries whether EU or non-EU, and
3. businesses in their value chains (both upstream and downstream).

The disclosure required under the CSRD must be included in a sustainability section of the EU Management Report for EU reporting entities. All EU reporting entities subject to the CSRD must have the sustainability section of their EU Management Report audited by an accredited third-party to confirm that it has been prepared in accordance with the relevant ESRS and Article 8 of Regulation (EU) 2020/852, or the EU Taxonomy Regulation. The assurance opinion must be published alongside the Management Report.

Compliance with the CSRD will require us to set up processes to gather the relevant data, to conduct double materiality assessments, and to substantially revise our existing sustainability report. These activities will require significant time and involvement from employees across the Company and will also incur additional costs beyond the cost of the additional audit required.

The disclosure requirements under the CSRD apply alongside the EU Taxonomy Regulation, which (a) creates a classification system to determine when an economic activity qualifies as “environmentally sustainable” and (b) requires companies in scope of the Non-Financial Reporting Directive, including those brought into scope by the CSRD, to disclose the proportion of turnover, capital, and operational expenditure related to economic activities that qualify as “environmentally sustainable” within the meaning of the EU Taxonomy Regulation and associated delegated acts. This information should be disclosed even if there is no contribution to environmentally sustainable activities.

The disclosures required under the CSRD and the EU Taxonomy Regulation should be also considered together with the proposed EU Directive on Corporate Sustainability Due Diligence, or CSDDD, which, if adopted and if applicable to Valneva, would set new due diligence duties for Valneva.

Assuming that the CSDDD is formally adopted into EU law, it would apply to companies established in the EU that: (1) have an average net worldwide turnover exceeding EUR 450 million in the previous financial year, and (2) over 1000 employees – including part time workers, temporary workers, and workers in non-standard forms of employment.

Currently, the CSDDD would not apply to Valneva. However, if the CSDDD were to become applicable to Valneva due to growth in worldwide turnover and employee numbers, we would be required to identify and, where necessary, prevent, end, or mitigate actual or potential adverse human rights and environmental impacts, such as child labor, exploitation of workers, pollution, and biodiversity loss. More specifically, we would be required to:

- Integrate human rights and environmental due diligence into our policies and risk management systems if they are not already integrated;
- Identify and assess actual and potential adverse human rights and environmental impacts in our own operations and those of our subsidiaries and upstream and downstream business partners;
- Take appropriate measures to prevent or mitigate potential adverse impacts on human rights or the environment;
- Bring to an end or minimize any actual adverse impacts on human rights or the environment that materialize and remedy these going forward;
- Establish and maintain a notification mechanism and complaints procedure;
- Monitor the effectiveness of our due diligence policy and measures; and
- Publicly communicate our due diligence procedures, to the extent this is not already covered in our CSRD reporting.

In addition, the CSDDD will require in-scope companies to adopt and put into effect a transition plan for climate change mitigation, which aims to ensure that, through best efforts, their business model and strategy are compatible with the transition to a sustainable economy and with limiting global warming to 1.5°C.

It is estimated that the CSDDD will be formally adopted in the second quarter of 2024, with the new requirements under the CSDDD starting to apply from 2027 for the largest companies and 2029 for other in-scope companies.

Additionally, we are subject to the rules adopted by the U.S. Securities and Exchange Commission on climate-related disclosure in March 2024. The SEC climate rules are subject to ongoing litigation, which may result in implementation delays and ongoing uncertainty.

Compliance with the CSRD, the EU Taxonomy Regulation, the CSDDD if Valneva is in-scope, and the SEC’s climate disclosure rules will require significant resources, time, and attention from management.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in Europe, the United States and other jurisdictions related to our product candidates and our technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some countries do not protect intellectual property rights to the same extent as European laws and federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the EEA or the United States, or from selling or importing products that infringe our patents in and into the EEA or the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in EEA countries, the United States, and other jurisdictions. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or could limit the duration of the patent protection of our technology and product candidates. For example, one of our patents that relates to VLA84 has been limited in scope in opposition proceedings in Europe. In another case in 2023, we decided to withdraw a patent covering IXIARO and VLA2001 following an opposition proceeding in Europe. More recently, we have also received a further opposition by a third party against a European patent that is directed at IXIARO, VLA2001 and VLA1601. The proceeding started in June 2023, and we will defend our position with one or more submissions. Although we do not expect these developments to have a significant impact on further commercialization of IXIARO, we may face similar proceedings in the future that could have a significant effect on our ability to commercialize our products. We have also recently received an opposition by a third party against a European patent that is directed to our Zika product candidate, VLA1601. The proceeding began in February 2023, and we will defend our position with one or more submissions.

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. As a result, such third parties, including governments and non-for-profit organizations, may have certain rights, including “march-in” rights, to such patent rights and technology. When new technologies are developed with such partners, they

generally obtain certain rights in any resulting patents, including a nonexclusive license authorizing the party to use the invention for noncommercial purposes. These rights may permit the funding partner to disclose our confidential information to third parties and to exercise “march-in” rights to use or allow third parties to use our licensed technology. The funding partner can exercise its “march-in” rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. or other country industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States or other countries. Any exercise by the funding partners of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

Patent terms may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in the United States a patent’s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations could be adversely affected.

Given the amount of time required for the development, testing, and regulatory review of our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. The Hatch-Waxman Act in the United States, and similar legislation in the European Union, permit a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable in the U.S. for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, in the United States, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. In the EEA, supplementary protection certificates, or SPCs, provide protection for the active ingredient of a patented and authorized medicinal product, which may extend for up to five years beyond the normal patent expiry date (providing together with the patent up to 15 years exclusivity from the first EU marketing authorization). In some cases an additional six months of SPC protection may be obtained by performing pediatric trials of the product. The protection afforded by an SPC extends only to the active ingredient of the authorized medicinal product, within the scope of the granted base patent. However, the applicable authorities may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data and may be able to launch their product earlier than might otherwise be the case.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market, and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U.S.- and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk may increase that our product candidates may give rise to claims of infringement of the patent rights of others. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we have in the past and may in the future decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in Europe, the United States, and other jurisdictions could uphold the validity of any such patent. Even if we are successful in obtaining a first-instance judgement from a court or patent office that such patents are invalid, such judgements may be subject to appeal procedures which suspend revocation of the patent until a final appeal judgment is reached. This may result in many years of uncertainty and could ultimately lead to reversal of the original judgment and the patent being upheld. Furthermore, because patent applications can take many years to issue and are typically confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate or technology platform infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties, or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or any return on our investment at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or may require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of

hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ordinary shares and ADSs.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects.

We may be subject to claims asserting that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants, or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications as a result of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

In some countries, the national law may stipulate that certain inventions made by an employee belong to the employer or employee and may restrict the ability of employment or other contracts to define which inventions belong *ab initio* to the employer. Thus in some countries employees could claim ownership of inventions by operation of national law and assignments may not be enforceable. Inventors may also assert additional rights relating to their inventive contribution, without necessarily claiming ownership. For instance, in some countries inventors are entitled to adequate remuneration or other benefit from an invention, even if the invention belongs by law to their employer. In some cases employee-inventors may also be entitled to pursue patent applications that the employer decides to abandon. Inventors claiming such rights may require us to pay additional compensation or might bring claims against us using the patent applications they acquire.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors, or our other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe, misappropriate, or otherwise violate our patents, the patents of our licensors, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. For example, Takeda has initiated an *inter partes* review proceeding before the U.S. Patent and Trademark Office on our Zika U.S. PATENT NO. 11,219,681. This proceeding has ended as the Patent Trial and Appeal Board decided to deny Institution for this proceeding following our withdrawal of some of the claims. The remaining claims continue to cover VLA1601.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO or similar foreign authorities or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, from time to time, the U.S. Congress, the USPTO, or similar foreign authorities may change the standards of patentability, and any such changes could have a negative impact on our business. In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a “first-to-invent” system to a “first-to-file” system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process, such as allowing third-party submission of prior art to the USPTO during patent prosecution. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. Under a first-to-file system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor made the invention earlier. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective in March 2013. Substantive changes to patent law associated with the America Invents Act, or any subsequent U.S. legislation regarding patents, may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our U.S. patent applications, our ability to obtain U.S. patents based on our discoveries, and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, prospects, financial condition, and results of operations.

In addition, changes to or different interpretations of patent laws in the United States and other countries may permit others to use our or our partners’ discoveries or to develop and commercialize our technology and product candidates without providing any compensation to us, or may limit the number of patents or claims we can obtain. The patent positions of companies in the biotechnology and pharmaceutical market are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of U.S. patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In Europe, the Enlarged Board of Appeal of the EPO has recently indicated that it is prepared to apply a “dynamic” interpretation of certain patent law provisions in view of political developments and thus could reverse previously pro-patentee positions relating to biotechnological and pharmaceutical inventions. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO, and the EPO, as well as similar bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future, which could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting, and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, such a license may be issued in circumstances where demand for a product cannot be met by the patent holder in cases of a public health emergency, such as the COVID-19 pandemic. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we rely on third parties to help us discover, develop, and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing, or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements, or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. We also enter into invention or patent assignment agreements with our employees, advisors, and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

In addition, our competitors may independently develop knowledge, methods, and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations, and prospects.

We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by our collaborators, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. Our collaborators also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize our proprietary information or invalidate our intellectual property.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Any trademarks we have and that we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. We entered into a co-existence agreement with respect to the VALNEVA trademark. The agreement places restrictions on how we can use this mark and how we can seek trademark protection for this mark.

In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- others may be able to develop technologies that are similar to our technology platforms but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that are covered by a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.

We have in-licensing agreements relating to certain of our products and product candidates, including with TechLab for VLA84 (*Clostridium difficile*) and VaccGen for IXIARO.

If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the license agreement and other issues relating to interpretation of the relevant agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license granted to us;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, on the one hand, and us and our sublicensees, on the other hand.

Risks Related to Our Reliance on Third Parties

We depend upon our existing collaboration partner, Pfizer, and other third parties to advance our business and may in the future depend on additional third parties. If we are unable to maintain our existing agreements or to enter into additional arrangements, our business could be adversely affected.

We have entered into, and in the future may seek to enter into additional, collaborations, partnerships, strategic alliances, and joint ventures, as well as licensing, distribution, or manufacturing arrangements with third parties that we believe will complement or augment our development and commercialization efforts. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish or maintain a collaboration, strategic partnership, or other alternative arrangements for our products or product candidates.

Further, collaborations and partnerships involving our products or product candidates are subject to numerous risks, which may include the following:

- collaborators and partners have significant discretion in determining the efforts and resources that they will apply to a collaboration or partnership;
- a collaborator or partner may not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization of our products or product candidates based on clinical trial results or delays, changes in their strategic focus, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- a collaborator or partner may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- disputes may arise between us and a collaborator or partner that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- a collaborator or partner could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator or partner with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of the one or more products;
- a collaborator or partner may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborations and partnerships may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- a collaborator or partner may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have any right or the exclusive right to commercialize such intellectual property.

Our strategic partnership with Pfizer to develop and commercialize our Lyme disease vaccine candidate is of critical importance to our business. In accordance with our agreement with Pfizer, we are obligated to provide 40% of the development costs for our Lyme disease vaccine candidate. If we cannot maintain enough cash to comply with this obligation, including any increase in costs as a result of developments with the Phase 3 clinical trial, the development and commercialization of our Lyme disease vaccine candidate could be significantly delayed. Additionally, Pfizer could terminate our existing agreement for a number of reasons, as discussed further under “Item 10.C—Material Contracts—Pfizer License Agreement.” If our partnership with Pfizer fails or is terminated for any reason, we may be unable to find another partner and may not have sufficient financial resources to complete Phase 3 development of our Lyme disease vaccine candidate without a partner.

Our distribution agreements with Bavarian Nordic are also important to our business, both for the sale of our own products IXIARO and DUKORAL and for the revenue we earn from our distribution of Bavarian Nordic’s RABIPUR and ENCEPUR vaccines. In 2023, Bavarian Nordic acquired two of Emergent BioSolutions’ travel vaccines, including the Vaxchora cholera vaccine, which is a competitor of DUKORAL in Europe. As a result of this acquisition, we amended our agreements with Bavarian Nordic with effect in May 2023. The agreements relating to our distribution of Bavarian Nordic’s rabies vaccine in Canada and the United Kingdom will terminate on December 31, 2024, and the remaining distribution agreements between Valneva and Bavarian Nordic will terminate on December 31, 2025. These additional distribution agreements provide for Bavarian Nordic’s distribution of our products in Germany and Switzerland and for our distribution of Bavarian Nordic’s RABIPUR and ENCEPUR vaccines in France, Austria, and the Benelux region. We are now making plans to ensure continued distribution of our products in Germany and Switzerland but cannot guarantee that the termination of these distribution agreements will not have an impact on our sales in these countries. For additional information about the agreements relating to Bavarian Nordic’s distribution of our vaccines, see “Item 10.C—Material Contracts—Bavarian Nordic Distribution Agreements” and Exhibits 4.13, 4.14, and 4.15 of this Annual Report. For

additional information about our sales of Bavarian Nordic's vaccines, refer to the Notes to our consolidated financial statements filed together with this Annual Report.

If we enter into collaborations, partnerships, strategic alliances, and joint ventures, as well as licensing, distribution, or manufacturing arrangements with third parties, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our business, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the synergies that justify such transaction.

Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We are dependent on single-source suppliers for some of the components and materials used in our products.

In certain cases, we rely on single suppliers for all of our requirements for some of our materials or components. In most cases we do not have long term contracts with these suppliers, and even in the cases where we do the contracts include significant qualifications that would make it extremely difficult for us to force the supplier to provide us with their services, materials, or components should they choose not to do so. We are therefore subject to the risk that these third-party suppliers will not be able or willing to continue to provide us with materials and components that meet our specifications, quality standards, and delivery schedules. Factors that could impact our suppliers' willingness and ability to continue to provide us with the required materials and components include disruption at or affecting our suppliers' facilities, such as work stoppages or natural disasters, adverse weather or other conditions that affect their supply, the financial condition of our suppliers, and deterioration in our relationships with these suppliers. In addition, we cannot be sure that we will be able to obtain these materials and components on satisfactory terms. Any increase in material and component costs could reduce our sales and harm our gross margins. In addition, any loss of a material supplier may permanently cause a change in one or more of our products that may not be accepted by our customers or that may cause us to eliminate that product altogether.

For example, we rely on a single-source supplier for fetal bovine serum, a critical and scarce raw material which is only available from our supplier and is used in the manufacturing of IXIARO. We also rely on a single-source supplier for the adjuvant contained in certain vaccine candidates. A loss of the supplier or any shortages of these or other materials for which we rely on a single supplier could adversely affect our ability to manufacture our products and significantly raise our cost of production.

We have not qualified secondary sources for all materials or components that we source through a single supplier, and we cannot assure investors that the qualification of a secondary supplier would prevent future supply issues. Disruption in the supply of materials or components would impair our ability to sell our products and meet customer demand and also could delay the launch of new products, any of which could harm our business and results of operations. If we were to have to change suppliers, the new supplier may not be able to provide us materials or components in a timely manner and in adequate quantities that are consistent with our quality standards and on satisfactory pricing terms. In addition, alternative sources of supply may not be available for materials that are scarce or components for which there are a limited number of suppliers.

If we experience shortages in the supply of our marketed products, our results could be materially impacted.

The marketing and distribution of our products and the late-stage development of our product candidates may depend on our ability to establish and maintain collaborations with biopharmaceutical companies.

In order to develop and market some of our products and product candidates, we rely on collaboration, research, and license agreements with biopharmaceutical companies to assist us in the marketing and distribution of our products and the development of product candidates and the financing of their development. For example, we entered into agreements with Bavarian Nordic to commercialize our products in Germany and Switzerland. As we continue to commercialize our products and identify new product candidates, we will determine the appropriate strategy for development and marketing, which may result in the need to establish additional collaborations with major biopharmaceutical companies. We may also enter into agreements with institutions and universities to participate in our other research programs and to share intellectual property rights.

We may fail to maintain or find collaboration partners and to sign new agreements for our other product candidates and programs. The competition for partners is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations, or the collaborator terminates the collaboration, including because of changes in the collaborator's business. Any collaboration, or other strategic transaction, may also require us to incur non-recurring or other charges, increase our near- and long-term expenditures, and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business;
- diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates, or technologies;

- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher than expected collaboration, acquisition or integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations, and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

We rely on third parties to supply key materials used in our research and development, to manufacture our products and product candidates, to provide services to us, and to assist with clinical trials.

We make considerable use of third-party suppliers for the key materials used in our business, such as the fetal bovine serum used in IXIARO and the adjuvant used in certain vaccine candidates. Additionally, we have outsourced an important step in the manufacturing of IXCHIQ to a third party, IDT Biologika, and Vetter performs the filling process for IXIARO and the filling of IXCHIQ diluent. The failure of third-party suppliers to comply with regulatory standards could result in the imposition of sanctions on us. These sanctions could include fines, injunctions, civil penalties, refusal by regulatory organizations to grant approval to conduct clinical trials or marketing authorization for our products, delays, suspension, variations or withdrawal of approvals, license revocation, seizure or recalls of our products, operating restrictions, and legal proceedings. Furthermore, the presence of non-conformities, as may be detected in regulatory toxicology studies, could result in delays in the development of one or more of our product candidates or in the supply of a commercial product and would require further tests to be financed. Although we are involved in establishing the protocols for the production of these materials, we do not control all the stages of production and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations or that we will be informed in a timely manner of any non-conformities or other failure to comply with obligations. In particular, a partner's failure to comply with protocols or regulatory constraints, or repeated delays by a partner, could compromise the development or manufacturing of our products. Such events could also inflate the product development or manufacturing costs incurred by us.

We also use third parties to provide certain services such as scientific, medical, or strategic consultancy services. These service providers are generally selected for their specific expertise, as is the case with the academic partners with whom we collaborate. We face intense competition to build and maintain such a network under acceptable terms. Such external collaborators may terminate their involvement at any time, and we can exert only limited control over their activities. We may not be able to obtain the intellectual property rights to the product candidates or technologies developed under collaboration, research, and license agreements under acceptable terms or at all. Moreover, our scientific collaborators may assert intellectual property rights or other rights beyond the terms of their engagement.

Finally, we use third parties to assist with conducting clinical trials. All clinical trials are subject to strict regulations and quality standards. Should any of these risks materialize, as in the case of the Phase 3 trial of VLA15 involving GCP violations by a third party engaged by Pfizer to conduct certain clinical trial sites, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Risks Related to the Manufacture of Our Products and Product Candidates

We may be unable to successfully manufacture our products or product candidates in sufficient quality and quantity, which would impact commercialization of our products and delay development of our product candidates.

We perform most of the manufacturing of our products and our product candidates in-house. Delays in manufacturing or inability to manufacture sufficient doses of a product or product candidate could adversely affect our business, financial condition, prospects, and results of operations. If we, or any third-party manufacturing partners, are unable to manufacture sufficient quantities of any vaccine, we may not be able to meet demand or fulfill our obligations under any agreements, or we may be forced to forego additional partnerships or supply agreements which would be advantageous for our business. We may encounter unexpected challenges relating to manufacturing efficiency, quality control, or stability profile that could impact the quantity of products or product candidates manufactured, the consistency of quantity across batches, or the length of time that manufactured material can be used. These problems could impact our supply of the market and require us to manufacture more than previously expected, leading to delays and added costs. Additionally, any supply shortages due to an inability to manufacture sufficient doses could result in fines.

We experienced supply shortages for both IXIARO and DUKORAL in 2022 and 2023 due to the faster than expected recovery of the travel market and, in 2023, to delays in internal processes. In February 2024, we announced anticipated difficulties in supplying the market in the beginning of 2024, and these are accounted for in our guidance.

We may be required to increase our manufacturing capacity to meet demand for approved products, and we may be unable to do this in a timely or cost-effective manner, or at all. We do not have experience manufacturing on the scale that would be required for a large-scale commercialization of vaccine candidates that may receive approval in the future. The process of developing additional manufacturing capacity is complex and affected by multiple external factors, many of which are beyond our control.

We, our contract manufacturers, any future collaborators, and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable regulatory authorities to monitor and ensure compliance with cGMP or other applicable regulations. Despite our efforts to audit and verify regulatory compliance, we or one or more of our third-party manufacturing vendors may be found on regulatory inspection by the authorities to be noncompliant with cGMP or other applicable regulations. This may result in shutdown of the relevant facility or invalidation of drug product lots or processes, as well as delays in clinical development programs which could ultimately negatively impact our regulatory and commercialization timelines and expectations. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

We have outsourced an important step in the manufacturing of IXCHIQ to a third party, IDT Biologika, and Vetter performs the filling process for IXIARO and the filling of IXCHIQ diluent. Outsourcing of manufacturing could result in delays, concerns about manufacturing consistency, or other manufacturing failures. Per the standard industry practice, we rather than the third-party provider would bear the risk of such problems, which could result in a material adverse impact on our business, prospects, financial condition, and results of operations.

Any of these factors impacting manufacturing quantity or quality could delay clinical trials, regulatory submissions, and/or commercialization of our products, interfere with current sales, entail higher costs, and result in our inability to effectively sell our products.

We rely primarily on our manufacturing facilities as the source of manufacturing for our products and for certain of our product candidates.

Our manufacturing facility in Livingston, Scotland is the sole source of commercial quantities of drug substance of our Japanese encephalitis vaccine IXIARO and our chikungunya vaccine IXCHIQ. Our manufacturing facility in Solna, Sweden, is the sole source of commercial quantities of DUKORAL. The destruction of either of these facilities by fire or other catastrophic events would prevent us from manufacturing the relevant product and supplying our customers or clinical trial centers, which would result in a material adverse impact on our business, prospects, financial condition, and results of operations.

We rely upon third parties to manufacture and supply components of certain substances necessary to manufacture our products and product candidates.

We currently rely upon several, and in the future may rely on additional, third-party contract manufacturing organizations, or CMOs, for the manufacture and supply of components and substances for all of the product candidates we are developing. In particular, we have outsourced one step in the manufacturing process of IXCHIQ to IDT Biologika. Additionally, certain component materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to manufacture these materials for us. We cannot assure you that, if required, we will be able to identify alternate sources with the desired scale and capability and establish relationships with such sources. Additionally, in the biopharmaceutical industry, supplier changes require lengthy validation and regulatory approval processes. A loss of any CMO or component supplier and delay in establishing a replacement could delay our clinical development and regulatory approval process and interrupt supply.

Manufacturing facilities and clinical trial sites are subject to significant government regulations and approvals. If we or any third parties fail to comply with these regulations or maintain these approvals, our business could be materially harmed.

Our manufacturing facilities are subject to ongoing regulation and periodic inspection by national authorities, including the competent authorities of EEA countries, the FDA, and other regulatory bodies to ensure compliance with cGMP and other applicable regulations when producing batches of our products and product candidates for clinical trials. CROs and other third-party research organizations must also comply with Good Laboratory Practice, or GLP, when carrying out regulatory toxicology studies. Any failure to follow and document our or their adherence to such cGMP and GLP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, may delay or prevent filing or approval of marketing applications for our products, or may cause us to not meet our obligations under our commercial agreements.

Failure to comply with applicable regulations at our manufacturing sites or at clinical trial sites could also result in national authorities, the competent authorities of EEA countries, the FDA, or other applicable regulatory authorities taking various actions, including:

- levying fines and other civil penalties;

- imposing consent decrees or injunctions;
- requiring us to suspend or put on hold one or more of our clinical trials;
- requiring an additional audit or validation of clinical trial data;
- suspending, varying, or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us to suspend manufacturing activities or product sales, imports, or exports;
- requiring us to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to our reputation, business, financial condition, or operating results. Furthermore, we or our key suppliers and partners may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all, or in delays to our clinical trials. In addition, before any additional products would be considered for marketing authorization in the EEA, the United States, or other jurisdictions, our suppliers will have to pass an inspection by the applicable regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such inspections, and the inspections and any necessary remediation may be costly. Failure to pass such inspections by us or any of our suppliers would adversely affect our ability to commercialize our products or product candidates in the EEA, the United States, or other jurisdictions. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Our production costs may be higher than we currently estimate.

Our products and our product candidates are manufactured according to manufacturing best practices applicable to drugs for clinical trials and to specifications approved by the applicable regulatory authorities. If any of our products were found to be non-compliant, we would be required to manufacture the product again, which would entail additional costs and may prevent delivery of the product on time.

Other risks inherent in the production process may have the same effect, such as:

- contamination of the controlled atmosphere area;
- unusable premises and equipment;
- new regulatory requirements requiring a partial and/or extended stop to the production unit to meet the requirements;
- unavailable qualified personnel;
- power failure of extended duration; and
- logistical error.

Additionally, if we externalize any aspect of manufacturing that we have historically performed internally, this could result in an increase in production costs. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We use hazardous chemicals and biological materials in our business and any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We also handle genetically recombined material, genetically modified species, and pathological biological samples. Consequently, in France, Sweden, and Scotland where we have production facilities and in the jurisdictions where we conduct clinical trials, we are subject to environment and safety laws and regulations governing the use, storage, handling, discharge, and disposal of hazardous materials, including chemical and biological products. We impose preventive and protective measures for the protection of our workforce and waste control management in accordance with applicable laws, including part four of the French Labor Code, relating to occupational health and safety.

If we fail to comply with applicable regulations, particularly those applicable to all BSL classifications, we could be subject to criminal prosecutions, fines, damages, and the suspension of all or part of our operations. Compliance with environmental, health, and safety regulations involves additional costs, and we may have to incur significant costs to comply with future laws and regulations in relevant jurisdictions. Compliance with environmental laws and regulations could require us to purchase equipment, modify facilities, and undertake considerable expenses. We do not have insurance

that specifically covers liability relating to hazardous materials and could be liable for any inadvertent contamination, injury, or damage, which could negatively affect our business and engage the civil and/or criminal liability of the Company and/or its representatives.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, and scientific personnel, our business will be harmed.

We are highly dependent on our management, scientific, and medical personnel, particularly our Chief Executive Officer Thomas Lingelbach, who we heavily rely on for a variety of matters. Our key personnel may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives, other than Thomas Lingelbach and Juan Carlos Jaramillo, or any of our employees.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel, and commercialization, manufacturing and sales and marketing personnel will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management, including in the context of our recent change in governance structure, as described in Item 6. Our failure to integrate new individuals and create effective working relationships among members of management could result in inefficiencies in the development and commercialization of our product candidates and other aspects of our business, which could negatively impact our results of operations.

We may encounter difficulties in managing our growth, which could disrupt our operations.

Our strategy involves continuing to grow our business internally. However, we may also grow externally through selective acquisitions of complementary products and technologies, or of companies with such assets, although no such plan is currently contemplated. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs, and sales, marketing and distribution for our approved products. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and recruit and train additional qualified personnel. Due to our limited financial resources and the extent of our anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing internal or external growth. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure and give rise to operational errors, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy.

If we were to acquire assets or companies, the success of such an acquisition would depend on our capacity to carry out such acquisitions and to integrate such assets or companies into our existing operations. The implementation of such a strategy could impose significant constraints, including:

- human resources: recruiting, integrating, training, managing, motivating, and retaining a growing number of employees;
- financial and management system resources: identification and management of appropriate financing and management of our financial reporting systems; and
- infrastructure: expansion or transfer of our laboratories or the development of our information technology system.

In addition, an acquisition could result in shareholder litigation, which could be costly and time consuming and divert management’s attention and resources. For example, following the merger between Vivalis SA and InterCell AG in 2013,

certain former Intercell shareholders initiated legal proceedings to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used for the non-departing shareholders who received Valneva shares in the merger. On February 8, 2021, the judicial committee in charge of these proceedings appointed an expert and requested that he give an opinion on the exchange ratio applied to this latter group. On October 6, 2021, we received the expert's opinion. With respect to the exchange ratio, the expert confirmed the prior calculation used but also recommended the calculation of safety margins. Additionally, the expert addressed the cash compensation paid to departing shareholders and recommended an increase in such compensation. If this increase is approved by the court, it would result in a liability lower than our current litigation reserves, which pertain to this plaintiff group specifically. The expert provided a supplemental opinion in April 2022, and the judicial committee in charge of the proceedings gave its opinion to the Vienna commercial court in April 2023. The court has not made a decision yet. The results of this litigation or any other legal proceedings are inherently uncertain, and adverse judgments or settlements in some of these legal disputes may result in adverse and potentially substantial monetary damages, penalties, or injunctive relief against us, which could negatively impact our financial position, cash flows, or results of operations. See Note 5.33.2 to our financial statements for the year ended December 31, 2023 appearing elsewhere in this Annual Report for a discussion of these legal proceedings.

If we are unable to manage internal growth or have difficulty integrating any acquisitions, it could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We will need to hire new employees and expand our use of service providers.

As of December 31, 2023, we had 676 employees. As we continue to commercialize our products and as our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel.

We currently rely, and for the foreseeable future will continue to rely, in part on certain independent organizations, advisors, and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our sales, research, development and commercialization goals.

Our business has been and could be materially adversely affected by the effects of health pandemics or epidemics. Future outbreaks of disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites, or other business operations, could materially affect our operations globally and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business has been and could in the future be materially adversely affected by the effects of pandemics or epidemics, including COVID-19 and future outbreaks of the disease. COVID-19 adversely affected economic activity across virtually all sectors and industries on a local, national, and global scale. We are unable to accurately predict the impact that any future developments of COVID-19 or a similar event would have on our business due to numerous uncertainties, including the duration of the outbreak, the result of vaccination efforts, resurgence of the virus including any new variants, actions that may be taken by governmental authorities, impacts on international travel, the impact on the business of our service providers and partners, and the impact on the global financial markets, which could limit our access to capital and affect our liquidity. These and similar, and perhaps more severe, disruptions in our operations could materially impact our business, operating results and financial condition.

We have engaged and may in the future engage in strategic transactions, such as acquisitions or investments in other companies or technologies, which could divert our management's attention and in some cases result in dilution to our shareholders and otherwise disrupt our operations and adversely affect our operating results.

We have engaged and may in the future engage in strategic transactions that may divert the attention of management and incur various expenses in identifying, investigating, and pursuing suitable transactions, whether or not they are consummated. For example, we may seek to acquire or invest in additional businesses and/or technologies that we believe complement or expand our product candidates, enhance our technical capabilities, or otherwise offer growth opportunities in the United States and internationally. In 2015 we acquired Crucell Sweden AB and all assets, licenses, and privileges related to DUKORAL. We may also consider divestment of specific assets to support different strategic objectives.

Realizing the benefits of acquisitions depends upon the successful integration of the acquired technology into our existing and future product candidates. Furthermore, we may not be able to integrate the acquired personnel, operations, and technologies successfully, or effectively manage the combined business following the acquisition. We also may not realize the anticipated benefits from any acquired business. The risks we face in connection with acquisitions and investments, whether or not consummated, include:

- unanticipated costs or liabilities associated with the acquisition;
- diversion of management's attention from other business concerns;
- adverse effects to our existing strategic collaborations as a result of the acquisition;
- assimilation of operations, intellectual property, and products of an acquired company;
- the potential loss of key employees;
- difficulty integrating the accounting systems, operations, and personnel of the acquired business;
- the assumption of additional indebtedness or contingent or unknown liabilities, or adverse tax consequences or unfavorable accounting treatment;
- claims and disputes by shareholders and third parties, including intellectual property claims and disputes;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- increased operating expenses and cash requirements; and
- use of substantial portions of our available cash to consummate the acquisition.

A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations, and prospects.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition, results of operations, and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CMOs, CROs, and other contractors and consultants, could be subject to cybersecurity attacks, earthquakes, power shortages, information technology or telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, armed conflict, wars, public health pandemics or epidemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop and commercialize our product candidates could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions.

We may be negatively impacted by volatility in the political and economic environment, including as a result of military conflicts, elections, economic downturns and increases in interest rates, and a period of sustained inflation across the markets in which we operate could result in higher operating costs and may negatively impact our business and financial performance.

Trade, monetary and fiscal policies, and political and economic conditions may substantially change, and credit markets may experience periods of constriction and variability. These conditions may impact our business. Furthermore, rising inflation may negatively impact our business, increase costs, and reduce profitability. While we would take actions, wherever possible, to mitigate the impact of the effects of inflation, in the case of sustained inflation across several of the markets in which we operate, it could become increasingly difficult to effectively mitigate the increases to our costs. If we are unable to take actions to effectively mitigate the effect of the resulting higher costs, our profitability and financial position could be negatively impacted.

The U.S. Federal Reserve and European Central Bank have raised interest rates multiple times in response to concerns about inflation, among other things, and they may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty. Similarly, the ongoing military conflicts between Russia and Ukraine and between Israel and Hamas have created volatility in the global capital markets and are expected to have further global economic consequences, including ongoing disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, including relative to cost or dilution. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, higher inflation and macro turmoil and uncertainty could also adversely affect our customers, which could reduce demand for our products.

Our available cash and cash equivalents are held in accounts managed by third party financial institutions in the United States and in Europe and consist of cash in our operating accounts. At any point in time, the funds in our operating

accounts at U.S. financial institutions may exceed the Federal Deposit Insurance Corporation insurance limits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail. We can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

Our IT systems and data, and those of our collaborators, consultants, service providers, and other contractors, are vulnerable to cyberattacks and security breaches, which could significantly disrupt our core operations, product development programs, and overall business and adversely affect our business strategy, financial condition, results of operations, and prospects.

Our computer and information technology systems, networks, infrastructure, hardware, software, and cloud-based computing services, collectively referred to as IT Systems, and those of our current and future collaborators, service providers, and other contractors or consultants are vulnerable to malware (such as ransomware), malicious code (such as computer viruses and worms), data corruption, cyber-based attacks, malfeasance by insiders, human error, natural disasters, public health pandemics or epidemics, terrorism, war, and telecommunication and electrical failures, all of which threaten the confidentiality, integrity, and availability of our IT Systems, key business processes, and intellectual property, proprietary business information, personal information, and other important data we process or maintain, collectively referred to as our Confidential Information.

We and certain of our third-party providers have in the past experienced cyberattacks and other security incidents, and we expect that to continue in varying degrees in the future. While to date no attacks or incidents have had a material impact on our operations or results, we cannot guarantee that material incidents will not occur in the future. We expect cyberattacks to accelerate on a global basis in both frequency and magnitude as threat actors are increasingly sophisticated in using techniques and tools – including artificial intelligence – that can circumvent controls, evade detection, and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate, or recover from future attacks or incidents or to avoid a material adverse impact on our IT Systems, Confidential Information, or business. Cybersecurity threats are increasingly difficult to detect and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, insiders and other personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Remote and hybrid working arrangements at our company (and at many third-party providers) also increase cybersecurity risks due to the challenges associated with managing remote computing assets and the security vulnerabilities that are present in many non-corporate and home networks. In addition, we cannot comprehensively identify all misconfigurations, “bugs”, or vulnerabilities in proprietary or third-party systems or software used by our business or guarantee that patches or compensating controls will be applied before vulnerabilities can be exploited by a threat actor. Moreover, any use or integration of generative or other artificial intelligence in our, or any third parties’, operations, products, or services will pose new and/or unknown cybersecurity risks and challenges. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our IT Systems and Confidential Information. Any significant system failure, accident, attack, or security breach could have a material adverse effect on our business, financial condition, and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, and security vulnerabilities or to respond to or recover from a cyberattack or security incident could be significant and could result in unexpected interruptions, delays, cessation of service, and other harm to our business and our competitive position, as well as regulatory investigations, litigation (including class action suits), reputational impacts, and the loss of partners, collaborators, and customers. If such an event were to occur and cause interruptions in our operations, it could also result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our product candidates, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our product candidates could be delayed.

In addition, our IT Systems and those of our current and any future collaborators, service providers, and other contractors or consultants are potentially vulnerable to data security breaches, whether by employees, contractors, consultants, malware, phishing attacks, or other cyberattacks, that may expose Confidential Information to unauthorized persons. For example, we have experienced phishing attacks in the past, and we expect to be a target of phishing attacks and other cyberattacks in the future. In addition, our IT Systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. Consequently, successful cyberattacks that disrupt or result in unauthorized access to third-party IT Systems can materially impact our operations and financial results. If a data security breach affects our systems, corrupts our data, or results in the unauthorized disclosure or release of personally identifiable information, for example, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, or individuals pursuant to various data protection, privacy, and security laws, regulations, and guidelines, as applicable, such as the EU and UK GDPR (as defined below). Accordingly, a data security breach or privacy violation that leads to unauthorized access to, disclosure, or modification of personal information (including protected health information), that prevents access to personal information, or that materially compromises the privacy, security, or confidentiality of the personal information, could result in fines, increased costs, or loss of revenue, and we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Furthermore, laws and regulations around the globe, such as the EU and UK GDPR, can expose us to enforcement actions and investigations by regulatory authorities and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail and if we fail to disclose any material cybersecurity incident in an adequate and timely manner. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We (and our service providers) receive, process, store, and use personal information and other data, which subjects us to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies, and other obligations related to data privacy and security. Our (and our service providers') actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, and otherwise adversely affect our business.

We, and our service providers, receive, process, store, and use personal information and other data about our clinical trial participants, employees, partners, and others. We, and our service providers, must comply with numerous foreign and domestic laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations regarding privacy and the storing, sharing, use, processing, disclosure, security, and protection of personal information and other data, such as information that we collect about patients and healthcare providers in connection with clinical trials in Europe, the United States, and elsewhere. We strive to comply with all applicable requirements and obligations; however, new laws, policies, codes of conduct, and legal obligations may arise, continue to evolve, be interpreted and applied in a manner that is inconsistent from one jurisdiction to another, and conflict with one another. Any failure or perceived failure by us or third parties working on our behalf to comply with applicable laws and regulations, any privacy and data security obligations pursuant to contract or pursuant to our stated privacy or security policies, or obligations to third parties may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims (to which we have been subject), litigation, damage to our reputation, and loss of goodwill, any of which could have a material adverse effect on our business, operations, and financial performance. With substantial uncertainty over the interpretation and application of these laws, regulations, and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in our efforts to do so.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., state surveillance and wiretapping laws such as California Invasion of Privacy Act). For example, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In addition, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, together referred to as the CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights, such as those noted below. The CCPA provides for fines of up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers.

The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations, and industry standards concerning privacy, data protection, and information security, and we cannot yet determine the impact that such future laws, regulations, and standards may have on our business. For example, in Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, apply to our operations. The EU General Data Protection Regulation and United Kingdom's implementation of the General Data Protection Regulation, known respectively as the EU and UK GDPR, as well as EEA Member States' and the United Kingdom's implementing national legislation, apply to the collection and processing of personal data, including health-related information, by companies located in the EEA or the United Kingdom. In certain circumstances, the EU and UK GDPR also apply to companies located outside of the EEA or United Kingdom who are processing personal data of individuals located in the EEA or United Kingdom. The EU and UK GDPR have increased compliance burdens on us, such as requiring the following:

- processing personal data only for specified, explicit, and legitimate purposes for which personal data were collected;

- establishing a legal basis for processing personal data and creating obligations for controllers and processors to appoint data protection officers in certain circumstances;
- increasing transparency obligations to data subjects for controllers (including presentation of certain information in a concise, intelligible, and easily accessible form about how their personal data is used and their rights vis-à-vis that data and its use);
- introducing the obligation to carry out so-called data protection impact assessments in certain circumstances;
- establishing limitations on collection and retention of personal data through “data minimization” and “storage limitation” principles;
- establishing obligations to implement “privacy by design”;
- introducing obligations to honor increased rights for data subjects (such as rights for individuals to be “forgotten,” rights to data portability, and rights to object, etc., in certain circumstances);
- formalizing a heightened and codified standard of data subject consent;
- establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data;
- introducing obligations to agree to certain specific contractual terms and to take certain measures when engaging third party processors and joint controllers;
- introducing the obligation to provide notice of certain personal data breaches to the relevant supervisory authority or authorities and affected individuals; and
- mandating the appointment representatives in the United Kingdom and/or EEA in certain circumstances.

The processing of sensitive personal data, such as health information, is subject to compliance with specific exceptions under the EU and UK GDPR which may impose heightened compliance burdens and is a topic of active interest among foreign regulators. The EU and UK GDPR increase our obligations with respect to clinical trials conducted in Europe (including the EEA, United Kingdom and Switzerland) by expressly expanding the definition of personal data to include “pseudonymized” or key-coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators.

The EU and UK GDPR also provide for more robust regulatory enforcement and greater penalties for noncompliance than previous data protection laws, including fines of up to 20 million euros under the EU GDPR, 17.5 million pound sterling under the UK GDPR, or in each case, 4% of global annual revenue for the preceding financial year, whichever is higher. In addition to administrative fines, a wide variety of other potential enforcement powers are available to competent supervisory authorities in respect of potential and suspected violations of the EU and UK GDPR, including extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by non-compliant actors. The EU and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU and UK GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanism that may be used to transfer personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the UK’s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA or UK, including, for example, obtaining individuals’ explicit consent to transfer their personal data from the EEA or UK to the United States or other countries, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal data from the EEA or United Kingdom. The inability to transfer personal data from the EEA, United Kingdom, or Switzerland may also restrict our clinical trials activities in such jurisdictions, limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to European data protection laws, and require us to increase our data processing capabilities in the EEA, United Kingdom, or Switzerland, likely at significant expense. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the EU and UK GDPR or regulatory frameworks of equivalent complexity.

The EU GDPR provides that EEA countries may make their own further laws and regulations to introduce specific requirements related to the processing of “special categories of personal data,” including personal data related to health,

biometric data used for unique identification purposes, and genetic information, as well as personal data related to criminal offences or convictions. In the United Kingdom, the United Kingdom Data Protection Act 2018 complements the UK GDPR in this regard. This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and/or United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use, and share data in the context of our EEA and/or United Kingdom establishments (regardless of where any processing in question occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

For example, in France, the conduct of clinical trials is subject to compliance with specific provisions. The French Law No.78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties, as amended, establishes a strict framework applicable to the processing of personal data in the health sector. This framework requires, among others, the filing of compliance undertakings with “reference methodologies” (such as the MR-001) adopted by the French Data Protection Authority, or CNIL, or, if not complying, obtaining an authorization from the CNIL. Failure to comply with the stringent provisions of the reference methodologies or failure to obtain the CNIL’s authorization could expose us to adverse consequences, including the interruption of our clinical trials in France, increased exposure to regulatory actions, or the need to relocate part of or all of our data processing activities to other jurisdictions at significant expense.

It is possible that the EU and UK GDPR or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices, and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations, and we cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. Furthermore, other jurisdictions outside the EEA are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, and our efforts to comply with the evolving data protection rules may be unsuccessful. We cannot guarantee that we, our third-party collaborators, or our vendors are in compliance with all applicable data protection and privacy laws and regulations as they are enforced now or as they evolve. Further, for example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws. Our non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures, and systems. In addition, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts.

In addition to data privacy and security laws, we may be subject to contractual obligations based on industry standards adopted by industry groups, such as best practices governing the conduct of clinical trials, and we are, or may become, subject to such obligations in the future. We are also subject to contractual obligations related to data privacy and security. Our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU and UK GDPR and CCPA, may require us to impose specific contractual restrictions on certain service providers that have access to personal data, such as clinical trial patient data or personal data of clinical trial site personnel. We publish privacy policies, marketing materials, and other statements regarding data privacy and security on our website. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, or unfair, or to misrepresent our practices, we may be subject to investigation, enforcement actions by regulators (such as the Federal Trade Commission), or other adverse consequences.

Our actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, penalties, orders that require a change in our practices, additional reporting requirements and/or oversight, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits, or reputational damage, all of which could materially affect our business, financial condition, results of operations, and growth prospects.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct, or unauthorized activities that violates (i) the laws and regulations of the EEA countries, FDA, and other regulatory authorities, including those laws requiring the reporting of true, complete, and accurate information to competent regulatory authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations in the EEA, the United States, and elsewhere and (iv) laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our

reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations, and prospects.

We benefit from tax credits in Austria and France that could be reduced or eliminated.

As a company with research and development activity, we benefit from certain tax advantages, including the Austrian Research and Development tax credit and the French Research Tax Credit (*Crédit Impôt Recherche*), which are tax credits aimed at stimulating research and development. Our Austrian Research and Development tax credits were €5.7 million, €13.9 million and €20.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. Our French Research Tax Credits were €1.1 million, €1.5 million, and €1.8 million for the years ended December 31, 2023, 2022, and 2021, respectively. The Austrian Research and Development tax credit is calculated based on claimed amount of eligible research and development in Austria, while the French Research Tax credit is calculated based on our claimed amount of eligible research and development expenditures in France. The main differences between the Austrian and French research tax credits are the applicable percentage of and the basis for the tax credit. The tax credits are a source of financing to us that could be reduced or eliminated by the Austrian and French tax authorities or by changes in Austrian and French tax law or regulations.

The Austrian Research and Development tax credit is reimbursed to us. While the Austrian Research and Development tax credit is reviewed as a part of the issuance of a certificate by the local auditor and the research and development projects need an approval from the Austrian Research Promotion Agency (FFG), the Austrian tax authority may audit each research and development claim. The Austrian tax authorities may challenge our eligibility for, our calculation of, certain tax reductions in respect of our research and development activities (and therefore the amount of Research and Development Tax Credit claimed). Furthermore, the Austrian Parliament may decide to eliminate, or to reduce the scope or the rate of, the Research Tax Credit benefit, either of which it could decide to do at any time.

The French Research Tax Credit can be offset against French corporate income tax due with respect to the year during which the eligible research and development expenditures have been made. The portion of tax credit in excess which is not being offset, if any, represents a receivable against the French Treasury which can in principle be offset against the French corporate income tax due by the company with respect to the three following years. The remaining portion of tax credit not being offset upon expiry of such a period may then be refunded to the company. The French Research Tax credit is reimbursed within the expiry of a period of three years.

The French tax authorities, with the assistance of the Higher Education and Research Ministry, may audit each research and development program in respect of which a Research Tax Credit benefit has been claimed and assess whether such program qualifies in their view for the Research Tax Credit benefit. The French tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities (and therefore the amount of Research Tax Credit claimed). Furthermore, the French Parliament may decide to eliminate, or to reduce the scope or the rate of, the Research Tax Credit benefit, either of which it could decide to do at any time.

If we fail to receive future Research Tax Credit amounts or if our calculations are challenged, even if we comply with the current requirements in terms of documentation and eligibility of its expenditure, our business, prospects, financial condition, and results of operations could be adversely affected.

We may be unable to carry forward existing tax losses.

We have accumulated tax loss carry forwards of €879.1 million, €821.6 million, and €628.3 million for the years ended December 31, 2023, 2022, and 2021, respectively. Applicable French law provides that, for fiscal years ending after December 31, 2012, the use of these tax losses is limited to €1.0 million, plus 50% of the portion of net earnings exceeding this amount. The unused balance of the tax losses in application of such rule can be carried forward to future fiscal years, under the same conditions and without time restriction. There can be no assurance that future changes to applicable tax law and regulation will not eliminate or alter these or other provisions in a manner unfavorable to us, which could have an adverse effect on our business, prospects, financial condition, cash flows or results of operations.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

Corporate tax reform, anti-base-erosion rules and tax transparency continue to be high priorities in many jurisdictions. As a result, policies regarding corporate income and other taxes in numerous jurisdictions are under heightened scrutiny and tax reform legislation has been, and will likely continue to be, proposed or enacted in a number of jurisdictions in which we operate.

In August 2022, the Inflation Reduction Act was signed into law in the United States incorporating some of the Biden Administration’s proposals for corporate tax reform. Other recently enacted legislation in the United States includes the Tax Act, the Families First Coronavirus Response Act, and the CARES Act. The U.S. Department of Treasury has broad authority to issue regulations and interpretative guidance that may have a significant impact on our results of operations in the period issued, including our effective tax rate.

In addition, many countries are implementing legislation and other guidance to align their international tax rules with those of the Organization for Economic Co-operation and Development, or OECD, whose Base Erosion and Profit Shifting recommendations and action plan aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. The OECD is also continuing discussions surrounding fundamental changes in allocation of profits among tax jurisdictions in which companies do business, as well as the implementation of a global minimum tax (namely the “Pillar One” and “Pillar Two” proposals). As a result of this heightened scrutiny, prior decisions by tax authorities regarding treatments and positions of corporate income taxes could be subject to enforcement activities and legislative investigation and inquiry, which could also result in changes in tax policies or prior tax rulings. Any such changes may also result in the taxes we previously paid being subject to change.

Our business may be exposed to foreign exchange risks.

We operate internationally and are exposed to foreign exchange risks arising from various currencies, primarily with respect to the Euro (EUR), the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK), and the U.S. Dollar (USD). Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations. Because a substantial part of sales of IXIARO and IXCHIQ are, or are expected to be, generated in the United States, with a significant part of production costs in GBP, and in Canada for DUKORAL, with production costs in SEK, we are exposed to foreign exchange risks, principally with respect to the USD, GBP, SEK, and CAD. We have entered into currency option contracts to limit the risk of foreign exchange losses. However, our results of operations continue to be impacted by exchange rate fluctuations. For example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euro at a reduced value. While we entered into currency option contracts in 2020 to limit the risk of foreign exchange losses, we cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Our ADSs are quoted in U.S. dollars on Nasdaq, while our ordinary shares trade in euro on Euronext Paris. Our financial statements are prepared in euro. Therefore, fluctuations in the exchange rate between the euro and the U.S. dollar will also affect, among other matters, the value of our ordinary shares and ADSs. We could also sign contracts denominated in other currencies, which would increase our exposure to currency risk. In accordance with our business decisions, our exposure to this type of risk could change depending on:

- the currencies in which we receive our revenues;
- the currencies chosen when agreements are signed, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on product candidates; and
- our policy for insurance coverage.

In addition, in light of the ongoing military conflict between Russia and Ukraine and the resulting tensions between the European Union, the United Kingdom, the United States and other countries with Russia, any resulting material change to the valuation of European and U.S. currencies could adversely impact our operating results. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Ownership of Our Ordinary Shares and the ADSs

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ordinary shares and ADSs. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth.

Therefore, the holders of our ordinary shares and ADSs are not likely to receive any dividends for the foreseeable future and the success of an investment in our ordinary shares and ADSs will depend upon any future appreciation in value. Consequently, investors may need to sell all or part of their holdings of the ordinary shares or ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ordinary shares or ADSs will appreciate in value or even maintain the price at which our shareholders have purchased them.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with accounting standards applicable in France. Moreover, pursuant to French law, we must allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends, should we propose to declare any, may be paid for that year, until the amount in the legal

reserve is equal to 10% of the aggregate nominal value of our issued and outstanding share capital. In addition, payment of dividends may subject us to additional taxes under French law. Therefore, we may be more restricted in our ability to declare dividends than companies that are not incorporated in France.

In addition, exchange rate fluctuations may affect the amount of euro that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euro, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

Future sales of ordinary shares or ADSs by existing shareholders could depress the market price of the ordinary shares or ADSs.

Future sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs and/or ordinary shares. Sales in the United States of our ADSs and ordinary shares held by our directors, officers, and affiliated shareholders or ADS holders are subject to restrictions. If these shareholders or ADS holders sell substantial amounts of ordinary shares or ADSs in the public market, or the market perceives that such sales may occur, the market price of our ADSs or ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Our ADSs are listed on the Nasdaq Global Select Market and our ordinary shares are listed on Euronext Paris. Trading of the ADSs or ordinary shares in these markets takes place in different currencies (U.S. dollars on Nasdaq and euro on Euronext Paris), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and France). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on Euronext Paris could cause a decrease in the trading price of the ADSs on Nasdaq. Investors could seek to sell or buy our ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange, and the ordinary shares available for trading on the other exchange. In addition, holders of ADSs will not be immediately able to surrender their ADSs and withdraw the underlying ordinary shares for trading on the other market without effecting necessary procedures with the depository. This could result in time delays and additional cost for holders of ADSs. We cannot predict the effect of this continued dual listing on the value of our ordinary shares and the ADSs. However, the continued dual listing of our ordinary shares and ADSs may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States.

The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a European public company with limited liability (*Societas Europaea* or *SE*), with our registered office in France. Our corporate affairs are governed by our bylaws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our Board of Directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our Board of Directors is required by French law to consider the interests of our company, its shareholders, its employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder or holder of ADSs. Further, in accordance with French law, as long as a double voting right is attached to each ordinary share which is held in registered form in the name of the same shareholder for at least two years, ordinary shares deposited with the depository will not be entitled to double voting rights. Therefore, holders of ADSs who wish to obtain double voting rights will need to surrender their ADSs, withdraw the deposited shares, and take the necessary steps to hold such ordinary shares in registered form in the holder's name for at least two years. See "Item 16G—Corporate Governance."

U.S. investors may have difficulty enforcing civil liabilities against our company and members of the Executive Committee and the Board of Directors.

Most of the members of our Executive Committee and Board of Directors and the experts named in this Annual Report are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the

directors of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters.

Our bylaws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our bylaws and French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of the share capital and voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the EEA Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, a non-resident of France as well as any French entity controlled by non-residents of France may have to file a declaration for statistical purposes with the Bank of France (Banque de France) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- under French law, certain investments in a French company relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France or controlled by entities not French or not resident in France, are subject to prior authorization of the Ministry of Economy;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our Board of Directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders may in the future grant our Board of Directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our ordinary shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our Board of Directors appoints the members of the Executive Committee, notably the Chief Executive Officer (*Directeur Général*) and Associate Managing Officers (*Directeurs Généraux Délégués*);
- our Board of Directors has the right to appoint members of the Board to fill a vacancy created by the resignation or death of a member of the Board for the remaining duration of such member's term of office, and subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our Board;
- our Board of Directors can be convened by the Chair, Vice-Chair, or Lead Independent Member or, if there has been no Board meeting for more than two months, by Directors representing one-third of the Board;
- our Board of Directors meetings can take place in person or by way of videoconference or teleconference and for decisions of the Board of Directors to be valid, at least half of the Directors must be present or represented;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove members of the Board of Directors with or without cause;
- the crossing of certain ownership thresholds has to be disclosed and can impose certain obligations;
- advance notice is required for nominations to the Board of Directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a member of the Board can be proposed at any shareholders' meeting without notice;

- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Regulation 596/2014 of April 16, 2014; and
- pursuant to French law, our bylaws, including the sections relating to the number of members of the Board of Directors and Associate Managing Officers, and election and removal of members of the Board of Directors and Associate Managing Officers from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

We have previously reported material weaknesses in our internal controls over financial reporting, and if we are unable to maintain effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence, and depress the market price of our securities.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting, and we are also required to have our independent registered public accounting firm issue an opinion on the effectiveness of our internal control over financial reporting on an annual basis. To ensure compliance with Section 404, we will need to continue to dedicate internal resources to remediation efforts for any material weaknesses that we identify, and we have previously engaged outside consultants to assist us in adopting a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. The process to document and evaluate our internal control over financial reporting is both costly and challenging.

We previously identified material weaknesses in our internal control over financial reporting in connection with the preparation of the consolidated financial statements for the years ended December 31, 2021 and 2022. In connection with the preparation of our consolidated financial statements as at and for the year ended December 31, 2022, we identified deficiencies in the control environment, risk assessment, control activities, information and communication, and monitoring components of the COSO Framework (as defined in Item 15 of this Annual Report). These deficiencies constituted material weaknesses, either individually or in the aggregate, were pervasive in nature, and impacted all significant accounts and disclosures. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. These material weaknesses did not result in a material misstatement to our financial statements. However, these material weaknesses could result in material inaccuracies in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. For further information about the material weaknesses previously identified, see Item 15 of this Annual Report.

We took steps to address these material weaknesses and implemented remediation plans. See Item 15 of this Annual Report for further details about these past remediation measures. We cannot assure you that the controls we have judged to be effective for the year ended December 31, 2023 will continue to be effective or that we will be able to prevent any future material weaknesses in our internal control over financial reporting.

The rules governing the standards for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing, and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. The process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation is time-consuming, costly, and complicated. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are or may be applicable to us as a public company listed in the United States. If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the United States, our business and reputation may be harmed, and the price of our ordinary shares and ADSs may decline. In addition, undetected material weaknesses in our internal control over financial reporting could lead to restatements of financial statements and require us to incur the expense of remediation. Any of these developments could result in investor perceptions of us being adversely affected, which could cause a decline in the market price of our securities.

Existing and potential investors in our ordinary shares or ADSs may have to request the prior authorization from the French Ministry of Economy prior to acquiring a significant ownership position in our ordinary shares or ADSs.

Under French law, investments of more than 25% by certain individuals or entities in a French company deemed to be a strategic industry may be subject to prior authorization of the French Ministry of Economy pursuant to Articles L. 151-1 et seq. and R. 151-1 et seq. of the French Monetary and Financial code.

If an investment requiring the prior authorization of the French Minister of Economy is completed without such authorization having been granted, the French Minister of Economy might direct the relevant investor to nonetheless (i) submit a request for authorization, (ii) have the previous situation restored at its own expense or (iii) amend the investment. The relevant investor might also be found criminally liable and might be sanctioned with a fine which cannot

exceed the greater of: (i) twice the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company and (iii) €5 million (for an entity) or €1 million (for an individual).

In the context of the ongoing COVID-19 pandemic, the Decree (*décret*) no. 2020 892 dated July 22, 2020, as amended by the Decree (*décret*) no. 2020-1729 dated December 28, 2020 created until December 31, 2021 a new 10% threshold of the voting rights for the non-European investments made (i) in an entity having its registered office in France and (ii) whose shares are admitted to trading on a regulated market, in addition to the 25% above-mentioned threshold. The transactions falling within the scope of the Decree (*décret*) no. 2020-892, as amended, benefit from a “fast-track procedure” pursuant to which the investor is exempt from the authorization request provided for in Article R. 151-5 of the Monetary and Financial Code, provided that the investment project has been the subject of prior notification to the French Minister of Economy and that the transaction is carried out within six months following the notification. Unless the French Minister of Economy objects, the authorization is granted at the end of a period of ten working days following notification.

Failure to comply with such measures could result in significant consequences on the applicable investor. Such measures could also delay or discourage a takeover attempt, and we cannot predict whether these measures will result in a lower or more volatile market price of our ADSs.

Purchasers of ADSs are not directly holding our ordinary shares.

A holder of ADSs is not treated as one of our shareholders and does not have direct shareholder rights, unless he or she withdraws the ordinary shares underlying his or her ADSs. French law governs our shareholder rights. The depositary, through the custodian or the custodian’s nominee, is the holder of the ordinary shares underlying ADSs. Purchasers of ADSs have ADS holder rights. The deposit agreement among us, the depositary, and ADS holders sets out ADS holder rights, as well as the rights and obligations of us and the depositary. ADS holders are encouraged to read the deposit agreement, which is filed as an exhibit to this Annual Report.

Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings.

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, our ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (i) the notice of the meeting or solicitation of consent or proxy sent by us and (ii) a statement as to the manner in which instructions may be given by the holders.

You may instruct the depositary of your ADSs to vote the ordinary shares underlying your ADSs. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the ordinary shares underlying the ADSs you hold. However, you may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for your instructions, the depositary, upon timely notice from us, will notify you of the upcoming vote and arrange to deliver our voting materials to you. We cannot guarantee you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares or to withdraw your ordinary shares so that you can vote them yourself. If the depositary does not receive timely voting instructions from you, it may give a proxy to a person designated by us to vote the ordinary shares underlying your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote, and there may be nothing you can do if the ordinary shares underlying your ADSs are not voted as you requested.

You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying ordinary shares.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer, or register transfers of your ADSs generally when our books or the books of the depositary are closed, or

at any time if we or the depositary think it is advisable to do so because of any requirement of law, government, or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting, or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes, and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders, including holders who acquire ADSs in the secondary market, waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action. Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents, or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, the members of our Board of Directors and Executive Committee are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Paris and expect to file financial reports on an annual and semi-annual basis, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. In addition, foreign private issuers are not required to file their Annual Report on Form 20-F until four months after the end of each fiscal year. Accordingly, there is less publicly available information concerning our company than there would be if we were not a foreign private issuer.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards, and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

As a foreign private issuer listed on Nasdaq, we are subject to Nasdaq's corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of its home country. Some corporate governance practices in France may differ significantly from Nasdaq corporate governance listing standards. We intend to continue to rely on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq corporate governance standards, to the extent possible. For example, neither the corporate laws of France nor our bylaws require a majority of the members of our Board of Directors to be independent, and although the corporate governance code to which we currently refer (the Middenext Code) recommends that, in a widely-held company like ours,

a majority of the members of the Board of Directors be independent (as construed under such code), this code only applies on a “comply-or-explain” basis, and we may in the future either decide not to apply this recommendation or change the corporate code to which we refer. Furthermore, we could include non-independent members of the Board of Directors as members of our Nomination, Governance and Compensation committee, and the independent members of our Board of Directors would not necessarily hold regularly scheduled meetings at which only independent members of the Board are present. In addition, we follow French law with respect to shareholder approval requirements in lieu of the various shareholder approval requirements of Nasdaq. Currently, we intend to continue to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter and, accordingly, our next determination will be made on June 30, 2024. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our Board of Directors or Executive Committee are residents or citizens of the United States, we could lose our foreign private issuer status. As of December 31, 2023, approximately 26% of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held by U.S. residents (assuming that all holders of ADSs as of such date are residents of the United States).

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer in the future, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices required of U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.

Under the Code, a non-U.S. company will be considered a passive foreign investment company, or PFIC, for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the weighted-average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property, and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation or partnership is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation or partnership. If we are a PFIC for any taxable year during which a U.S. holder (as defined in Item 10D, “Taxation”) holds our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds our ordinary shares or ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

We do not believe that we were characterized as a PFIC for the taxable year ending December 31, 2023. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance regarding if we currently are treated as a PFIC, or may be treated as a PFIC in the future. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current or future taxable year.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see Item 10D of this Annual Report.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group, if any. Our group currently includes one U.S. subsidiary and, therefore, under current law our current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income”, and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Code. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes, or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

A tax authority may take the position that material income tax liabilities, interest, and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

General Risk Factors

The trading price of our equity securities has been and may continue to be volatile, and purchasers of our ordinary shares or ADSs could incur substantial losses.

The price of our ordinary shares and ADSs has been, and likely will continue to be, significantly affected by events such as announcements regarding scientific and clinical results concerning product candidates currently being developed by us, our collaboration partners, or our main competitors, changes in market conditions related to our sector of activity, announcements of new contracts or amendments or terminations to existing contracts, technological innovations and collaborations by us or our main competitors, developments concerning intellectual property rights, the development, regulatory approval and commercialization of new products by us or our main competitors, and changes in our financial results.

Equity markets are subject to considerable price fluctuations, and often, these movements do not reflect the operational and financial performance of the listed companies concerned. In particular, biotechnology companies’ share prices have been highly volatile and may continue to be highly volatile in the future. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry. Fluctuations in the stock market as well as the macro-economic environment could significantly affect the price of our ordinary shares. As a result of this volatility, investors may not be able to sell their ordinary shares or ADSs at or above the price originally paid for the security. The market price for our ordinary shares and ADSs may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, divestitures, strategic partnerships, joint ventures, collaborations, or capital commitments;
- adverse results or delays in our or any of our competitors’ pre-clinical studies or clinical trials or regulatory timelines;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination or amendment of a strategic alliance, partnership, or collaboration or the inability to establish additional strategic alliances, partnerships, or collaborations;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- ordinary share and ADS price and volume fluctuations attributable to inconsistent trading volume levels of our ordinary shares and ADSs;
- price and volume fluctuations in trading of our ordinary shares on Euronext Paris;
- additions or departures of key management or scientific personnel;
- regulatory or legal developments in the United States, European Union and other jurisdictions;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent and other intellectual property protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions, including macroeconomic factors such as geopolitical instability, rising interest rates and inflation.

These and other market and industry factors may cause the market price and demand for our ordinary shares and ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares or ADSs and may otherwise negatively affect the liquidity of the trading market for the ordinary shares and ADSs. In addition, in the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could be costly and time consuming and divert management’s attention and resources.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ordinary shares or ADSs and their trading volume could decline.

The trading market for the ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. As a public company in France since 2013 and in the United States since May 2021, our equity securities are currently subject to coverage by a number of analysts. If fewer securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares could be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of our ordinary shares and ADSs would likely decline. Additionally, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our ordinary shares and ADSs could decrease, which could cause the price of our ordinary shares and ADSs or their trading volume to decline.

Item 4. Information on the Company

A. History and Development of the Company

Our legal name is “Valneva SE”. We are a public company listed on the Nasdaq Global Select Market and Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We were incorporated on March 24, 1999 as a limited liability company and converted into a European Company (*Societas Europaea*, or SE) on May 28, 2013. Our registered office is located at 6 rue Alain Bombard, 44800 Saint-Herblain, France. We are registered at the Nantes Trade and Companies Registry under the number 422 497 560. Our telephone number at our principal executive offices is +33 2 28 07 37 10.

We have nine wholly owned subsidiaries—Valneva Austria GmbH, a limited liability company formed under the laws of Austria in 2013, Valneva Scotland Ltd., a private company limited by shares formed under the laws of Scotland in 2003, Valneva USA, Inc., a Delaware corporation formed in 1997, Vaccines Holdings Sweden AB, a private limited company formed under the laws of Sweden in 2014, Valneva Sweden AB, a private limited company formed under the laws of Sweden in 1992, Valneva Canada, Inc., a corporation formed under the laws of Canada in 2015, Valneva UK Ltd., a private company formed under the laws of England and Wales in 2015, Valneva France SAS, a *société par actions simplifiée* formed under the laws of France in 2019, and VBC 3 Errichtungs GmbH, a limited liability company formed under the laws of Austria that we acquired in 2023 in connection with the purchase of the office building we occupy in Vienna.

Our agent for service of process in the United States is Valneva USA, Inc. Our website address is www.valneva.com. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not incorporated by reference into this Annual Report and does not constitute a part of this Annual Report.

The SEC maintains an internet site at <http://www.sec.gov> that contains reports and other information regarding issuers that file electronically with the SEC.

Our capital expenditures in the years ended December 31, 2023, 2022, and 2021 totaled €6.4 million, €29.0 million and €18.9 million, respectively, primarily related to investments in our manufacturing facilities in Scotland and Sweden. We expect our capital expenditures in 2024 to be primarily financed from our existing cash and cash equivalents.

B. Business Overview

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best-, or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early Research & Development (R&D) to approvals, and currently market three proprietary travel vaccines, including the world’s first and only chikungunya vaccine, IXCHIQ, as well as certain third-party vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This pipeline includes the only Lyme disease vaccine candidate (VLA15) in advanced clinical development, which we are developing in partnership with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

Our clinical portfolio is composed of highly differentiated vaccine candidates that are designed to provide preventative solutions to diseases with high unmet need. VLA1553 is a vaccine candidate which was approved by the U.S. Food and Drug Administration (FDA) under the brand name IXCHIQ in November 2023. It is indicated in the U.S. for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. At the end of February 2024, the U.S. Advisory Committee on Immunization Practices (ACIP) provided recommendations on how to use IXCHIQ and these recommendations were then adopted by the U.S. Centers for Disease Control and Prevention (CDC). The vaccine is still undergoing several clinical trials with a view to support additional marketing approvals and potential label extensions. VLA15 is a Phase 3 vaccine candidate targeting *Borrelia*, the bacterium that causes Lyme disease, under development in collaboration with Pfizer, and it is the only vaccine candidate against Lyme disease currently undergoing late-stage clinical trials. VLA15 targets the six most prevalent serotypes, or variations, of *Borrelia* in the United States, where approximately 476,000 people are diagnosed with Lyme disease each year and in Europe, where at least a further 200,000 cases occur annually. VLA1601 is a Phase 1 vaccine candidate targeting the Zika virus (ZIKV), a mosquito-borne viral disease whose transmission has been reported in 89 countries and

territories and persists in several countries in the Americas and other endemic regions. There are no preventive vaccines or effective treatments available. As such, Zika remains a public health threat and is included in the FDA’s Tropical Disease Priority Review Voucher Program. VLA1601 is being developed on the original manufacturing platform of our licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop our inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe.

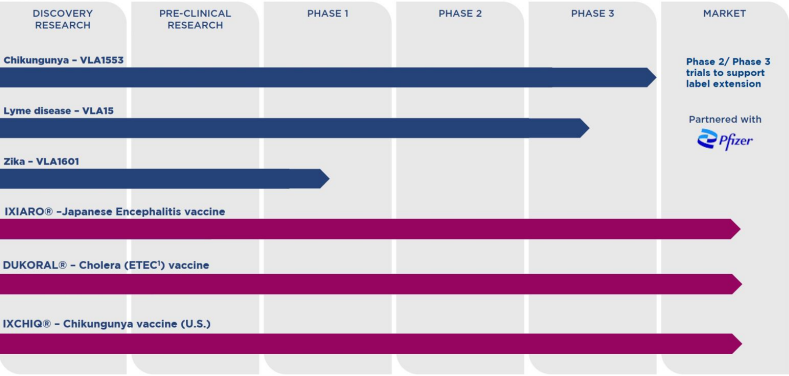
We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand, and Thailand, prevention of diarrhea caused by Enterotoxigenic Escherichia coli, or ETEC, the leading cause of travelers’ diarrhea. At the beginning of 2024, we launched our chikungunya vaccine IXCHIQ in the U.S. Additionally, we distribute vaccines for third parties in selected countries where we have a commercial infrastructure.

We have a highly developed, nimble and sophisticated manufacturing infrastructure with facilities across Europe to meet our clinical and commercial needs, including BioSafety Level 3 (BSL-3) manufacturing and R&D facilities. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior leadership team has extensive experience and demonstrated ability to move vaccines through the clinic and into successful commercialization. Members of our team have previously worked at industry leaders such as Novartis, Chiron, GlaxoSmithKline and Daiichi Sankyo.

Our Pipeline and Proprietary Commercial Portfolio

Our pipeline consists of assets at all stages of research & development. Our goal is to develop vaccine candidates that are first-, best-, or only-in-class and address unmet needs in infectious diseases. Our aim is to develop these assets for future commercialization either in-house or through and with partners.

Our advanced clinical pipeline and commercialized products are summarized below:



1. Indications differ by country. ETEC stands for Enterotoxigenic Escherichia coli (E. Coli) bacterium.

Our clinical pipeline includes:

- VLA1553 – a single-dose, live-attenuated vaccine candidate against CHIKV. VLA1553 was approved by the FDA under the brand name IXCHIQ in November 2023 and with this approval, became the world’s first licensed chikungunya vaccine available to address this unmet medical need. It is indicated in the United States for the prevention of disease caused by CHIKV in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. Alongside the approval, we received a Priority Review Voucher which we sold for \$103 million in February 2024. At the end of February 2024, the U.S. ACIP provided recommendations on how to use IXCHIQ and these recommendations were then adopted by the U.S. CDC. Regulatory review is ongoing in several other jurisdictions. We submitted a Marketing Authorization Application (MAA) to the European Medicines Agency, or EMA, in October 2023, and EMA’s CHMP confirmed accelerated assessment for the application based on the vaccine candidate’s “major interest for public health and therapeutic innovation”. A marketing application is also under review by Health Canada and Anvisa in Brazil. We expect to receive approval decisions in Europe, Canada, and Brazil in 2024. In the Phase I clinical trial of VLA1553, we observed development of antibodies to chikungunya virus and a rapid onset of immune response with 100% seroconversion of the 120 healthy participants and 100% of participants reaching the immune threshold established with the FDA

at day 14. VLA1553 advanced directly to a Phase 3 clinical trial, for which we reported final results in March 2022, final lot-to-lot consistency data in May 2022, as well as 12- and 24-month antibody persistence data in December 2022 and 2023, respectively. The pivotal Phase 3 data were published in *The Lancet*, the world's leading peer-reviewed medical journal, in June 2023. The Phase 3 results showed that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration. Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 and 24 months by 99% and 97% of participants, respectively, and was equally durable in younger and older adults. This dedicated antibody persistence trial, VLA1553-303, will continue to evaluate persistence for a period of at least five years. Additionally, a clinical study in 754 adolescents 12 to 17 years of age, VLA1553-321, is ongoing in Brazil, for which we reported positive pivotal Phase 3 immunogenicity and safety data in November 2023. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and conducted in collaboration with Instituto Butantan, this adolescent trial is intended to support the label extension in this age group following approvals in adults. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. We also initiated a pediatric trial in children 1 to 11 years of age, VLA1553-221, in January 2024 to support a Phase 3 pivotal pediatric study and potentially extend the label in this age group following initial regulatory approvals in adults and possibly in adolescents. In 2024, we will also start preparing the initiation of two Phase 4 post-marketing studies required as part of our approval under the FDA's accelerated approval pathway.

- VLA15 – a vaccine candidate against *Borrelia*, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of *Borrelia* representing the most common serotypes found in North America and Europe. VLA15 is the only Lyme disease program in advanced clinical development today and has received Fast Track designation from the FDA. We reported results for three Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which we observed high levels of antibodies against all six serotypes. These include the announcement in September 2023 of positive Phase 2 pediatric and adolescent immunogenicity and safety data following a booster vaccination with VLA15. These results from the VLA15-221 Phase 2 study showed a strong anamnestic antibody response for all serotypes in pediatric (5 to 11 years of age) and adolescent participants (12 to 17 years of age), as well as in adults (18 to 65 years of age), one month after administration of a booster dose (month 19). The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies. In August 2022, jointly with Pfizer, we initiated a Phase 3 clinical study, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)", to investigate the efficacy, safety, and immunogenicity of VLA15 in participants five years of age and older in highly endemic regions in the United States and Europe. In February 2023, Pfizer, as the study sponsor, decided to discontinue approximately half of the total enrolled participants in the trial following violations of Good Clinical Practice, or GCP, at certain clinical trial sites run by a third party clinical trial site operator. The clinical trial remains ongoing with other sites not operated by the third party and new sites in the U.S. and Canada. In December 2023, we and Pfizer announced that we completed recruitment for the study. 9,437 participants 5 years of age and older were enrolled in the trial and will receive three doses of VLA15 or a saline placebo (1:1 ratio) within the first year, and one booster dose approximately one year after vaccination with the first three doses, as part of the primary series. The VALOR trial is expected to be concluded by the end of 2025, with the aim for Pfizer to submit a Biologics Licence Application (BLA) to the FDA and a MAA to the EMA in 2026, subject to positive data. According to the terms of our collaboration, Pfizer will lead late phase development of VLA15. If VLA15 is approved, Pfizer will have sole control over its commercialization, and we will be eligible to receive milestone and royalty payments. In June 2022, the terms of our collaboration with Pfizer were updated, and Pfizer invested €90.5 (\$95) million in Valneva as part of an Equity Subscription Agreement. As per the terms of the collaboration agreement, we received a \$25 million milestone payment from Pfizer following initiation of the Phase 3 study.
- VLA1601 – a highly purified inactivated, adjuvanted vaccine candidate against the mosquito-borne viral disease caused by the Zika virus, or ZIKV. Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. Zika virus transmission persists in several countries in the Americas and in other endemic regions. To date, a total of 89 countries and territories have reported evidence of mosquito-transmitted Zika virus infection; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available. As such, Zika remains a public health threat and is included in the FDA's Tropical Disease Priority Review Voucher Program. VLA1601 is being developed on the original manufacturing platform of our licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop our inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. We reported positive Phase 1 results for the first generation of our Zika vaccine candidate in 2019, showing a favorable safety profile and immunogenicity in all tested doses and schedules, comparable to IXIARO and other clinical stage ZIKV vaccines. We now expect to start the clinical evaluation of our second-generation vaccine in the coming weeks. A vaccine against the Zika virus would nicely complement Valneva's portfolio of travel vaccines against mosquito-borne diseases, which already includes IXCHIQ and IXIARO.

In addition to our clinical-stage assets, our portfolio includes a series of pre-clinical assets against disease targets that reflect our strategy of providing prophylactic solutions to significant diseases that lack a preventative and effective therapeutic treatment option. These include VLA2112, a vaccine candidate targeting the Epstein-Barr virus, or EBV, which is one of the most common human viruses. EBV can cause infectious mononucleosis and is strongly associated with the development of several types of cancer and multiple sclerosis. We have also been working on a vaccine candidate targeting the human metapneumovirus, or hMPV, which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection, and we are currently exploring potential partnering opportunities.

We commercialize our fully owned travel vaccines IXIARO/JESPECT, DUKORAL, and IXCHIQ and previously supplied our inactivated COVID-19 vaccine VLA2001 under government contracts. Sales from these products are complemented by sales from the distribution of third-party products in markets where Valneva operates its own marketing and sales infrastructure (United States, Canada, Nordic countries, United Kingdom, Austria, and France):

- IXIARO – an inactivated Vero cell culture-derived Japanese encephalitis vaccine that is the only Japanese encephalitis vaccine licensed and available in the United States, Canada, and Europe. IXIARO is indicated for active immunization against Japanese encephalitis, the most prevalent cause of viral encephalitis in Asia, for adults, adolescents, children, and infants aged two months and older. Sales of IXIARO were €73.5 million in the year ended December 31, 2023 compared to €41.3 million in the year ended December 31, 2022. The 78% increase in sales is primarily the result of the continued travel market recovery after being impacted by the COVID-related decline in travel in 2020 and 2021, as well as price increases. At the end of September 2023, we also signed a new one-year contract with the U.S. Department of Defense (DoD) worth a minimum of \$32 million for the supply of IXIARO.
- DUKORAL – an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and, in Canada and certain other countries, heat-labile toxin producing ETEC, the leading cause of travelers’ diarrhea. We acquired DUKORAL in 2015 and recorded €29.8 million of sales in the year ended December 31, 2023 compared to €17.3 million in the year ended December 31, 2022. DUKORAL sales in 2023 also benefited from the continued travel market recovery. DUKORAL is authorized for use in the European Union and Australia to protect against cholera and in Canada, Switzerland, New Zealand, and Thailand to protect against cholera and ETEC.
- IXCHIQ – a single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. We received marketing approval for IXCHIQ from the FDA in November 2023 under an accelerated pathway based on anti-CHIKV neutralizing antibody titers. Continued approval for this indication is contingent upon verification of clinical benefit in Phase 4 confirmatory studies. At the end of February 2024, the U.S. ACIP provided recommendations on how to use IXCHIQ and these recommendations were then adopted by the U.S. CDC. With this U.S. approval, IXCHIQ became the world’s first licensed chikungunya vaccine available to address this unmet medical need and the third vaccine Valneva brought from early R&D to approval. Valneva started commercializing IXCHIQ in the U.S. in the first quarter of 2024.
- VLA2001 – the only inactivated whole-virus COVID-19 vaccine approved in Europe and the first COVID-19 vaccine to receive a full marketing authorization from the European Medicines Agency. It was produced using our established Vero cell platform, leveraging the manufacturing technology for our commercial Japanese encephalitis vaccine, IXIARO. In addition to its marketing approval in Europe, our COVID-19 vaccine received conditional marketing authorization in the United Kingdom and emergency use authorization in the United Arab Emirates and Kingdom of Bahrain. In 2021, we signed advance purchase agreements with the European Commission and the Kingdom of Bahrain. In light of a reduced order volume from EU Member States, we suspended manufacturing of the vaccine in August 2022, and inventories were fully written-down as of December 31, 2022. In 2023, VLA2001 sales amounted to €5.7 million compared to €29.6 million in 2022. Sales of VLA2001 in 2023 resulted from the last deliveries made to the Kingdom of Bahrain.

Our Strategy

Our strategy supports our vision to contribute to a world in which no one dies or suffers from a vaccine preventable disease. Our strategy is based on an integrated business model that has allowed us to build a portfolio of differentiated clinical and pre-clinical assets as well as a growing commercial business. We are focused on utilizing our proven and validated product development capabilities to rapidly advance solutions addressing unmet needs in infectious diseases towards regulatory approval, with the goal of becoming first-, best-, or only-in-class. We have entered into strategic partnerships with other well-established pharmaceutical companies to leverage their clinical and commercial capabilities to optimize the potential value of select assets. As we advance our late stage portfolio, we also remain focused on investing in our research and development pipeline in order to develop our earlier stage assets as well as identify new targets and indications where we believe we can make a significant difference.

In order to execute upon this strategy as an independent, financially sustainable company, we are pursuing the following strategic goals:

- **Successfully launch IXCHIQ in target markets and conduct additional clinical trials.** After receiving approval from the FDA at the end of 2023, we will focus on commercializing the vaccine in the U.S. in 2024. After submitting marketing applications to EMA, Health Canada, and the Brazilian agency Anvisa in 2023, we also expect to receive marketing approval decisions in Europe, Canada, and Brazil in 2024. We will also conduct additional clinical trials in 2024, notably in pediatric and immunocompromised participants, and we will start preparing the initiation of the Phase 4 studies required as part of our approval under the FDA’s accelerated approval pathway. A clinical trial in adolescents is also ongoing in Brazil which is expected to support licensure of the vaccine in Brazil and potential label extensions in countries where the vaccine will be initially approved in adults.
- **Advance VLA15 for the prevention of Lyme disease in collaboration with Pfizer.** We are developing VLA15 as a vaccine against Borrelia, the bacterium that causes Lyme disease in North America and Europe. We reported results for three Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which VLA15

generated high levels of antibodies against all six *Borrelia* strains. Together with Pfizer, we announced the initiation of a Phase 3 clinical study, “Vaccine Against Lyme for Outdoor Recreationists (VALOR)”, in August 2022 and completed recruitment of 9,437 participants for the study in December 2023. The VALOR trial is expected to be concluded by the end of 2025, with the aim for Pfizer to submit a BLA to the FDA and a MAA to the EMA in 2026, subject to positive data. If VLA15 is approved, Pfizer will have sole control over its commercialization, and we will be eligible to receive milestone and royalty payments.

- **Grow product sales focusing on proprietary products, and build a leading position in the travel vaccines market.** We will focus on continuing to grow sales of our proprietary travel vaccines (IXIARO and DUKORAL) and launch IXCHIQ in the markets where the vaccine is or may be approved. The third-party product business supported Valneva’s revenues as a complement to its existing travel vaccine portfolio, especially during the COVID-19 pandemic. However, 2023 third-party sales of more than €35 million yielded only 36% gross margin, diluting our overall margins, and we have therefore decided to focus resources on direct sales of our proprietary products.
- **Expand our pipeline of clinical and pre-clinical programs to develop new vaccines addressing diseases with significant unmet need.** To remain an industry leader in the development of prophylactic vaccines, we intend to continue identifying disease targets with the potential to be effectively prevented by vaccines and develop vaccine candidates against those targets. We notably expect to launch a Phase 1 clinical trial of our Zika vaccine candidate in the near future and initiated pre-clinical programs focusing on EBV and hMPV.
- **Opportunistically pursue strategic partnerships to maximize full potential of our clinical and commercial portfolios.** We intend to continue to selectively evaluate partnerships to leverage the clinical and commercial expertise of large pharmaceutical companies. Additionally, we will continue to evaluate in-licensing opportunities for both our clinical and commercial portfolio.
- **Focus on stringent cost management.** In the mid-term, we will continue focusing on stringent cost management with a particular focus on marketing and distribution as well as general and administrative costs.
- **Become an ESG (environmental, social, and governance)-driven enterprise.** As a member of the United Nations Global Compact, we intend to ramp up ESG initiatives and continue to develop the four pillars of our responsible business commitments: Protecting Lives, Acting Ethically, Developing our People, and Respecting the Environment. In 2023, we recruited Laura Galindo Alfonso as ESG Director and Petra Pesendorfer as Chief People Officer to achieve this goal.

Background to Vaccine Development

Infectious diseases have widely affected, and continue to widely affect, humankind. Prevention of infectious diseases through vaccination, known as prophylactic vaccination, is considered one of the most beneficial and cost-effective health care interventions. Prophylactic vaccines often represent the preferred solution to debilitating and widespread infectious diseases given their capacity to bring about significant health benefits to both individuals and communities, while remaining highly cost effective. This is a result of the fact that vaccines provide health benefits not only to individuals who have actually received the vaccine, but also to the broader community as the vaccinated population brings the immunological benefits of protection to non-vaccinated populations through the “herd immunity” effect that helps to reduce the spread of the disease.

Despite the large and growing need for vaccines, many urgent medical needs remain unaddressed—including infectious diseases, such as Lyme disease and Zika, and hospital-acquired infections, such as infections with *C. difficile*. Developing vaccines for such diseases remains a high priority for the research and development world.

There are a number of approaches to engineering vaccine candidates. Most vaccines in use today utilize one of the following five technological approaches:

- **Live attenuated vaccines.** Live attenuated vaccines use a weakened, or attenuated, form of the virus or bacteria that causes a disease. Live attenuated vaccines typically provoke more durable immunological responses. However, they may not be safe for use in immunocompromised individuals, and on rare occasions can mutate to a virulent form and cause disease. Live attenuated vaccines protect against diseases such as measles/mumps/rubella, rotavirus, smallpox, chickenpox and yellow fever. Our chikungunya virus vaccine IXCHIQ is an example of a live attenuated vaccine.
- **Inactivated vaccines.** Inactivated vaccines use a version of the disease-causing virus or bacteria that has been destroyed with chemicals, heat or radiation. Inactivated vaccines have a long history of use and are among the safest types of vaccine, with possibilities for use in special target populations, such as patients with weakened immune systems. We believe that the extensive knowledge and experience with the existing viral inactivation procedures for vaccine manufacture will continue to serve as a foundation of vaccinology for novel inactivated vaccines. Today millions of people are, and will be, protected worldwide with inactivated viral vaccines. Inactivated vaccines protect against diseases such as hepatitis A, flu, polio, and rabies. Our products IXIARO and VLA2001 are both inactivated vaccines.
- **Subunit, recombinant, polysaccharide, and conjugate vaccines.** Subunit, recombinant, polysaccharide, and conjugate vaccines use specific pieces of the virus or bacteria, such as its protein, sugar, or casing, to generate an immune response. Rather than introducing an inactivated or attenuated microorganism to an immune system

(which would constitute a “whole-agent” vaccine), a subunit vaccine uses a fragment of the microorganism to generate an immune response. Subunit vaccines can produce a long-lived immunity and are relatively safe since only parts of the virus are used and can be applicable to people with weakened immune systems. These vaccines protect against diseases such as Hib (Haemophilus influenza type b), hepatitis B, HPV (human papillomavirus), whooping cough (part of the DTaP combined vaccine), pneumococcal disease, meningococcal disease, and shingles. Our clinical development and manufacturing technology have allowed us to develop our VLA15 vaccine candidate, a multivalent, protein subunit vaccine for prevention of Lyme disease.

- **Toxoid vaccines.** Toxoid vaccines use a toxin made by the virus or bacteria that causes a disease. These vaccines are used to protect against diseases such as diphtheria and tetanus.
- **Messenger RNA (mRNA) vaccines.** mRNA vaccines are one of the newest areas in vaccine technology. As shown during the COVID-19 pandemic, they can be developed quickly using the pathogen’s genetic code. When an mRNA vaccine is delivered, the RNA material teaches our body how to make a specific type of protein that is unique to the virus, but does not make the person sick. The protein triggers an immune response, which includes the generation of antibodies that recognize the protein. That way, if a person is ever exposed to that virus in the future, the body would likely have the tools (antibodies) to fight against it.

Additionally, there are companies pursuing novel technologies such as DNA vaccines, which transfect a specific antigen DNA-coding sequence onto the cells of an immunized species, and dendritic cell vaccines, which combine dendritic cells with antigens in order to present the antigens to the body’s white blood cells, thus stimulating an immune reaction. Although some of these novel technologies have shown promise, they largely remain in the early stages of development and face significant challenges related to manufacturing and distribution.

Our deep expertise and capabilities across many of these approaches gives us the flexibility to follow our strategy of first targeting diseases that lack a preventative solution and then developing an efficacious and safe vaccine candidate based on our determination of the most effective approach.

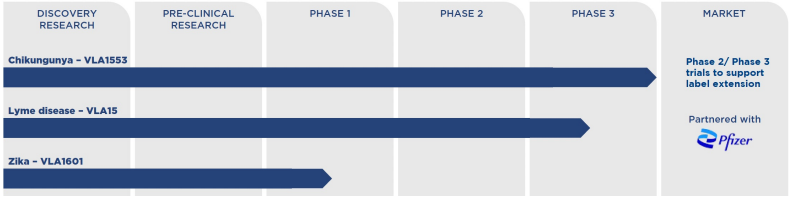
In addition to the vaccine’s primary component, such as an inactivated virus, vaccines may contain adjuvants, which are used to improve the immune response to the vaccine, for example through producing more antibodies. Adjuvants used in human vaccines include alum (aluminium hydroxide) and others (e.g. CpG-1018, manufactured by Dynavax). Adjuvants have a proven safety record based on more than 60 years of use. Effective use of adjuvants requires expertise around vaccine formulation and development. We have utilized different adjuvants in a number of our vaccine candidates or licensed vaccines.

Vaccines are administered through various routes such as orally, subcutaneously, intramuscularly, intradermally and intranasally. These various methods of administration help to simplify the vaccination process, allowing more people to be vaccinated and promoting adherence to the recommendations, such as receiving a follow-up dosage.

The different approaches to vaccine development cannot be universally applied to infectious diseases and be effective; instead, each approach must be targeted against a disease according to a compelling biological rationale. As such, development of vaccines are intensive and complicated processes that require evaluation of multiple modalities, endpoints and clinically meaningful data points. The efficacy and safety of vaccines are measured using multiple methodologies and approaches, although research and regulatory bodies often focus on the following measures:

- Immunogenicity — the ability of a foreign substance, such as an antigen, to provoke an immune response
- Seroconversion rates (SCR) — the proportion of subjects in a trial for whom a specific antibody develops and becomes detectable in blood
- Seroconversion — an antibody response capable of preventing infection
- Titer — a laboratory test that measures the presence and amount of antibodies in the blood
- Viremia — the presence of a virus in the blood

Our Clinical Pipeline



VLA1553 / IXCHIQ—Our vaccine targeting the chikungunya virus

VLA1553 is a single-dose, live-attenuated vaccine candidate against CHIKV, which was approved by the FDA under the brand name IXCHIQ in November 2023. It is indicated in the United States (U.S.) for the prevention of disease caused by CHIKV in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. With this approval, IXCHIQ became the world’s first licensed chikungunya vaccine available to address this unmet medical need. Alongside the approval, we received a Priority Review Voucher (PRV) which we sold for \$103 million in February 2024. At the end of February 2024, the ACIP provided recommendations on how to use IXCHIQ and these recommendations were then adopted by the U.S. CDC. Additionally, we submitted a MAA to the EMA in October 2023, and EMA’s CHMP confirmed accelerated assessment for the application based on the vaccine candidate’s “major interest for public health and therapeutic innovation”. A marketing application is also under review by Health Canada and Anvisa in Brazil. We expect to receive approval decisions in Europe, Canada, and Brazil in 2024.

In our Phase 1 clinical trial, we observed that VLA1553 led to the development of antibodies to chikungunya virus and a rapid onset of immune response resulting in 100% seroconversion of the 120 healthy participants and 100% of participants reaching the immune threshold established with the FDA at day 14. VLA1553 was also generally well-tolerated in all dose groups. Based on this Phase 1 dataset, we were able to advance directly into Phase 3 clinical development and concluded a pivotal Phase 3 trial in over 4,000 healthy adults. We received confirmation from the FDA and EMA for our proposal to seek licensure under the accelerated approval pathway. We received FDA licensure in November 2023 based on a surrogate endpoint (seroresponse rate) agreed with the FDA and the EMA. The surrogate endpoint is an immune response that is reasonably likely to predict protection from chikungunya infection. This eliminates the need to execute a time-intensive and costly field trial where a group of patients receiving a placebo is compared to groups of patients receiving VLA1553. However, this approach requires that vaccine effectiveness, i.e. the proof that the vaccine can prevent cases of disease, is demonstrated post-licensure. We reported positive topline results of our pivotal Phase 3 trial involving over 4,000 healthy adults in August 2021, final results, including six-month follow-up data, in March 2022 and 12 and 24 month antibody persistence data in December 2022 and 2023, respectively. These antibody persistence results confirmed a very high level of seroconversion, with 99% and 97% of participants showing protective CHIKV neutralizing antibodies twelve and twenty-four months, respectively, after receiving a single vaccination. The dedicated antibody persistence trial, VLA1553-303, will continue to evaluate persistence for a period of at least five years. The final pivotal Phase 3 data were published in The Lancet, the world’s leading peer-reviewed medical journal, in June 2023. The Phase 3 results showed that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration compared to the 70% threshold (for non-acceptance) agreed with the FDA.

Additionally, in May 2020, we partnered with the Instituto Butantan in Brazil to develop, manufacture, and market VLA1553 in certain low and middle income countries. As part of this collaboration, we initiated an adolescent clinical trial of VLA1553 in 754 healthy volunteers in Brazil in 2022, which has been approved by the local regulatory agency, Anvisa, and is sponsored by Instituto Butantan. In November 2023, we announced positive pivotal Phase 3 immunogenicity and safety data in 754 adolescents 12 to 17 years of age. This adolescent trial is intended to support the label extension in this age group following approvals in adults. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. We have been awarded up to \$24.6 million in funding from CEPI in relation to this partnership. See “Item 10.C—Material Contracts—CEPI Funding Agreement” for more information about this agreement.

Additionally, we initiated a Phase 2 pediatric trial in children 1 to 11 years of age, VLA1553-221, in January 2024 to support a Phase 3 pivotal pediatric study and potentially extend the label in this age group following initial regulatory approvals in adults and possibly in adolescents. In 2024, we will also start preparing the initiation of the two Phase 4 post-marketing studies required as part of our approval under the FDA’s accelerated approval pathway.

Overview of the chikungunya virus

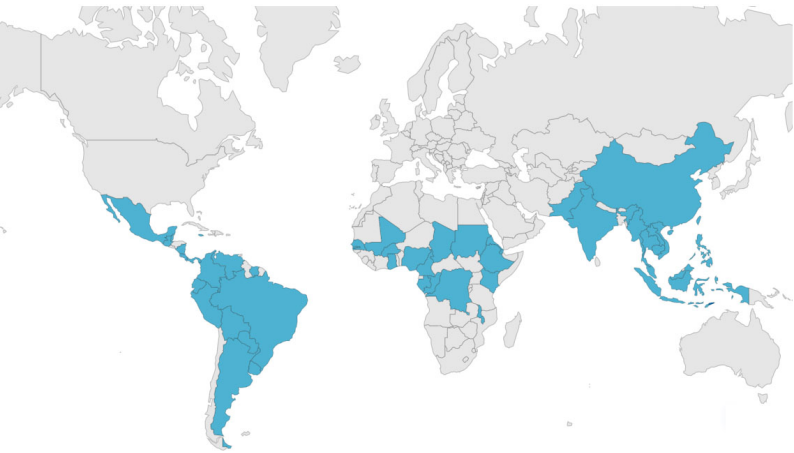
Chikungunya is a mosquito-borne virus posing a serious public health problem in tropical and sub-tropical regions. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating and can cause a significant economic impact. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas. The true incidence of chikungunya is likely to be much higher due to the level of under-reporting, with available studies suggesting an under-reporting factor of five times due to difficulty in diagnosing the symptoms, which can be similar to those of dengue and Zika, and due to lack of access to good medical care in certain areas where outbreaks are prevalent. It is estimated that the global market for a chikungunya vaccine, including travel and endemic markets, will exceed \$500 million annually by 2032.

Chikungunya infection is characterized by an acute onset of fever, rash, myalgia, and sometimes debilitating arthritic pain in multiple joints. Chikungunya causes symptomatic infection in 72-92% of infected humans around four to seven days after infection. Mortality of chikungunya is low (<1%) but the chronicity of its joint pain (arthralgia) and inflammatory symptoms represent a significant burden of disease with potential long-term debilitating impact. For example, following a significant outbreak in 2005, 94% of symptomatic travelers infected in La Reunion, an island in the Indian Ocean, complained of joint or bone pain six months after the epidemic peak, and this pain was constant in 41% of the cases. The effect of chronic symptoms on the quality of life was defined as totally disabling or important in almost half of the patients. Even at 32 months post-infection, 83% of people continued to report joint pain.

In addition to having significant impact on patients who become infected, chikungunya is highly transmissible, and prior outbreaks have led to significant spread of the virus. For example, in 2004, a chikungunya epidemic in Kenya triggered the spread of this virus to nearly all regions of the world with cases reported in Africa, Asia, Europe, the Americas, the Indian

Ocean, the Pacific Ocean, and the Caribbean islands. Cases in Europe and the United States are typically tied to recent travel to endemic areas. However, one of the vector mosquitos, the tiger mosquito, is established in southern regions of Europe and the United States, and travel-related cases have generated local outbreaks as reported from Italy and France.

The below map shows countries and territories with current or previous transmission of chikungunya virus as of March 5, 2024 (it does not include countries or territories where only imported cases have been documented):



Source: CDC. Reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention.

Without vaccination, we believe the spread of chikungunya will continue to increase rapidly, driven by a number of key factors:

- The recent development that chikungunya can be spread by a second species of mosquitos, one that has a broader worldwide distribution, is tolerant to colder temperatures, and is highly abundant in large parts of the world;
- The current lack of herd immunity in large portions of the human population;
- The ease of chikungunya’s spread by travel, which can occur if an uninfected mosquito feeds on an infected person who has returned home from an endemic area; and
- An increase in the geographic distribution and size of the population at risk due to climate change.

The current standard of care to treat individuals who have become infected with chikungunya is the application of non-steroidal anti-inflammatory drugs to relieve symptoms. To date, apart from our vaccine IXCHIQ which has recently been launched in the U.S., preventive measures in other territories rely on avoiding mosquito bites. Effective mosquito control has proven challenging, even in higher income countries.

In addition to IXCHIQ, there are two third-party advanced chikungunya vaccine candidates. The first is a virus-like particle vaccine candidate in development by Bavarian Nordic, which reported Phase 3 clinical trials in August 2023. The second is an inactivated vaccine candidate manufactured by Bharat Biotech of India, which initiated a seamless Phase 2/3 clinical trial in August 2021. We believe that both of these potential vaccine candidates may face limitations relative to IXCHIQ, including IXCHIQ being designed to only require a single administration, while Bharat’s and potentially Bavarian Nordic’s vaccine candidates are likely to require multiple shots to either reach or maintain high levels of effectiveness.

VLAI553 / IXCHIQ Approach

IXCHIQ is a live-attenuated chikungunya vaccine based on the East, Central, and Southern African, or ECSA, strain which has spread across the Indian Ocean. It is cross-reactive with other strains, meaning that it is designed to protect against those as well, including the strain of Asian lineage which is rapidly spreading across the Americas as observed in pre-clinical studies. Additionally, given that we have engineered IXCHIQ as a live-attenuated vaccine, we believe it may confer life-long immunity.

IXCHIQ is engineered using a strain of chikungunya, where specific segments of the virus have been deleted, thereby weakening, or attenuating, the virus. This approach enables IXCHIQ to catalyze the patient's immune system into generating the antibodies necessary to provide protection against the virus while the weakened strain does not cause the patient to develop significant symptoms. In our pre-clinical studies, growth of this strain on Vero cells resulted in a viral titer 35 times lower than observed with the original unattenuated strain, demonstrating the attenuation of our chikungunya strain. The deleted segment also remained absent following replication of the virus in the Vero cells, suggesting that the weakness of the virus is sustained.

Phase 1 Clinical Trial and Results

We conducted a single blind, randomized dose-escalation Phase 1 clinical trial of VLA1553 in 120 adults, at multiple centers in the United States, the results of which were published in the Lancet Infectious Diseases in 2020. In this trial we examined three doses of VLA1553: a low dose having a viral titer of 3.2 x 10³, a medium dose of 3.2 x 10⁴, and a high dose of 3.2 x 10⁵. Participants in the low and medium dose cohorts and half of the patients in the high-dose cohort received a single dose of VLA1553 on Day 0 through intramuscular injection and a re-vaccination at 12 months. Half of the patients in the high-dose cohort received a re-vaccination at six months instead of 12 months. The primary endpoint of the trial was evaluation of safety measures including frequency and severity of injection site and systemic reactions.

Chikungunya virus neutralizing antibodies were observed in 100% of patients for 12 months at all three of the doses evaluated. A single vaccination was sufficient to induce sustaining high-titer neutralizing antibodies at 12 months post-vaccination.

Individuals that received a single high dose of VLA1553 did not exhibit an increase in antibody titers following subsequent re-vaccination at month six. Similarly, none of the dose levels that were re-vaccinated at month 12 exhibited an increase in antibody titers after re-vaccination. This result suggests that a single dose of VLA1553 could offer sufficient protection with no additional booster required.

The titer of these neutralizing antibodies was assessed by determining how far the antibodies in the plasma could be diluted and still reduce in vitro viral infection by 50%, a commonly used parameter referred to as the neutralization titer or NT50. Seroconversion was defined as having an NT50 of 20 or greater, meaning that dilution by 20-fold or greater still resulted in inhibiting the virus-induced cytopathic effects by at least half. We found that 100% of participants had seroconverted by day 14 at all three of the doses tested and this seroconversion persisted for one year across all dose groups. When re-evaluated with the assay that was used to define the seroresponse threshold for Phase 3, we confirmed that 100% of participants had seroresponded by day 14.

Plasma of the trial volunteers was screened for viremia, which peaked at day three in all groups and was lower in the low-dose and medium-dose groups. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

The majority of adverse events across the dose groups were assessed as mild or moderate and were reported after the single vaccination. No adverse event of special interest, meaning adverse events resembling a chikungunya-like infection, and no vaccine-related serious adverse events were reported. Injection site reactogenicity was low, with less than 7% of individuals in the high-dose group reporting any local adverse event, all of which were mild in severity. Systemic adverse events were predominantly headache (32.5%), fever (26.7%) and fatigue (24.2%), followed by muscle pain (20.0%) and joint pain (13.3%), all of which were transient and are typical reactions after immunization and similar to those reported after vaccination with other vaccines in the general population. Severe fever (a temperature of 102.1°F or higher) was reported by seven participants. Adverse events decreased on re-vaccination at month six.

Phase 3 Clinical Trials

VLA1553-301 Clinical Trial

In September 2020, we initiated our pivotal Phase 3 clinical trial, VLA1553-301, in the United States. In this double-blind, multi-center, randomized Phase 3 clinical trial, 4,115 participants aged 18 years and above were randomized 3:1 into two groups to receive either VLA1553 0.5mL or placebo. Immunogenicity was determined with a µPRNT50 assay.

The primary endpoint was safety and immunogenicity 28 days after a single vaccination with VLA1553. The trial met its primary endpoint, inducing protective CHIKV neutralizing antibody titers in 98.9% of participants 28 days after receiving a single shot (263 of 266 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 96.7-99.8). The seroconversion rate result of 98.9%, and specifically the lower bound of the 95%CI of 96.7%, exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The excellent immunogenicity profile was maintained over time, with 96.3% of participants showing protective CHIKV neutralizing antibody titers six months after receiving a single vaccination (233 of 242 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 93.1-98.3). VLA1553 was highly immunogenic, with a GMT of approximately 3,362, confirming the immunogenicity profile seen in the Phase 1 clinical trial.

VLA1553 was generally well tolerated across all age groups among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. The final data safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within three days. 2.0% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of trial participants experienced solicited systemic adverse events, most commonly headache, fatigue, and myalgia. The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

Additionally, VLA1553 was highly immunogenic in elderly study participants (65 years of age or older), who achieved equally high seroconversion rates and neutralizing antibody titers over time as younger adults. The final pivotal Phase 3 data were published in The Lancet in June 2023.

VLA1553-302 Clinical Trial

We also initiated a lot-to-lot consistency Phase 3 trial, VLA1553-302, in February 2021 to show manufacturing consistency of VLA1553, which is a requirement for licensure. We announced completion of recruitment for this trial in June 2021 and positive topline and final data from this trial in December 2021 and May 2022, respectively.

VLA1553-302 was a prospective, multicenter, randomized, pivotal Phase 3 clinical trial. Participants in the VLA1553-302 trial were randomized and followed for a total of six months. The objective of the trial was to show manufacturing consistency of the vaccine by demonstrating that three consecutively manufactured lots elicit equivalent immune responses measured by neutralizing antibody titers on Day 29 after vaccination. Lyophilized VLA1553 were administered as a single intramuscular immunization. Equivalence of immune responses were determined based on neutralizing antibody titers. The primary objective of the trial was to evaluate a pair-wise comparison of the 95% CI on the ratio of GMTs on Day 29 after vaccination in the three vaccine lots. The two-sided 95% CI on the GMT ratio should be within 0.67 and 1.5 in order to demonstrate consistency.

The VLA1553-302 trial met its primary endpoint, demonstrating that three consecutively manufactured vaccine lots elicited equivalent immune responses measured by neutralizing antibody titer GMT ratios on Day 29 after vaccination. The trial included 408 participants aged 18 to 45 and confirmed the excellent immunogenicity profile observed in the pivotal Phase 3 trial, VLA1553-301. All three lots were equally well tolerated and the safety profile was consistent with results in VLA1553-301. The trial therefore confirmed clinical equivalence as well as manufacturing consistency of the three lots.

The lot-to-lot data were part of our submission to the FDA which we completed in December 2022.

VLA1553-303 Clinical Trial

In April 2021, we initiated an antibody persistence trial that will follow annually up to 375 subjects in the immunogenicity subset of the VLA1553-301 trial for a period of five years. VLA1553-303 is a prospective, multicenter trial. The primary objective is to evaluate persistence of antibodies annually for five years after a single immunization. Subjects will have annual follow-up visits at Months 12, 24, 36, 48 and 60 after immunization. Secondary outcome measures include frequency and relatedness of any serious adverse events, immune response as measured by CHIKV-specific neutralizing antibody titers post-vaccination, proportion of subjects with seroconversion, fold increase of CHIKV-specific neutralizing antibody titers post-vaccination as compared to baseline, and proportion of subjects reaching at least 4-fold, 8-fold, 16-fold or 64-fold increase in CHIKV-specific neutralizing antibody titers post-vaccination as compared to baseline.

In December 2022 and 2023, we reported 12- and 24-month data, respectively, for this trial. 12 and 24 months after the single-dose vaccination, 99% and 97% of participants, respectively, retained neutralizing antibody titers above the seroresponse threshold of 150. The antibody persistence was similar in older adults aged ≥65 years, who retained neutralizing antibody titers comparable to younger adults throughout the follow-up. No safety concerns were identified for the duration of the follow-up study, confirming the safety profile observed in previous studies.

VLA1553-321 Clinical Trial

In January 2022, we announced the initiation of a Phase 3 trial of VLA1553 in 754 adolescents 12 to 17 years of age. Conducted in Brazil by Institution Butantan and funded by CEPI, the VLA1553-321 trial is intended to support the label extension in this age group following the initial regulatory approval in adults from the FDA. This trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations.

VLA1553-321 is a prospective, double-blinded, multi-center, randomized, and placebo-controlled Phase 3 trial. In November 2023, we reported positive Phase 3 immunogenicity and safety data showing that a single-dose vaccination with VLA1553 induced a robust immune response in adolescents, thereby confirming the excellent immunogenicity previously observed in adults. VLA1553 induced levels of protective antibody titers in 98.8% of participants 28 days after a single vaccination significantly exceeding the FDA's requirement for study success of the lower bound of the 95% CI for seroresponse rate >70%. Additionally, VLA1553 was generally well tolerated in adolescents, irrespective of previous CHIKV infection, and showed a similar safety profile as reported in adults. Participants will be followed up to 12 months.

VLA1553-221 Clinical Trial

In January 2024, we initiated a Phase 2 pediatric trial in children 1 to 11 years of age. The multicenter, prospective, randomized, observer-blinded Phase 2 clinical trial is planned to enroll approximately 300 healthy children at three trial sites in the Dominican Republic and Honduras. Following a safety run-in phase, participants will be randomized to receive either a full dose formulation of the vaccine (120 participants), a half dose formulation (120 participants), or a control vaccine (60 participants). Once available, the Phase 2 pediatric data are intended to support a Phase 3 pivotal study in children with the objective to extend the label in this age group following initial regulatory approvals in adults and possibly in adolescents.

VLA15— Our vaccine candidate targeting Lyme disease

We are developing VLA15 as an investigational vaccine against *Borrelia*, the bacterium that causes Lyme disease. VLA15 is a recombinant protein vaccine candidate that targets six serotypes of *Borrelia* representing the most common serotypes found in North America and Europe. We have reported initial results of three Phase 2 clinical trials of VLA15 in over 900 healthy adults, and results have demonstrated the presence of high titers of antibodies against all six serotypes. In August 2022, together with Pfizer, we initiated a Phase 3 clinical study, “Vaccine Against Lyme for Outdoor Recreationists (VALOR)”, to investigate the efficacy, safety, and immunogenicity of VLA15 in participants five years of age and older in highly endemic regions in the United States and Europe. In February 2023, we announced that Pfizer, as the study sponsor, decided to discontinue approximately half of the total recruited participants in the trial following violations of GCP at certain clinical trial sites run by a third-party clinical trial site operator. The discontinuation of these participants was not due to any safety concerns with the investigational vaccine and was not prompted by a participant-reported adverse event. The clinical trial remains ongoing with other sites not operated by the third party and new sites in the U.S. and Canada. In December 2023, we and Pfizer announced that we completed recruitment for the study. 9,437 participants five years of age and older have been enrolled and will receive three doses of VLA15 or a saline placebo (1:1 ratio) within the first year, and one booster dose approximately one year after completion of the first three doses, as part of the primary immunization. The VALOR trial is expected to be concluded by the end of 2025, with the aim for Pfizer to submit a BLA to the FDA and a MAA to the EMA in 2026, subject to positive data.

We announced our collaboration with Pfizer for late phase development and commercialization of VLA15, if approved, in April 2020 and received a \$130 million upfront payment on signing. In June 2022, the terms of this agreement were updated and Pfizer invested €90.5 (\$95) million in Valneva as part of an Equity Subscription Agreement. As per the updated terms, Pfizer will fund 60% of the remaining shared development costs compared to 70% in the initial agreement. We will receive tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement, which will be complemented by up to \$100 million in milestones payable to us based on cumulative sales. Other development and early commercialization milestones were unchanged, of which \$143 million remain to date. We received a \$25 million milestone payment from Pfizer following initiation of the Phase 3 study. See “Item 10.C—Material Contracts—Pfizer License Agreement” for more details.

Overview of Lyme disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks. It is considered the most common vector-borne illness in the Northern Hemisphere. According to the U.S. Centers for Disease Control and Prevention, approximately 476,000 people in the United States are diagnosed with Lyme disease each year, and at least a further 200,000 cases occur in Europe. Research suggests that Lyme disease cases may rise 92% by 2100 in the United States due to climate change. Although most patients recover from Lyme disease, 10-20% have persistent symptoms, which for some are chronic and disabling. Studies indicate that Lyme disease costs up to approximately \$1.3 billion each year in direct medical costs in the United States alone. The global market for a Lyme disease vaccine is estimated to reach \$1 billion by 2030.

The transmission of Lyme disease infection is well understood and documented. *Borrelia* bacteria colonize in the salivary glands of ticks. When a tick attaches for feeding, it injects its saliva into the human or animal host, bringing along with it antihistamines, cytokine blockers, and anticoagulants and, in the case of an infected tick, *Borrelia* bacteria as well.

Early symptoms of Lyme disease can often be overlooked or misinterpreted as they are often associated with other, often less severe, illnesses. These symptoms include fever, chills, headache, fatigue, muscle and joint aches, as well as swollen lymph nodes. In 70-80% of cases, a gradually expanding rash called *Erythema migrans* forms. As this rash enlarges, it appears as a target or bulls-eye, three to thirty days after infection. Left untreated, the disease can disseminate beyond this initial area into the circulation, the joints, the heart, the brain, and the rest of the central nervous system. If not treated, once the infection has progressed it can cause serious complications, including arthritis with severe joint pain, heart palpitations or irregular heartbeat, and inflammation of the brain and spinal cord.

When diagnosed sufficiently early, Lyme disease can be successfully treated with a two-week to four-week course of oral antibiotics. However, given that the disease is often misdiagnosed in its early stages, patients often miss this therapeutic window. Additionally, chronic symptoms can commonly persist beyond antibiotic treatment, a set of conditions referred to as Post-Treatment Lyme Disease Syndrome, or PTLDS. There are no proven treatments for PTLDS, which often resolves over time but unfortunately may take many months. There is therefore a strong emphasis on prophylactic approaches to preventing the disease through behavior modification – avoiding areas where ticks are prevalent, wearing clothing which minimizes tick exposure, using insect repellants and physically removing ticks that have attached. However, even with education and behavior modification, Lyme disease remains a serious and prevalent disease in the regions where it is endemic.

VLA15 Approach

VLA15 provides a potential prophylactic solution to Lyme disease by generating antibodies that target the OspA protein on the surface of *Borrelia*, killing the bacteria before it can be transmitted from the infected tick to the human host. Third-party studies have shown that antibodies against OspA, which are immunoglobulin G, or IgG, antibodies, in the blood of an animal bitten by an infected tick are transmitted to the tick during feeding and kill the *Borrelia* in the tick’s gut before it can migrate to the tick’s salivary glands and be transmitted to the animal. VLA15 is a recombinant protein subunit vaccine that

is designed to achieve this protective effect using a truncated form of the OspA protein to generate IgG antibodies against the OspA protein through a process summarized in the table below.

Step 1	Step 2	Step 3	Step 4
Vaccine, when injected, elicits high levels of anti-OspA antibodies	Tick attaches to vaccinated human and begins feeding on blood (24- to 48-hour attachment needed to transmit <i>B. burgdorferi</i>)	Anti-OspA antibodies from vaccine enter tick via consumed blood	Antibodies kill <i>B. burgdorferi</i> in midgut, preventing transmission to human host

There are multiple serotypes or variants of *Borrelia* that lead to Lyme disease. The difference among the serotypes includes the fact that they have variant genetic sequences in the code for the OspA protein, meaning that each serotype requires a specific antigen targeting its OspA protein. In the United States, Lyme disease is predominantly associated with *B. burgdorferi* infection, or serotype 1 (ST1), while in Europe, there are multiple serotypes with *B. afzelii*, or serotype 2 (ST2), accounting for slightly more than half of infections. We have developed VLA15 as a single vaccine candidate that includes the OspA antigens from the six most frequently observed serotypes of *Borrelia* in North America and Europe.

To simplify production of the antigenic proteins, we linked the antigenic regions of two OspA proteins from different serotypes into a fusion construct. This allows us to produce the antigens against the six primary serotypes of *Borrelia* with just three protein constructs.

Phase 1 Clinical Trial and Results

We evaluated VLA15 in a partially randomized, multi-center dose escalation Phase 1 clinical trial conducted in Belgium and the United States in 179 healthy adults below 40 years of age. The first 24 subjects were included in an open-label trial in which they participated in a staggered dose escalation design. The remaining 155 subjects were enrolled in one of six blinded treatment groups, receiving VLA15 at a dose of either 12 µg, 48 µg, or 90 µg, with or without alum as an adjuvant, by intramuscular injection on Days 0, 28, and 56. The trial was designed to investigate the safety and tolerability as well as immunogenicity of VLA15. The primary endpoint was safety and tolerability of VLA15 up to three months after enrollment (Day 84).

The final Phase 1 data supported the tolerability profile observed at all time-points, as reported in the interim analysis. The Phase 1 trial met its study endpoints in terms of safety and immunogenicity. The majority of adverse events were mild or moderate, and there were no vaccine-related serious adverse events, allergic reactions, or reactions potentially related to Lyme borreliosis observed. The most common local adverse events were injection site pain (67.0%) and tenderness (84.4%). Solicited systemic adverse events were reported by 58.1% (48 µg with alum group, 90 µg with alum group) to 76.7% (90 µg without alum group) of subjects. The most common solicited systemic adverse events were headache (44.7%), excessive fatigue (25.1%), and myalgia (25.1%). Adverse event rates following subsequent doses in the primary series declined compared to the first dose, indicating no enhanced reactogenicity risk with subsequent vaccinations.

In addition, the final Phase 1 immunogenicity results indicated that the alum-adjuvanted formulations elicited higher immune responses at all time-points, confirming interim data findings as compared to respective non-adjuvanted groups of the same dose level. As expected, based on the interim Phase 1 data, antibody titers declined post Day 84 across all groups, trending towards baseline at approximately one year after initial vaccination.

For some vaccines, immunity begins to decline after a certain period of time, at which point a “booster” dose is needed to raise immunity levels. To evaluate the benefit of a booster dose, 64 subjects across the two higher dose groups (48 µg and 90 µg, both with and without alum) from the Phase 1 trial received a booster in the period 12 to 15 months after their initial dose in the primary immunization. Safety and immunogenicity of VLA15 was evaluated up to month 19, with an interim analysis four weeks after the booster. This booster dose resulted in a significant anamnestic response, yielding OspA antibody titers at levels from 2.7-fold for ST2 and ST3 to 5.8-fold for ST1 over the initial titers observed at Day 84. This potent immunogenic response was observed against all six OspA variants. Additional data about a booster dose follow in the Phase 2 discussion below.

Phase 2 Clinical Trials and Results

We have evaluated the safety and immunogenicity of VLA15 at different dosage levels and schedules in three Phase 2 clinical trials in Europe and the United States. Together, these trials enrolled 1443 healthy participants of 5 to 65 years of age.

VLA15-201 Clinical Trial and Results

Our first Phase 2 clinical trial, VLA15-201, was a randomized, observer-blind, placebo-controlled, multi-center Phase 2 clinical trial conducted in Belgium, Germany, and the United States, consisting of a “run-in phase” and a “main study phase.” In the run-in phase, a total of 120 participants aged 18–40 were randomized into one of four groups: a placebo group and three groups at different dosage levels of VLA15 with alum (90 µg, 135 µg, or 180 µg). The participants

received intramuscular injections on Days 1, 29, and 57. Based on the elicited higher antibody responses across all serotypes observed from the run-in phase, we selected the two higher VLA15 dose levels to be evaluated in the main study phase. A total of 452 subjects aged 18-65 were randomized 2:2:1 to receive one of two VLA15 doses (135 µg or 180 µg) or placebo and received intramuscular injections on Days 1, 29, and 57. The primary endpoint for the trial was GMTs for IgG against each OspA serotype ST1 to ST6. Secondary endpoints examined SCR, geometric mean fold rise, or GMFR, and occurrence of adverse events.

In July 2020, we announced results from our Phase 2 clinical trial of VLA15-201 in which we observed VLA15 was immunogenic across all dose groups tested. Compared to results from the Phase 1 clinical trial, the higher doses used in our Phase 2 clinical trial elicited higher antibody responses across all serotypes than those observed after the primary series in the Phase 1 clinical trial. SCR in the highest dose ranged from 81.5% (ST1) to 95.8% (ST2) on Day 85. No statistically significant differences between 135 µg and 180 µg treatment groups were observed.

In the age group comparable to the age group investigated in the Phase 1 clinical trial (18-39 years), SCRs ranged from 85.6% to 97%. The immunological response in older adults (50-65 years), one of the main target groups for a Lyme vaccine, had SCRs ranging from 71.9% to 93%. Results indicated that prior exposure to *Borrelia burgdorferi sensu lato* (Bb sl), the bacteria that causes Lyme disease (baseline Bb sl sero-positivity) did not have an impact on immunogenicity or safety.

VLA15 was generally well tolerated across all dose and age groups tested. No serious adverse events related to VLA15 were observed in any treatment group. The most common solicited local adverse events were injection site pain (68.4%) and tenderness (76.6%), whereas the most common solicited systemic adverse events were headache (33.2%), fatigue (31.6%), and muscle pain (myalgia) (41.1%). The proportion of adverse events decreased with subsequent vaccinations and were transient. Overall, the tolerability profile including rates of fever appeared to be comparable to what has been observed in third-party trials of other lipidated recombinant vaccines or lipid-containing formulations.

VLA15-202 Clinical Trial and Results

Our second Phase 2 clinical trial, VLA15-202, was a randomized, observer-blind, placebo-controlled multi-center Phase 2 clinical trial conducted in the United States with 246 healthy volunteers aged 18-65. The subjects were randomized 2:2:1 to receive either VLA15 with alum (either 135 µg or 180 µg) or placebo, administered through intramuscular injection at month zero, two, and six. The primary endpoint of the trial was GMTs for IgG against each OspA serotype, measured at month 7 to highlight the importance of further increases in OspA-specific IgG titers after the primary immunization series, which are likely necessary to achieve a successful vaccine candidate. Secondary endpoints evaluated SCRs, GMFRs, and the occurrence of adverse events.

On October 20, 2020, we reported interim results from VLA15-202. Compared to VLA15-201, immunogenicity was further enhanced using an immunization schedule of vaccinating at zero, two, and six months. SCRs, after completion of the primary vaccination series, showed similar responses and ranged from 93.8% (ST1) to 98.8% (ST2, ST4).

Antibody responses were comparable in the two dose groups tested as of Day 208. The immunological response in older adults, one of the main target groups for a Lyme vaccine, was consistent with our observations in VLA15-201. Furthermore, results did not indicate that prior exposure to *Borrelia burgdorferi sensu lato* (Bb sl), the bacteria that causes Lyme disease (baseline Bb sl sero-positivity) has an impact on immunogenicity or safety, also consistent with our observations in VLA15-201.

Unlike our previous trials, we also performed a Serum Bactericidal Assay, or SBA, assessing the functional immune response against Lyme disease after vaccination with VLA15. Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses. Over the course of our trial, the SBAs demonstrated functionality of antibodies against all OspA serotypes.

VLA15 was generally well tolerated across all doses and age groups tested in VLA15-202. The tolerability profile including fever rates was comparable to what has been observed in trials of other lipidated recombinant vaccines or lipid containing formulations. Overall, 232 of 246 participants (94.3%) reported any adverse event, solicited or unsolicited, up to Day 208. Rates of participants who experienced adverse events were similar in the VLA15 treatment groups: 96.9% (135 µg group) and 99.0% (180 µg group), compared with 80.4% in the placebo group. Most adverse events were mild or moderate in severity and no related serious adverse events were reported. A total of 6.1% of participants experienced severe related adverse events; 5.7% of participants experienced at least one severe solicited Grade 3 reactogenicity event, and as such, were considered to be related, including 6.2% in the 135 µg group, 7.1% in the 180 µg group, and 2.0% in the placebo group. One participant in the 135 µg group experienced a severe unsolicited adverse event of ventricular extrasystoles 13 days after the second vaccination, which was assessed as possibly related to the study vaccine by the investigator. The participant had a history of benign premature ventricular contractions, was treated with propranolol and recovered after 39 days. Six unrelated serious adverse events were reported: 3.1% in the 135 µg group (invasive ductal breast carcinoma, prostate cancer, and vertigo) and 2.0% in the 180 µg group (intervertebral disc protrusion, osteoarthritis). One case of Lyme disease (135 µg group) was reported as an adverse event of significant interest: erythematous rash, developed approximately two weeks after the first vaccination.

On September 28, 2021, we announced further positive results from VLA15-202. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all dose groups, remaining above baseline and confirming the need for a booster strategy. Participants who received a complete primary vaccination series with the 180 µg dose of VLA15 were invited to continue the trial in a booster extension phase and were randomized 2:1 to receive an additional 180 µg dose of VLA15 or placebo at Month 18. VLA15's acceptable safety profile was confirmed through one-month post-

booster. No related serious adverse events were observed in any treatment group. Administration of the booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (GMT) in anti-OspA IgG antibody titers compared with titers observed after primary immunization. All participants seroconverted to anti-OspA IgG after the booster dose, meaning SCRs were 100% for all OspA serotypes. SCR was defined as the rate of participants that changed from seronegative at baseline to seropositive. Additionally, participants who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by SBA, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The trial is continuing to monitor persistence of antibody responses.

VLA15-221 Clinical Trial

On December 2, 2020, we announced the acceleration of the pediatric development of VLA15. The Phase 2 clinical trial VLA15-221, which commenced in March 2021, is the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old. We announced completion of recruitment for VLA15-221 in July 2021 and reported positive topline and booster data in February 2022 and September 2023, respectively. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of \$10 million.

VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 clinical trial. A total of 625 participants, 5 to 65 years of age and in groups with age ranges of 5-11, 12-17 and 18-65, were randomized to receive VLA15 at Month 0-2-6 or Month 0-6 (approximately 200 volunteers each) or placebo at Month 0-2-6 (approximately 200 volunteers). The trial was conducted at sites in the US which are located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with *Borrelia burgdorferi* as well as *Borrelia burgdorferi*-naïve volunteers. Participants received VLA15 at a dose of 180µg, which was selected based on data generated in the two previous Phase 2 clinical trials.

The main safety and immunogenicity readout was performed approximately one month after completion of the primary vaccination schedule (i.e. at Month 7), when peak antibody titers were anticipated. A subset of participants received a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed for three additional years to monitor antibody persistence. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3 clinical development.

In the sub-analysis of participants 18-65 years old who received VLA15 in either the two-dose schedule (N=90) or the three-dose schedule (N=97), performed one month after the last vaccination, VLA15 was found to be immunogenic with both vaccination schedules tested. These data are consistent with the strong immunogenicity profile observed for this age group in previous Phase 2 studies. However, the induction of anti-OspA IgG (anti-outer surface protein A immunoglobulin G) antibody titers was higher in participants who received the three-dose primary series compared to those who received the two-dose primary series. Based on these results, we and Pfizer proceeded with a three-dose primary series vaccination schedule in the Phase 3 clinical trial discussed below. The analysis was also consistent with the acceptable safety and tolerability profile observed in previous studies of VLA15. No vaccine-related serious adverse events were observed.

In April 2022, together with Pfizer, we reported positive pediatric data for the VLA15-221 trial. In pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was found to be more immunogenic than in adults with both vaccination schedules tested. The safety and tolerability profile observed in the 5- to 17-year age group was similar to the previously reported profile in adult participants. No vaccine-related serious adverse events (SAEs) were observed. Like in adults, the immunogenicity and safety data supported a three-dose primary vaccination schedule in pediatric participants in the Phase 3 trial.

Additionally, in September 2023, we reported positive booster results for this trial. The results showed a strong anamnestic antibody response for all serotypes in pediatric, adolescent, and adult participants one month after administration of a booster dose (month 19). Depending on the primary schedule they received (month 0-2-6 or month 0-6), participants seroconverted after the booster dose, yielding seroconversion rates of 95.3% and 94.6% for all OspA serotypes in all age groups, respectively. Additionally, OspA antibody titers were significantly higher one month after the booster dose compared to one month after the primary schedule with 3.3- to 3.7-fold increases (GMT) in adults, 2.0- to 2.7- fold increases in adolescents and 2.3- to 2.5-fold increases in children for all serotypes. The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies as the vaccine candidate was well-tolerated in all age groups regardless of the primary vaccination schedule. No vaccine-related serious adverse events and no safety concerns were observed by an independent Data Safety Monitoring Board.

Phase 3 Trial

In August 2022, together with Pfizer, we announced the initiation of a Phase 3 clinical trial, Vaccine Against Lyme for Outdoor Recreationists (VALOR), to investigate the efficacy, safety, and immunogenicity of VLA15.

The randomized, placebo-controlled, Phase 3 VALOR trial has been enrolling participants five years of age and older and is being conducted in areas where Lyme disease is highly endemic, including Finland, Germany, the Netherlands, Poland, Sweden, Canada, and the United States.

As per the terms of our collaboration, we received a \$25 million milestone payment from Pfizer following initiation of the Phase 3 study. In February 2023, Pfizer, as the study sponsor, decided to discontinue a significant percentage of enrolled U.S. study participants following violations of Good Clinical Practice at certain clinical trial sites run by a third-party clinical trial site operator. The discontinuation of these participants was not due to any safety concerns with the investigational vaccine and was not prompted by a participant-reported adverse event. The trial has continued with other sites not operated by the third party and new sites in the U.S. and Canada. In December 2023, we and Pfizer announced

that we completed recruitment for the study. 9,437 participants five years of age and older were enrolled and will receive, as part of the full primary series, three doses of VLA15 180 µg or a saline placebo (1:1 ratio) within the first year, and one booster dose of VLA15 or saline placebo approximately one year after vaccination with the first three doses. The VALOR trial is expected to be concluded by the end of 2025, with the aim for Pfizer to submit a BLA to the FDA and an MAA to the EMA in 2026, subject to positive data.

VLA1601—Our Zika virus development program

Zika is a mosquito-borne viral disease caused by the Zika virus (ZIKV). It is the first and only flaviviral disease that was declared a public health emergency because of devastating birth defects following maternal infection. According to the World Health Organization, there is scientific consensus that Zika virus is a cause of microcephaly and Guillain-Barré syndrome.

VLA1601 is a highly purified inactivated, adjuvanted vaccine candidate against the Zika virus. It is being developed on the original manufacturing platform of Valneva’s licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop the Company’s inactivated, adjuvanted COVID-19 vaccine VLA2001, the first one to receive a standard marketing authorization in Europe. Valneva reported Phase 1 results from its first-generation Zika vaccine candidate in 2019. The inactivated vaccine candidate met the study’s primary endpoint showing a favorable safety profile in all doses and schedules tested comparable to IXIARO and other clinical stage ZIKV vaccines. VLA1601 was also immunogenic in all treatment groups and induced both dose- and schedule-dependent neutralizing antibodies against the Zika virus with the kinetics expected for an inactivated, alum-adjuvanted whole-virus vaccine. Seroconversion rates reached up to 85.7% on Day 35 for the highest dose level tested. Antibodies declined during six-month follow-up, as expected for this vaccine class, with seroconversion rates remaining up to 40%.

The incidence of Zika significantly declined after its peak in 2016 due to high population level immunity in affected countries. Back in November 2018, we therefore decided to put this program on hold and chose to prioritize our Lyme disease and chikungunya programs representing a greater health crisis. However, Zika virus transmission persists in several countries in the Americas and in other endemic regions. According to the World Health Organization, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection to date however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat and is included in the Food and Drug Administration’s Tropical Disease Priority Review Voucher Program. As a result, we have decided to re-initiate the program and expect to start the clinical evaluation of our second-generation vaccine in the coming weeks. A vaccine against the Zika virus would nicely complement Valneva’s portfolio of travel vaccines against mosquito-borne diseases, which already includes IXCHIQ and IXIARO.

VLA84—Our Clostridium difficile vaccine candidate that remains on hold

We have developed VLA84, a vaccine candidate targeting the prevention of primary symptomatic *Clostridium difficile* infection, or CDI, a leading cause of life-threatening, healthcare-associated infections worldwide. VLA84 is designed to produce an immune response to neutralize the effects of C. difficile toxins A and B, considered to be largely responsible for CDI. We completed Phase 2 development of VLA84.

The key objectives of the Phase 2 trial were met, the vaccine candidate generated strong immune responses against C. difficile toxins A and B, and the safety and tolerability profile was good. We could advance into Phase 3 if we find a suitable partner to reactivate this program.

Our Pre-clinical Portfolio

In addition to our clinical-stage assets, our portfolio includes several pre-clinical assets against disease targets that reflect our strategy of providing prophylactic solutions to significant diseases that lack a preventative and effective therapeutic treatment option.

Our pre-clinical work involves exploratory study of a given disease, including extensive review of existing literature and early data that will inform our view of whether and how we could develop a vaccine for that disease.

Our preclinical portfolio is summarized below:



Our two most advanced pre-clinical assets against hMPV and EBV are presented below. Additionally, we initiated pre-clinical work on vaccine candidates against different enteric diseases.

VLA1554—Our vaccine candidate targeting hMPV

Human metapneumovirus, or hMPV, is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection in the pediatric population. hMPV is also a common cause of morbidity and mortality in immunocompromised patients and older adults. Repeated infections are common, resulting in a heavy medical burden. However, there is currently no hMPV-specific prevention or specific treatment. Despite the high frequency of viral respiratory tract infections and over 50 years of research in this field, the virus was discovered relatively recently, and no licensed vaccine against hMPV is currently available.

Our hMPV vaccine candidate, VLA1554, is a recombinant F protein subunit vaccine, designed to be stabilized in a pre-fusion conformation. It is produced in CHO cells, using an initial classical purification process that has been established with suitable production yield.

First readouts of pre-clinical proof of concept studies showed that immunization with the pre-fusion design A1 F protein generated a superior neutralizing antibody response against hMPV subgroups A1 and B1 as compared to pre-fusion B1 F protein. Low doses of the vaccine candidate generated hMPV-neutralizing responses that protected mice from challenge. We are currently exploring potential partnering opportunities for this candidate.

VLA2112 - Our vaccine candidate targeting Epstein-Barr Virus (EBV)

Epstein-Barr virus (EBV), also known as human herpesvirus 4, is a member of the herpes virus family. It is found all over the world and is one of the most common human viruses. Most people get infected with EBV by early adulthood. EBV spreads most commonly through bodily fluids, primarily saliva. EBV can cause infectious mononucleosis, also called mono, and is strongly associated with different cancers and multiple sclerosis.

Our EBV vaccine candidate, VLA2112, is based on adjuvanted, subunit viral glycoproteins to elicit high titers of EBV-neutralizing antibodies.

The selection of antigens that best neutralize infection of both epithelial cells and B cells was completed in 2023 and we now expect to complete initial preclinical proof of concept by the end of 2024.

Our Commercial Portfolio

Our commercial portfolio is composed of three vaccines, our travel vaccines IXIARO/JESPECT, DUKORAL, and IXCHIQ. We stopped manufacturing our inactivated COVID-19 vaccine, VLA2001, in August 2022 in light of reduced order volumes. Our travel vaccines serve a wide range of potential travelers where the diseases they prevent are endemic, from business and leisure travelers to government and military personnel traveling on behalf of their government. We also distribute certain third-party vaccines in countries where we operate our own marketing and sales infrastructure. Our commercial activities have generated meaningful revenues, much of which we have reinvested in our research and development capabilities in order to advance our clinical assets and drive future growth.

IXIARO—Our Japanese encephalitis vaccine

IXIARO, or JESPECT in Australia and New Zealand, is an inactivated Vero cell culture-derived Japanese encephalitis vaccine and is the only Japanese encephalitis vaccine currently approved for use in the United States, Canada, and Europe. IXIARO is indicated for active immunization against Japanese encephalitis in adults, adolescents, children, and infants aged two months and older, and is a required vaccine for U.S. military personnel who are deployed to areas of risk for Japanese encephalitis. The pediatric indication of IXIARO was granted Orphan Drug designation by the FDA.

Japanese encephalitis virus, or JEV, is spread by mosquitos and is the most important cause of viral encephalitis in Asia and the Western Pacific.

Japanese encephalitis background

Japanese encephalitis is a considerable public health problem for many Asian countries, with recent estimates pointing to 67,900 cases annually. Close to three billion people live in regions at risk for this mosquito-borne viral disease. JEV is transmitted to humans by mosquitos that have bitten an infected animal and less than 1% of infected individuals develop the disease. Those that do develop the disease face a 20-30% mortality rate and up to 50% of survivors have significant permanent neurological damage. Many individuals infected by JEV develop symptoms within five to 15 days, usually starting as a flu-like illness with fever, chills, tiredness, headache, nausea, and vomiting. Confusion and agitation also occur in the early stage of Japanese encephalitis. Later symptoms may include swelling around the brain and coma, which can result in death.

In 2023, over 32 million people traveled from Europe and North America to the countries where JEV is endemic. Vaccination remains the single most important control measure against Japanese encephalitis worldwide.

IXIARO Overview

IXIARO is an inactivated vaccine administered as two doses either seven or 28 days apart. In a randomized clinical trial, high titers of neutralizing antibodies were detected in 96.4% of adults 28 days after the last dose. The immune response to Ixiaro was durable, with high levels of neutralizing antibodies in 84.9% of participants three years after initial immunization. A separate trial administration of a booster dose at 14 months after completion of the initial two doses resulted in 100% of participants having neutralizing antibodies.

IXIARO is approved for the prevention of disease caused by JEV in individuals two months of age and older. This intramuscular vaccine is administered in two parts, between seven and 28 days apart depending on the age of the recipient, and with the second dose completed at least a week prior to potential exposure to JEV. A booster shot may be given at least 11 months after completion of the primary immunization series if ongoing exposure or re-exposure to JEV is expected. In 2020, the FDA approved the extension of Ixiaro's shelf life from 24 months to 36 months.

Sales of Ixiaro

IXIARO was first approved by the FDA and European Commission in 2009, and reached pre-pandemic sales of €94.1 million during the year ended December 31, 2019. Due to travel restrictions in light of the ongoing COVID-19 pandemic, sales for Ixiaro declined to €48.5 million during the year ended December 31, 2020 and €45.1 million during the year ended December 31, 2021. In the year ended December 31, 2022, sales of €41.3 million were driven by lower sales to the U.S. Department of Defense. This decrease was partly offset by the significant recovery of the private travel markets, with private sales reaching €28.8 million in the year ended December 31, 2022 compared to €7.1 million in the year ended December 31, 2021. In the year ended December 31, 2023, Ixiaro sales increased 78% to €73.5 million primarily benefiting from the continued travel market recovery and price increases. At the end of September 2023, we also signed a new one-year contract with the U.S. Department of Defense (DoD) worth a minimum of \$32 million for the supply of Ixiaro.

DUKORAL—Our vaccine against cholera and ETEC

DUKORAL is an oral vaccine containing four inactivated strains of the bacterium *Vibrio cholerae* serotype O1, and part of a toxin from one of these strains as active substances. DUKORAL is authorized for use in the European Union and Australia to protect against cholera and in Canada, Switzerland, New Zealand, and Thailand to protect against cholera and ETEC, the leading cause of travelers' diarrhea. Originally licensed in Sweden by SBL Vaccines in 1991, and subsequently in the European Union in 2004 through a centralized procedure followed by other international markets, the vaccine was acquired by us in 2015 from Janssen Pharmaceuticals as part of our strategic vision to extend our proprietary travel vaccine portfolio.

Cholera disease background

Cholera is an acute diarrheal disease caused by ingestion of food or water contaminated with the bacterium *V. cholerae*. Cholera remains a global threat to public health and an indicator of inequity and lack of social development. Researchers have estimated that every year, there are roughly 1.3 to 4.0 million cases, and 21,000 to 143,000 deaths worldwide due to cholera. Cholera is an extremely virulent disease that can cause severe acute watery diarrhea. It takes between 12 hours and five days for a person to show symptoms after ingesting contaminated food or water. Cholera affects both children and adults and can kill within hours if untreated.

Most people infected with *V. cholerae* do not develop any symptoms, although the bacteria are present in their feces for up to 10 days after infection and are shed back into the environment, potentially infecting other people. Among people who develop symptoms, the majority have mild or moderate symptoms, while a minority develop acute watery diarrhea with severe dehydration. This can lead to death if left untreated.

ETEC disease background

ETEC is the leading cause of travelers' diarrhea and a major cause of diarrheal disease in lower-income countries. There are approximately 5-18 million reported cases of ETEC per year worldwide. ETEC is transmitted by food or water contaminated with animal or human feces. Infection by ETEC can cause profuse watery diarrhea and abdominal cramping. Illness develops one to three days after exposure and usually lasts three to four days. Most patients recover without any specific treatment other than rehydration.

DUKORAL Overview

DUKORAL is intended for active immunization against cholera (and LT-ETEC diarrhea in certain jurisdictions) in adults and children from two years of age who will be visiting endemic/epidemic areas. The use of DUKORAL should be determined on the basis of official recommendations, taking into account the variability of epidemiology and the risk of contracting disease in different geographical areas and travelling conditions. DUKORAL is a drinkable vaccine that helps prevent diarrhea caused by heat-labile toxin-producing ETEC as well as cholera.

DUKORAL is administered orally after dissolving the product in a glass of water. Vaccination requires two doses given one to six weeks apart. In an efficacy trial done in Bangladesh in 89,596 adults and children aged two years and older, the efficacy of DUKORAL against cholera was 85% in the six months after the third dose and 57% in the second year after immunization. Protective efficacy declined over the three-year trial period. DUKORAL conferred 67% protection against episodes of diarrhea caused by ETEC during the initial three months of follow-up but demonstrated no protection thereafter.

Sales of DUKORAL

DUKORAL was granted marketing authorization throughout the European Union in 2004, having previously been licensed in Sweden and Norway in 1991 through national licensure processes. DUKORAL was approved in Canada in 2003. Sales of DUKORAL were €29.8 million, €17.3 million, and €2.4 million in the years ended December 31, 2023, 2022, and 2021, respectively, of which Canada represented €17.5 million, €11.4 million, and €0.6 million, respectively, of global sales due to the strong overlap between Canadian travelers to regions of high ETEC prevalence and the vaccine's approved indication. Similar to other travel vaccines, sales in 2021 were significantly impacted by ongoing COVID-19 travel restrictions. In 2022 DUKORAL sales started to benefit from the recovery in the private travel markets, and this recovery intensified in 2023.

IXCHIQ—Our Chikungunya Vaccine

IXCHIQ is the world’s first licensed chikungunya vaccine available to address this unmet medical need and the third vaccine we brought from early R&D to approval. We received marketing approval for IXCHIQ from the FDA in November 2023 under an accelerated pathway based on anti-CHIKV neutralizing antibody titers. Continued approval for this indication is contingent upon verification of clinical benefit in Phase 4 confirmatory studies.

Chikungunya disease background

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus, a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in up to 97% of humans after four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia.

Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. Before IXCHIQ, there were no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

IXCHIQ Overview

IXCHIQ is a single-dose, live-attenuated vaccine licensed in the U.S. and is indicated for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. At the end of February 2024, the U.S. Advisory Committee on Immunization Practices (ACIP) voted on the vaccine’s recommendations. In the U.S., IXCHIQ is recommended for persons aged ≥18 years traveling to country or territory where there is a chikungunya outbreak. Additionally, it may be considered for persons traveling to a country or territory without an outbreak but with evidence of CHIKV transmission within the last five years, who are aged >65 years and likely to have at least moderate exposure to mosquitos (at least two weeks, cumulatively) or who are traveling for a longer duration (six months or more, cumulatively). ACIP also recommended chikungunya vaccination for laboratory workers with potential for exposure to CHIKV.

Sales of IXCHIQ

Our commercial team launched the vaccine in the U.S. at the beginning of 2024. Considering IXCHIQ is the first and only vaccine worldwide against this unmet need, we will focus this year on raising awareness on the disease, shaping the market and booking first sales.

VLA2001—Our discontinued SARS-CoV-2 Vaccine

VLA2001 was the only inactivated whole-virus COVID-19 vaccine approved in Europe and the first COVID-19 vaccine to receive a full marketing authorization from the EMA. It was produced using our established Vero-cell platform, leveraging the manufacturing technology for our commercial Japanese encephalitis vaccine, IXIARO. In addition to its marketing approval in Europe, which we chose to withdraw effective December 2023, VLA2001 received conditional marketing authorization in the United Kingdom and emergency use authorization in the United Arab Emirates and Kingdom of Bahrain. During the third quarter of 2022, the World Health Organization also issued recommendations for use of the vaccine, including for a booster dose of VLA2001 four to six months after completion of the primary series.

SARS-CoV-2 disease background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a strain of coronavirus that causes COVID-19 (coronavirus disease 2019), the respiratory illness responsible for the recent COVID-19 pandemic. First identified in the city of Wuhan, China, the World Health Organization, or WHO, declared the outbreak a public health emergency of international concern on January 30, 2020, and a pandemic on March 11, 2020.

Sales of VLA2001










In November 2021, we signed an advance purchase agreement with the European Commission to provide up to 60 million doses of VLA2001 in 2022 and 2023. In December 2021, we signed an advance purchase agreement with the Kingdom of Bahrain to provide one million doses of VLA2001 in 2022. An amendment to the purchase agreement with the European Commission in July 2022 reduced the orders of VLA2001 to 1.25 million doses, which we delivered to participating EU Member States (Germany, Austria, Denmark, Finland, and Bulgaria). VLA2001 sales in Europe and Bahrain amounted to

€29.6 million in the year ended December 31, 2022. In light of reduced order volume from EU Member States, we suspended manufacturing of the vaccine in July 2022. Our remaining inventories were fully written-down as of December 31, 2022. In 2023, we made our last deliveries to the kingdom of Bahrain with VLA2001 sales amounting to €5.7 million.

Third-party Vaccines

We distribute certain third-party vaccines in countries where we operate our own marketing and sales infrastructure. In June 2020, we entered into a distribution agreement with Bavarian Nordic, pursuant to which we agreed to commercialize Bavarian Nordic’s marketed vaccines for rabies and tick-borne encephalitis, leveraging our commercial infrastructure in Canada, the United Kingdom, France and Austria. In September 2022, we also announced a partnership with VBI Vaccines for the marketing and distribution of the only 3-antigen Hepatitis B vaccine, PreHevbri, in select European markets. Valneva and VBI expect PreHevbri to be available in these countries in 2023. In the year ended December 31, 2023, third party product sales grew to €35.7 million compared to €26.5 million in the year ended December 31, 2022, an increase of 34%. For additional information about our agreements with Bavarian Nordic and VBI Vaccines, see “Item 10.C—Material Contracts” of this Annual Report.

The following table summarizes our current third-party agreements:

3rd-Party Distribution	 Active immunization against Flu	 2016	Rights licensed from Seqirus in Austria
	 Passive, transient post-exposure prevention of rabies infection	 2018	Rights licensed from Kamada in Canada
	 Active immunization against rabies in individuals of all ages		Rights licensed from Bavarian Nordic in select markets: CA, UK, FR, BE, NL, AT
	 Active immunization against tick-borne encephalitis in adults and children		Rights licensed from Bavarian Nordic in select markets: Austria & France
	 Active immunization against hepatitis B virus in adults	 2022	Rights licensed from VBI in select markets: UK, Nordics, Netherlands, & Belgium

Competition

We compete in an industry characterized by rapidly advancing technologies, significant competition and a complex intellectual property landscape. We face substantial competition from large pharmaceutical, specialty pharmaceutical, and biotechnology companies. During the COVID-19 pandemic, we have also seen that academic research institutions and governmental agencies can and will continue to compete in this rapid environment with support from public and private research institutions. Many of our competitors, either alone or through their collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, commercialize, and market products before or more successfully than we do. Below is a description of competition surrounding each of our disease targets and other technologies in development in the vaccines field.

IXIARO/JESPECT Competition

Our commercial vaccine against Japanese encephalitis, IXIARO (marketed as JESPECT in Australia and New Zealand), is the only approved and marketed vaccine for travelers to Japanese encephalitis endemic areas who originate in the U.S., Canada, and European countries.

Given the large population in the Japanese encephalitis endemic region, consisting of over 3 billion people, and the inclusion of the Japanese encephalitis vaccine in many national immunization programs, the competitive landscape in the endemic region is more crowded. Many of the first generation, locally manufactured mouse-brain derived vaccines have been phased out over the past 5-10 years, making way for the introduction of second-generation technologies. This includes companies such as Biken and Kaketsuken (Japan), both with inactivated vero-cell based vaccines, Chengdu (China and GAVI/UNICEF markets) with a live-attenuated vaccine, and Sanofi’s live-attenuated chimeric vaccine, IMOJEV (Australia/some Asian territories). None of these vaccines are currently approved for sale in the European Union, Canada or the United States. Therefore, there is currently no direct competitor to IXIARO in those markets, which represented over 95% of total IXIARO revenues in 2023.

The only country where our Japanese encephalitis vaccine currently faces direct competition is Australia, where it splits market share with the IMOJEV vaccine, originally manufactured by Sanofi and now owned by Substipharma, a French company. This acquisition may result in future competition for IXIARO in travel markets.

DUKORAL Competition

DUKORAL has historically been the only vaccine licensed and marketed to travelers within the European Union, Canada, and Australia against cholera and, in certain countries including Canada, Switzerland, and New Zealand, ETEC. Canada, the Nordic countries, and Australia accounted for approximately 82% of DUKORAL sales in 2023, with Canada alone representing over 59%. DUKORAL is also registered in several endemic countries, and is on the WHO's list of prequalified vaccines, meaning it has been assessed as safe and effective.

While DUKORAL is relevant for both traveler and endemic segments, our commercial strategy focuses on the traveler market, which included approximately 453 million travelers to Asia, South America, and Africa in 2019.

Endemic market sales currently represent less than 3% of DUKORAL sales. This segment is supplied directly and through UNICEF procurement programs by an Indian vaccine, Shancol, and a Korean vaccine, Euvichol.

Product sales for DUKORAL are driven by typical factors associated with travelers' vaccines, including the number of travelers in endemic regions, national recommendations, awareness about the illness, and the perception of risk by health practitioners and tourists.

An indication for ETEC diarrhea in Canada, in conjunction with educational and promotional efforts, has resulted in higher penetration rates of DUKORAL in this market.

Bavarian Nordic announced its acquisition of Emergent BioSolutions' oral cholera vaccine, Vaxchora in February 2023 and started commercializing the vaccine in Europe in May 2023. Vaxchora received FDA approval in the United States in 2016. The clinical trial attempting to demonstrate the vaccine's protection against ETEC was not successful in the Phase 1 clinical trial. Vaxchora was approved by the European Commission in April 2020 for protection against cholera only.

Competition related to our product pipeline

Chikungunya

We are aware of companies such as Bavarian Nordic, NIAID, Barath Biotech, Moderna Therapeutics, Inovio, DRDE, Indian Immunological, and UAB that are developing clinical stage vaccine candidates with neutralizing antibodies mechanism of action for chikungunya. Companies such as Takeda Pharmaceuticals, Profectus, Nanotherapeutics, Medigen, Vaxart, Ti Pharma, Arbovax, GlaxoSmithKline, and GenPhar are developing vaccine candidates with similar mechanism of action although they are currently at pre-clinical stage of development.

Lyme disease

We are aware of companies developing mRNA vaccines such as Moderna, therapeutic antibiotic drug candidates such as Ixodes, or antibody-mediated treatment such as Takeda Pharmaceuticals, Inovio Pharmaceuticals, Tarsus, and Euroimmun. However, their programs are in pre-clinical and/or Phase 1/2 clinical stage. Other companies such as GlaxoSmithKline, Sanofi, and Baxter had clinical programs against Lyme disease. LYMERix, from GSK, achieved approval in the U.S. and was later taken out of the market due to lack of market access and potential safety concerns, although it was later proven to be safe by a FDA advisory committee. Sanofi and Baxter were not successful and stopped their programs before requesting a marketing authorization.

Sales and Marketing

We have a specialist commercial capability comprising approximately 52 employees for the distribution of our travelers' vaccines, IXIARO and DUKORAL, and third-party vaccines.

We have established our own commercial operations in certain travel vaccine markets including the United States, Canada, the United Kingdom, Sweden, France, Austria, Norway, Denmark, Finland, Belgium, and the Netherlands. We commercialize our own and third-party vaccine brands to both private and government customers, including the U.S. military. In other markets, we have entered into marketing and distribution agreements with companies that specialize in the promotion of travel brands and/or for which there is a strategic fit with their product portfolio. Examples of such distribution partnerships include Germany (Bavarian Nordic), Eastern Europe (IMED), Israel (Kamada), and Australia and New Zealand (Seqirus/CSL).

Commercial Operations in Key Markets

We manage nearly all of our global product sales revenues through our own commercial operations. Local operations include expertise in Sales, Marketing, Medical Affairs, Governmental Affairs (U.S.), business support functions, and General Management.

Our commercial teams work continuously to improve service and performance, including embracing digital technology, which allows us to better connect with travelers, physicians, and other health care professionals. We put the customer at the heart of our activities and focus on their needs for improved awareness, a deeper understanding of the travel health landscape, and tailor-made services to achieve their objectives.

We have also continued to leverage our commercial organization to distribute third-party products and aim to attract additional products to further leverage our commercial infrastructure. We entered into a partnership with Seqirus in 2016 to commercialize two differentiated flu vaccines in Austria. We also entered into a marketing and distribution partnership with Kamada in 2018 to commercialize their Rabies immunoglobulin in Canada and with Bavarian Nordic in 2020 to commercialize their Rabipur and Encepur brands in Austria, the UK, France, Belgium, the Netherlands, and Canada. In

September 2022, we announced a marketing and distribution agreement with VBI Vaccines Inc. to commercialize their Hepatitis B vaccine PreHevbri in the United Kingdom, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands.

Manufacturing

Manufacturing of vaccines is considered one of the most complex pharmaceutical manufacturing operations. It can take between six to 36 months to produce, package, and deliver high quality vaccines to those who need them. The process includes testing each batch of vaccine at every step of its journey, and repeat quality control of batches by different authorities around the world.

Our manufacturing base provides a long-term and sustainable industrial network to supply clinical trial material and commercial products based on objectives for delivery schedule, costs, flexibility and quality.

We operate three manufacturing sites augmented by contract manufacturing partners. Our manufacturing network has been operating and producing licensed vaccines for more than ten years. We have a highly experienced management team and workforce operating our production network. We have the expertise and capability to produce most types of viral or bacterial vaccines.

Livingston (Edinburgh), Scotland, UK

Our fully owned property, comprising approximately 65,000 square feet of currently operational manufacturing space, operates under a Manufacturers License from MHRA. The site is qualified to meet required quality standards of several regulatory bodies including FDA, the European Commission, EMA, TGA and Health Canada. We employ currently around 175 staff on the site. The site is a multi-product, FDA-registered manufacturing site and viral vaccines center of excellence.

The Livingston site operates dedicated bulk production units for IXIARO and a BioSafety Level 3 multi-purpose unit used for IXCHIQ clinical supply and commercial manufacturing.

In addition, and as part of our COVID-19 vaccine program, the Livingston site was expanded to include two additional production units in a state-of-the-art manufacturing facility. In light of reduced order volume from EU Member States, we stopped manufacturing of our COVID-19 vaccine and took the decision to transfer the production of IXIARO and IXCHIQ to the new manufacturing facility. This transfer will take place in 2024.

Solna (Stockholm), Sweden

Our Solna facility can operate on a multi-product basis and comprises approximately 11,000 square meters. The site is qualified to meet required standards of several regulatory bodies including the competent Swedish authorities, Health Canada, and TGA. Our Solna site has a heritage and history from more than 100 years in vaccines operations. It is currently our center of excellence for fill-finish operations. As part of our COVID-19 activities, we expanded our fill-finish capacity by fitting out a nearby site for formulation, filling, and packaging and have now transferred our manufacturing activities to this new site. With around 124 employees, the site operates as a dedicated and integrated production unit for DUKORAL. In 2023, as part of a review of our global R&D strategy, we took the decision to divest our Clinical Trial Manufacturing (CTM) unit to NorthX Biologics. Our Solna site is operated on a long-term lease under a Manufacturers License from MPA.

Vienna, Austria

Our facility in Vienna includes a dedicated Quality unit for Quality control (in vitro and in vivo) and Quality Assurance. This unit covers both proprietary and third party products. As such, this facility is registered with the FDA and operated under respective licenses from the Austrian Agency for Health and Food Safety. In Vienna, where we have centralized our product development capabilities we also have a GMP technical development unit that establishes our new vaccines prior to the final industrialization stage. The management of all contract manufacturing partners is managed by a dedicated external manufacturing unit based in Vienna.

Intellectual Property

Our commercial success depends in part on obtaining and maintaining patent, trade secret, and other intellectual property and proprietary protection of our technology, current and future products, and product candidates and methods used to develop and manufacture them. We cannot be sure that patents will be granted with respect to any of the pending patent applications or to any patent applications that we file in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be sufficient to protect our technology or will not be challenged, invalidated, or circumvented. Our success also depends on our ability to operate our business without infringing, misappropriating, or otherwise violating any patents and other intellectual property or proprietary rights of third parties.

We manage our intellectual property by:

- seeking protection for our products, technologies, and processes by actively using the patent, trademark, copyright, and trade secrets systems in Europe, the United States, Japan, China, and other jurisdictions where we might have business interests;
- defending, and if needed, enforcing our property rights in selected jurisdictions; and

- reviewing and monitoring third party patent rights and challenging and invalidating such rights where applicable, in order to establish and ensure the unrestricted use and operation of our products, product candidates, and technologies, in those jurisdictions where we have business interests.

Patents and patent applications

We consider protecting technologies and products through patents and patent applications essential to the success of our businesses.

As of December 31, 2023, we had a portfolio of 440 issued patents, including 81 granted in Germany, France, the United Kingdom, Spain, and Italy, 43 issued in the United States, and 178 pending patent applications, including 27 pending in Europe and three pending international, or PCT, patent applications.

In countries where we seek legal protection through patents, the duration of legal protection for a particular product, method, or use is generally 20 years from the filing date. This protection may be extended in some countries, particularly in the European Union, China, Japan, South Korea, Australia, Canada, and the United States. The protection, which may also vary by country, depends on the type of patent and its scope. In most industrialized countries, any new active substance, formulation, indication, or manufacturing process may be legally protected. We conduct ongoing checks to protect our inventions and to act against any infringement of our patents.

IXIARO

In regards to our Japanese encephalitis vaccine, IXIARO, as of December 31, 2023, we own a patent family that includes five issued U.S. patents (9,884,115; 9,895,437; 9,913,898; 10,668,146; and 11,110,170) with claims covering the aqueous composition of IXIARO and methods for preparing IXIARO, and one pending U.S. patent application. This patent family also includes two granted European patents with claims directed to compositions comprising IXIARO and/or methods for preparing IXIARO, and one pending European patent application. One of the granted European patents directed to a method for preparing an aqueous composition comprising aluminium, a reactive compound and a protein, was opposed at the EPO in June 2023. Patent applications, if issued, and patents in this family are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a pending U.S. and a European patent application with claims covering the manufacturing processes of IXIARO and potentially other vaccines. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

DUKORAL

In regards to our DUKORAL product, we own an International and a European patent application with claims directed to stable pharmaceutical compositions covering a currently non-commercialized formulation of DUKORAL and methods of use thereof, and patent applications or applications related to these applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. Patents covering the composition of matter of DUKORAL are expired.

VLA15—Borrelia vaccine candidate

In regards to our Borrelia vaccine candidate VLA15 which is currently licensed to Pfizer, as of December 31, 2023, we own a patent family which includes five issued U.S. patents, two pending U.S. patent applications and two European patents that are validated, one in 38 of the European Patent Convention member states and the other in 12 of those member states, as well as 26 foreign patents and two patent applications with claims covering the composition of matter of VLA15. We further own a second patent family which includes three issued U.S. patents and one granted European patent as well as 16 foreign patents and six patent applications with claims covering the composition of matter of VLA15. Patent applications, if issued, and patents in these families are expected to expire in 2033 and 2035, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to immunogenic polypeptides with C-terminus domains of OspA to induce a protective immune response that includes a European patent validated as a Unitary patent, UK patent, and Spanish patent and patent applications pending in the U.S., Canada, and Hong Kong. Patent applications, if issued, in this family are expected to expire in 2038, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of December 31, 2023, we also own two patent families with claims directed to compositions comprising OspA fusion proteins including uses thereof and to improved methods for producing a vaccine. Both families have been nationalized in Europe, the U.S., and Canada in 2022. Patent applications claiming priority to these patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. We further co-own with a third party a patent family which includes pending patent applications in Europe, the U.S., and 13 further foreign jurisdictions. Patent applications claiming priority to these patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

IXCHIQ

In regards to our IXCHIQ product, as of December 31, 2023, we own two patent families that include four granted U.S. patents with claims covering methods of preparing and methods of purifying VLA1553 and three pending European patent applications. Patent applications, if issued, and patents in this family are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to pharmaceutical compositions of VLA1553 that includes two U.S. patents, one Brazilian patent, and over 20 pending patent applications in such jurisdictions as the U.S., Europe, Australia, Brazil, Canada, China, India, Japan, and Mexico. Patent applications, if issued, and patents in this family are expected to expire in 2038, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of December 31, 2023, we also own two patent families with claims covering formulations and manufacturing processes of VLA1553. Each of these two families were nationalized in 17 jurisdictions and all are still pending except in South Africa. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to the administration of IXCHIQ in immunocompromised subjects. As of December 31, 2023, this family is still in the priority year. Patent applications if issued, are expected to expire in 2044, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

VLA2001—SARS-CoV-2 vaccine

In regards to our SARS-CoV-2 vaccine, VLA2001, as of December 31, 2023, we co-own together with Dynavax two patents with one U.K. patent and one U.S. patent with claims related to adjuvant formulation and processes of preparing the formulation of VLA2001. These patents, if maintained, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

VLA84—Clostridium difficile candidate

In regards to our *C. difficile* candidate VLA84, as of December 31, 2023, we own a patent family with five granted U.S. patents with claims covering the composition of matter of VLA84 and methods of use thereof, one pending U.S. patent application, and 12 granted foreign patents in such jurisdictions as Australia, China, and Japan. This patent family also includes a granted European patent validated in over 35 countries that has been opposed now has been maintained by the European Patent Office in amended form, which still covers VLA84. A second European patent has not been opposed and a third European patent application is pending. Patent applications, if issued, and patents in this family are expected to expire in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also filed an opposition against two European patents owned by a third party that has claims that might cover our *C. difficile* vaccine candidate. The European Patent Office revoked both of these in opposition proceedings and after the patentee withdrew both appeals, they were canceled without substantive decisions.

VLA1601—Zika vaccine candidate

In regards to our Zika vaccine candidate VLA1601, as of December 31, 2023, we own a patent family that includes five issued U.S. patents with claims covering the aqueous composition of VLA1601 and methods for preparing IXIARO, and one pending U.S. patent application. This patent family also includes two granted European patents with claims directed to compositions comprising VLA1601 and/or methods for preparing VLA1601 and one pending European patent application. One of the granted European patents, directed to a method for preparing an aqueous composition comprising aluminium, a reactive compound and a protein, was opposed at the EPO in June 2023. Patent applications, if issued, and patents in this family are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Furthermore, we own a patent family with two granted U.S. patents with claims covering the formulation VLA1601, three pending U.S. patent applications, nine pending foreign patent applications, and six foreign patents. Patent applications, if issued, and patents in this family are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. A third party has filed an Inter Partes Review Proceeding against one of the U.S. patents, for which the U.S. Patent Trial and Appeal Board has now issued a decision denying Institution after we withdrew some of the claims.

We also own two patent families that include three granted U.S. patents with claims covering methods of preparing and methods of purifying VLA1601 and one granted and two pending European patent applications. Patent applications, if issued, and patents in these families are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a pending U.S. and a European patent application with claims covering the manufacturing processes of VLA1601 and potentially other vaccines. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to large scale manufacturing processes of VLA1601. As of December 31, 2023, this family is still in the priority year. Patent applications if issued, are expected to expire in 2044, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Other protection mechanisms

Our core technologies and products and many of our projects for the development of products candidates depend upon the knowledge, experience, and skills of our scientific and technical personnel. In order to protect our trade secrets, proprietary know-how, and technologies, we generally require all employees, contractors, advisors, and collaborators to enter into confidentiality agreements. These agreements prohibit the disclosure of our confidential information. Agreements with employees and consultants also require disclosure and assignment to us of any ideas, developments, discoveries, and inventions.

The expiration of a patent for a product may result in significant competition, due to the emergence of biosimilar or similar products, and in a strong reduction of product sales which benefited from patent protection. However, the vaccine field is largely protected from direct substitutions, as regulatory and manufacturing complexity has for now blocked the pathway in developed markets for vaccine biosimilars. However, this is not the case regarding similar products relying on a full or abbreviated regulatory approval process and this situation may also change in the future, thus opening a pathway to biosimilars. Nevertheless, in many cases, we may still continue to reap commercial benefits from our product manufacturing secrets, even when the patents for such product have expired.

Trademarks

The trademark rights we hold are national, international and European-wide in scope. The rights are generally granted for a period of ten years and are indefinitely renewable, although in some cases, their validity is contingent on the trademark’s continued use. We hold the title to the names of the products used and those associated therewith.

Our trademarks benefit primarily from protection for pharmaceutical products included in Class 5 and for services in Class 42 of the International Classification of Products and Services.

Our company name, key products, technologies, and product candidates, namely VALNEVA, IXIARO, JESPECT, DUKORAL, IXCHIQ, EB66 and IC31, and the number of trademarks related to these products and our company held by us at December 31, 2023 are shown in the table below.

Trademarks	Number of registrations or applications
Valneva®, Valneva logos	84
IXIARO®, Ixiaro logo	137
JESPECT®	19
DUKORAL®	60
IXCHIQ®	50
EB66®	11
IC31®	8

We also hold registrations for our different entities names, as well as the slogan and logo which constitute our graphic charter. We defend our trademark rights by filling a notice of opposition against applications for identical or similar trademarks, and initiate, if such is the case, legal actions to have our rights recognized.

“VALNEVA” trademark

Valneva SE and the company KRKA, tovarna zdravil, d.d., Novo Mesto signed a co-existence agreement on January 20, 2014, with respect to KRKA’s earlier trademark DALNEVA covering goods of Class 5. We agreed on restricting the specification of goods for the trademark Valneva, by adding the limitation “none of the afore-mentioned goods for the treatment of cardiovascular diseases” to the European Union Trademark (EUTM) application No. 011441268, and to any future applications.

Moreover, we also filed a notice of opposition before the European Union Intellectual Property Office, or EUIPO, against the trademark application VALNECOR (application No. 13.519889) of the company Vetpharma Animal Health S.L., for Class 5, invoking articles 8(1)b and 8(4) of the Regulation (EC) No. 207/2009 on the Community trademark (EUTMR—as amended). On February 19, 2016, the Opposition Division of the EUIPO decided in our favor and upheld the opposition (No. B 2508755) for all the contested goods in Class 5.

A letter of undertakings effective as of July 25, 2016 has been signed by VALNÉVA, a French Simplified Joint Stock company, and Valneva SE, in order to:

- acknowledge our prior rights; and
- record VALNÉVA's undertaking never to contest or challenge the company name and the trademarks Valneva—registered or filed—for any goods and services.

VALNÉVA further agreed not to use the name VALNÉVA for scientific R&D in the fields of medicine, antibodies and vaccines.

We and Boehringer Ingelheim International GmbH also signed a prior rights agreement on July 28, 2016. In this agreement, we undertake not to use the trademark Valneva as a product name or part of a product name for the identification of specific products, but only to identify the fabricant of the product (“house mark” or “manufacturers brand”). We also undertake to limit the registration of the mark “Valneva” in Class 5 to the “Pharmaceutical products for human and veterinary use, namely vaccines and antibodies and fragments thereof, blood serum, adjuvants for medical or veterinary use”, only if so specifically requested by Boehringer Ingelheim.

We filed a notice of opposition before EUIPO against the trademark application VALNOBI n°17579525 made in Class 5 in the name of Bayer AG. On February 4, 2019, the Opposition Division of the EUIPO decided in our favor and upheld the opposition (No. B 3 047 941) for all the contested goods in Class 5.

We filed notices of opposition against the EU trademark application VALENA no. 017895207 and the Austrian trademark application VALENA no. 295810. The Austrian trademark application was withdrawn and the EU trademark application was rejected to a large part of the contested goods and services, and in particular to all of the goods in class 5.

“IXIARO” trademark

On October 30, 2015, Valneva Austria GmbH acquired from GSK (GlaxoSmithKline Biologics SA, GlaxoSmithKline GmbH and CO.KG) the trademark “IXIARO” and the related trademarks and domain names, for all jurisdictions. No co-existence or prior rights agreements exist for the trademark Ixiaro.

OxARO v Ixiaro

We filed an Opposition in 2021 and signed a prior rights agreement with the result that SafeRx withdrew the application OxARO in the U.S. The Settlement Agreement was signed on January 26, 2022. According to the Settlement Agreement SafeRx undertakes to refrain from asserting rights deriving from U.S. Application Serial No. 90/233,007 or use of the trademark OXARO for pharmaceutical preparations and agrees to expressly abandon U.S. Application Serial No. 90/233,007. SafeRx agrees never to use OXARO by itself on a product distributed in the marketplace and will instead use “OxARO ER” and “OxARO IR”. SafeRx may use OXARO solely for fundraising for product development and FDA review, but once through FDA review, SafeRx agrees never to use the mark OXARO by itself, but instead will use the marks “OxARO ER” and “OxARO IR”.

“DUCORAL” trademark

Various prior rights agreements related to the trademark “DUCORAL” were executed in the years 1996 to 2002. A further prior rights and delimitation agreement between Crucell Sweden AB, now Valneva Sweden AB, and Berlin-Chemie AG was signed on June 29, 2012. For mutual settlement of the opposition filed by then Crucell Sweden AB, Berlin-Chemie AG undertakes not to derive any rights from the registration and use of their German trademark DUCORA against the Community Trademark registration of DUCORAL, and to tolerate new applications and modifications of the prior DUCORAL trademark, provided that Crucell Sweden AB shall not apply for the trademark DUCORA. Berlin-Chemie AG restricted the goods and services of their German registration of DUCORA. Crucell then agreed to the registration or use of German trademark DUCORAL under the conditions specified and to withdraw the opposition. Since this agreement is effective worldwide, the party who possesses prior rights in any country agrees to consent to the registration or use of the other party’s respective mark under the same conditions as mentioned in this agreement.

Domain names

As at December 31, 2023, we hold 190 domain names (reserved or in the process of being reserved).

Government Regulation

Government authorities in the United States at the federal, state, and local level and in other countries and jurisdictions including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of biological products, such as our products, product candidates, and any future product candidates we develop. We, along with our third-party contractors, will be required to navigate the various pre-clinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies, seek approval or licensure of our product candidates, and distribute and market our products, if approved. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

Regulatory Approval in the United States

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and other federal, state, local, and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity, and potency of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application, or BLA, after completion of all clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with current Good Manufacturing Practice, or cGMP requirements to assure that the facilities, methods, and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data; and
- FDA review and approval of the BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Pre-clinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous pre-clinical testing. Pre-clinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term pre-clinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product candidate, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA submission and approval, clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2, and Phase 3, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, absorption, metabolism, and distribution of the product candidate in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies conducted in a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide statistically significant evidence of clinical efficacy of the product for its intended use, further evaluate its safety, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

Phase 1, Phase 2, Phase 3, and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic does not undergo unacceptable deterioration over its shelf life.

FDA Review Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

The FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing and may request additional information from the sponsor. The FDA will make a decision on accepting a BLA for filing within 60 days of receipt, and may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with any additional information requested in order to be reviewed by FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets 10 months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

The cost of preparing and submitting a BLA is substantial. Under PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether such facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety, purity, and potency of the product candidate. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally considers such recommendations carefully when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. A CRL or deferred action on the application may also occur where FDA is unable to complete required pre-approval inspections due to travel restrictions. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies, or manufacturing in order for FDA to reconsider the application. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months from receipt, depending on the type of information included. Even if data and information are submitted in response to the deficiencies identified in a CRL, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use, or ETASU. An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above,

if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. For example, Fast Track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and where pre-clinical or clinical data demonstrate the potential to address unmet medical needs for the disease condition. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. The sponsor of a biological product candidate can request the FDA to designate the candidate for a specific indication for Fast Track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner. The designation also includes all of the Fast Track program features, including eligibility for rolling review of BLA submissions if the relevant criteria are met.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify the product's clinical benefit in relationship to the surrogate endpoint. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Additional Controls for Biologics

To help reduce the increased risk of the unintentional introduction of other microorganisms, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, completing, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as applications, with all of the benefits that designation confers.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Once a BLA is approved, a product will be subject to certain additional post-approval requirements.

The FDA also may require post-marketing testing, known as Phase 4 testing, impose a REMS and/or post-market surveillance to monitor the effects of an approved product, or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Manufacturers are subject to periodic unannounced inspections by the FDA, including those focused on manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warnings, or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity, and potency that are consistent with the provisions of the FDA-approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, issuance of

warning or untitled letters, requirements to issue corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict the manufacturer's communications on the subject of off-label use of their products, as well as actions taken on behalf of the manufacturer, such as sponsored scientific and educational activities conducted by a third party.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

Under the BPCIA an application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period.

Regulatory Approval in the EU

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies, and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in EU Member States for a marketing authorization application, or MAA, and granting of a marketing authorization, or MA, by competent authorities in EU Member States or the European Commission before the product can be marketed and sold in the EU.

Clinical Trial Approval

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20, or CTD.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials, and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State concerned. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before

January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 as implemented by Regulation (EC) No. 847/2000 provides that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating, or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the ten-year period if: (i) the MA holder of the authorized product consents to a second original orphan medicinal product application, (ii) the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) the second applicant can establish that its product, although similar, is safer, more effective, or otherwise clinically superior to the authorized orphan medicinal product. A company may voluntarily remove a product from the register of orphan products. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA’s Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Marketing Authorization

To obtain a marketing authorization for a product in the EU, an applicant must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions,

and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients authorization through, the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has an initial validity of five years in principle. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety, and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention, or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a “conditional” MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information,

or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations, and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. MA holders and/or manufacturing and import authorization, or MIA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States’ requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Regulatory Requirements after Marketing Authorization

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion, and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Advertising Regulation

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States’ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Regulatory Approval in the United Kingdom

On January 31, 2020, the United Kingdom left the EU (commonly referred to as “Brexit”) and accordingly is no longer an EU Member State. As the United Kingdom is no longer an EU Member State, the United Kingdom’s participation in the European Medicines Regulatory Network has ceased and the United Kingdom Medicines and Healthcare products Regulatory Agency, or MHRA, has assumed the functions that were previously undertaken by the EU institutions for

human medicines on the United Kingdom market (with the exception of Northern Ireland, which, pursuant to the Protocol on Ireland/Northern Ireland has remained aligned with EU regulations). The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023, confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure, and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures, are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in Great Britain.

International Regulation

In addition to regulations in the United States and the EU, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA, European Commission, or EU Member State competent authority approval.

Other Healthcare Laws and Regulations and Legislative Reform in the United States and the EU

U.S. Healthcare Laws and Regulations

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, third-party payors, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell, and distribute our products. Our current and future operations are subject to regulation by various federal, state, and local authorities in addition to the FDA, including but not limited to the Centers for Medicare & Medicaid Services, or CMS, the Department of Health and Human Services, or HHS, (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Services Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between

pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil *qui tam* actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious, or fraudulent claims for payment of federal funds, and knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- The Health Insurance Portability and Accountability Act, or HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses, and certain healthcare providers, known as covered entities, and their respective business associates and their covered subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value provided to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Similar healthcare laws and regulations in other jurisdictions, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts; and
- State laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state laws that prohibit various marketing-related activities, such as the provision of

certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

U.S. Legislative Reform

We operate in a highly regulated industry, and new laws, regulations, and judicial decisions, or new interpretations of existing laws, regulations, and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition, and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the ACA, which included changes to the coverage and reimbursement of drug products under government healthcare programs. The ACA, among other things,

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs;
- implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- expanded eligibility criteria for Medicaid programs;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial, and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for the purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the

American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, in 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market, and sell any product candidates we may develop. Moreover, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries, Presidential executive orders, and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

For example, at the federal level, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to President Biden’s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Additionally, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future.

Coverage and Reimbursement

Market acceptance and sales of any vaccine candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations, and other private health insurers.

Third-party payors decide which therapies they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. One payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, and on what tier of its formulary it will be placed. The position on a payor’s list of covered drugs, biological, and vaccine products, or formulary, generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of such product by patients and physicians. Patients who are prescribed treatments for their conditions and

providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. In addition, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

Third-party payors are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the EMA, FDA, or other government regulators; is not used in accordance with cost-effective treatment methods as determined by the third-party payor; or is experimental, unnecessary, or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third-parties is the biggest driver of the prices of our products.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced pharmaceutical pricing or reimbursement rates for medical products. For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care organizations, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of various laws including the ACA, that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on drugs (including vaccines) sold to certain Medicare Part D beneficiaries in the coverage gap (the so-called “donut hole”).

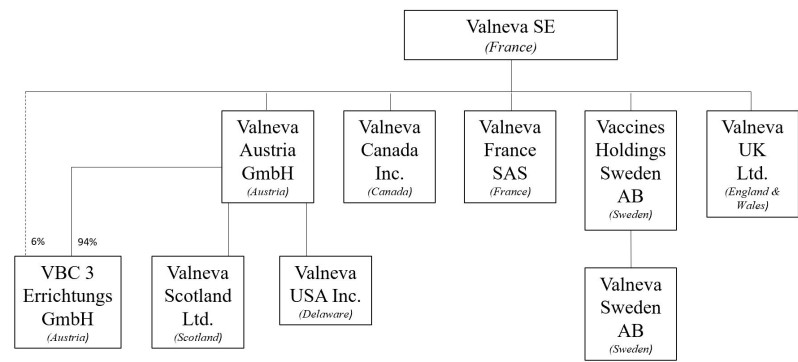
In the EU, pharmaceutical companies, products and distributors are also generally subject to extensive governmental price controls and other market regulations. In many EU Member States, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits.

In various EU Member States, continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper products as an alternative apply. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including countries representing major markets. The HTA process, which is currently governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

On December 15, 2021, the Health Technology Regulation, or HTA Regulation, was adopted. The HTA Regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the MHRA is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium, the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

C. Organizational Structure

The chart below presents our significant subsidiaries as of December 31, 2023. Each subsidiary shown is 100% owned by the relevant parent company unless otherwise noted.



D. Property, Plants and Equipment

Our registered office is located at 6 rue Alain Bombard, 44800 Saint-Herblain, France. We also have key manufacturing facilities located in Scotland and Sweden. We believe that our existing facilities are adequate for our near-term needs, and we believe that suitable additional or alternative manufacturing and office space will be available as required in the future on commercially reasonable terms.

We own the following facilities:

- a 3,178 square meter building located at 6 rue Alain Bombard in Saint-Herblain, France, used as laboratories and offices;
- two neighboring facilities in Livingston, Scotland, used primarily for vaccine production, storage, and offices. One of these facilities is fully operational with a size of 3,547 square meters. The second facility was added in August 2020 and has approximately 6,500 square meters. This expansion of the Almeida facility is discussed further in “Item 3.D—Risk Factors”; and
- a 10,725 square meter building located in Vienna, Austria, used as laboratories and offices. We acquired the building in October 2023 after the previous lease agreement expired on September 30, 2023.

We lease the following facilities:

- premises of approximately 766 total square meters across two office spaces located in the same building in Lyon, France, dedicated to sales and marketing activities. Valneva France SAS subleases around 152 square meters to Valneva SE for offices;
- a 10,739 square meter facility located in Solna, Sweden, including:
 - 4,005 square meters used for industrial operation manufacturing, including production activities and housing laboratories and offices;
 - 1,450 square meters used for the development and manufacture of Clinical Trial Material, in addition to laboratories and offices (now subleased to NorthX Biologics Matfors AB following the divestment in July 2023);
 - 1,504 square meters supporting supply chain activities and customer service, including pick and pack activities, in addition to office space;
 - 1,206 square meters of laboratories and offices supporting quality control; and
 - 2,574 square meters of office space for commercial operations, quality assurance, administration, legal, information technology, and other support functions;
- a 4,000 square meter facility in Solna, Sweden, including:

- 630 square meters used for industrial operation manufacturing, including fill-finish activities and a GMP area;
- 3,370 square meters used for Clean Not Classified areas, media production, cool rooms, goods reception and offices for industrial operations and quality assurance;
- 72 square meters of office space in Fleet, England, dedicated to sales and marketing activities;
- Approximately 5,600 square meters of combined office and warehouse space across four facilities in Livingston, Scotland, located near Valneva’s owned sites;
- 136 square meters of office space in Kirkland, Quebec, dedicated primarily to sales and marketing activities; and
- 470 square meters of offices in Bethesda, Maryland, dedicated to sales and marketing activities.

Currently, about 183.2 square meters of our facility in Saint Herblain are subleased to Vital Meat SAS, a Groupe Grimaud affiliate, and a total of 2,128 square meters of the larger facility in Solna are subleased to NorthX Biologics Matfors AB.

Item 4A. Unresolved Staff Comments.

Not applicable.

Item 5. Operating and Financial Review and Prospects

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related Notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in "Item 3.D—Risk Factors" of this Annual Report, our actual results could differ materially from the results described in or implied by these forward-looking statements.

Our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 and the three years ended December 31, 2023 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

Overview

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best-, or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early Research & Development (R&D) to approvals, and currently market three proprietary travel vaccines, including the world’s first and only chikungunya vaccine, IXCHIQ, as well as certain third-party vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This pipeline includes the only Lyme disease vaccine candidate (VLA15) in advanced clinical development, which we are developing in partnership with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

Our clinical portfolio is composed of highly differentiated vaccine candidates that are designed to provide preventative solutions to diseases with high unmet need. VLA1553 is a vaccine candidate which was approved by the U.S. Food and Drug Administration (FDA) under the brand name IXCHIQ in November 2023. It is indicated in the U.S. for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. At the end of February 2024, the U.S. Advisory Committee on Immunization Practices (ACIP) provided recommendations on how to use IXCHIQ and these recommendations were then adopted by the U.S. Centers for Disease Control and Prevention (CDC). The vaccine is still undergoing several clinical trials with a view to support additional marketing approvals and potential label extensions. VLA15 is a Phase 3 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease, under development in collaboration with Pfizer, and it is the only vaccine candidate against Lyme disease currently undergoing late-stage clinical trials. VLA15 targets the six most prevalent serotypes, or variations, of Borrelia in the United States, where approximately 476,000 people are diagnosed with Lyme disease each year and in Europe, where at least a further 200,000 cases occur annually. VLA1601 is a Phase 1 vaccine candidate targeting the Zika virus (ZIKV), a mosquito-borne viral disease whose transmission has been reported in 89 countries and territories and persists in several countries in the Americas and other endemic regions. There are no preventive vaccines or effective treatments available. As such, Zika remains a public health threat and is included in the FDA’s Tropical Disease Priority Review Voucher Program. VLA1601 is being developed on the original manufacturing platform of our licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop our inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe.

We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand, and Thailand, prevention of diarrhea caused by Enterotoxigenic Escherichia coli, or ETEC, the leading cause of travelers’ diarrhea. At the beginning of 2024, we launched our chikungunya vaccine IXCHIQ in the U.S. Additionally, we distribute vaccines for third parties in selected countries where we have a commercial infrastructure.

We have a highly developed, nimble and sophisticated manufacturing infrastructure with facilities across Europe to meet our clinical and commercial needs, including BioSafety Level 3 (BSL-3) manufacturing and R&D facilities. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior leadership team has extensive experience and demonstrated ability to move vaccines through the clinic and into successful commercialization. Members of our team have previously worked at industry leaders such as Novartis, Chiron, GlaxoSmithKline and Daiichi Sankyo.

Since our inception as Vivalis in 1998, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, establishing our commercial infrastructure, growing our commercial portfolio, establishing and advancing our manufacturing capabilities and conducting pre-clinical studies and clinical trials. As of December 31, 2023, we had €126.1 million in cash and cash equivalents. This does not include the gross proceeds of \$103 million for the sale of our Priority Review Voucher (PRV)

which we received in February 2024. Our operating losses were €82.1 million, €113.4 million and €61.4 million for the years ended December 31, 2023, 2022 and 2021, respectively. Our net losses were €101.4 million, €143.3 million and €73.4 million for the years ended December 31, 2023, 2022 and 2021, respectively. We expect to continue to incur significant operating expenses and net losses for the foreseeable future.

Factors Affecting Our Results

We believe that our financial performance has been and for the foreseeable future will continue to be primarily driven by the factors discussed below. While many of these factors present opportunities for our business, they also pose challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in “Item 3.D—Risk Factors”.

Revenues

We principally derive our revenues from the sale of our commercialized travel vaccines in their respective markets, as well as from sales of third-party products. In the years covered by this Annual Report, revenues from our products derived from the sale of IXIARO, DUKORAL, and VLA2001. We also derive revenues from partnerships related to our vaccine candidates, as well as from collaborations, services, and licensing agreements and by offering our technologies and services to third parties. On January 1, 2023, we changed from reporting revenues under four segments to reporting under a single operating segment. See Note 5.4 of the Notes to the Financial Statements for additional information.

Product Sales of IXIARO, DUKORAL, VLA2001, and Third-party Products

Product sales of IXIARO and DUKORAL represented in aggregate 71.4%, 51.1%, and 75.5% of our revenues for the years ended December 31, 2023, 2022, and 2021, respectively. Our primary markets for these products are the United States and Germany for IXIARO and Canada for DUKORAL.

Product sales of VLA2001 represented 3.9% of our revenues for the year ended December 31, 2023, during which we sold VLA2001 to the Kingdom of Bahrain. In 2022, VLA2001 sales amounted to 25.8% of our product sales, mostly to the Kingdom of Bahrain and certain European Union member states. There were no VLA2001 sales for the year ended December 31, 2021.

In addition, we generate revenues by leveraging our existing sales and marketing infrastructure to sell third-party products. Revenues from sales of third-party products represented 24.7%, 23.1%, and 24.4% of our revenues for the years ended December 31, 2023, 2022, and 2021, respectively.

Sales trends in travel vaccines are primarily driven by travel volume to endemic regions, national travel advisories, awareness about illness, and the perception of risk by health practitioners and tourists. Although the COVID-19 pandemic and the impact on travel caused a material reduction in our revenues during 2020 and 2021, the recovery of the travel market allowed for increased sales in 2022 and 2023.

While COVID-19 has impacted sales of our travel vaccines to the general public, sales of IXIARO to the U.S. Government’s Department of Defense, or DLA, which purchases the Japanese encephalitis vaccine for military personnel being deployed to endemic regions, have remained significant over the periods presented herein. Sales of IXIARO to the DLA derived from one contract signed in September 2020 and another signed in September 2023. The terms of the 2020 agreement contemplated an initial base year followed by two option years, each with a range of minimum and maximum potential dose orders. In September 2021, we announced that DLA had exercised the first year option of this agreement. Due to the ongoing impact of the COVID-19 pandemic on DLA’s operations, the option terms were amended such that the minimum number of doses for the first option year was 200,000 with an approximate value of \$28.8 million. We also agreed to provide additional inventory to the DLA after September 2023 to mitigate the potential impact of unused stock that may expire. This replacement inventory will be provided free of charge and resulted in a contract liability of \$5.2 million (€4.7 million) recognized as at December 31, 2023 (December 31, 2022: \$5.2 million; December 31, 2021: \$5.4 million). In August 2022, we announced that DLA had decided not to exercise the second option year of the initial contract, as DLA considered its existing IXIARO supply sufficient to meet current needs. The new agreement signed in September 2023 is for one year and has a minimum value of approximately \$32.3 million for approximately 200,000 doses.

For the years ended December 31, 2023, 2022, and 2021, 25.5%, 30.3%, and 84.3%, respectively, of our total product sales of IXIARO were from sales to the DLA.

Other revenues

Revenues from Collaboration

We derive revenues from collaboration and partnership agreements. Our primary source of collaboration revenues is through our research collaboration and license agreement, or the Collaboration and License Agreement, with Pfizer Inc., entered into in April 2020, to co-develop and commercialize our Lyme disease vaccine candidate, VLA15. As partial consideration for the license grant under the agreement, in June 2020 Pfizer paid us a one-time upfront payment of \$130 million, and we received subsequent milestone payments of \$10 million in 2021 and \$25 million in 2022. Valneva and Pfizer amended the terms of the agreement in June 2022 and November 2022. Under the terms of the agreement, as amended, we will fund 40% of the remaining shared development costs from May 1, 2022 onward (compared to 30% in the initial agreement), and Pfizer will pay us tiered royalties ranging from 14% to 22%. Pfizer is obligated to pay us up to

\$178 million (of which we have received \$35 million as of December 31, 2023) in development milestones and tiered royalties on net sales of licensed products, subject to specified offsets and reductions, and we are eligible for up to \$100 million on the achievement of cumulative sales targets. The early commercialization milestones and royalties are not included in the transaction price as of December 31, 2023. In the year ended December 31, 2023, we did not receive any milestone payments.

As of December 31, 2023 and 2022, we recognized €33.1 million and €135.5 million, respectively, as discounted refund liabilities relating to the Collaboration and License Agreement. The amounts not recognized in revenue are disclosed as refund liabilities as well as trade receivables and were €10.7 million for the year ended December 31, 2023 and €4.6 million for the year ended December 31, 2022. In the year ended December 31, 2022, we recognized negative revenue of €45.9 million, while no revenues were booked during the year ended December 31, 2023. As of December 31, 2023 and 2022, €3.7 million in contract costs were included in other assets. In 2023, no contract liabilities were disclosed while in 2022 €4.2 million were included.

Revenues from Technologies and Services

We also derive revenues from our technologies and services. Revenues from our technologies consists of revenues from our EB66 cell line, which is derived from duck embryonic stem cells and provides an alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines, and our IC31 vaccine adjuvant, which is a synthetic adjuvant targeting antigens to improve immune response and has been licensed to several pharmaceutical companies. Services revenues consist of research and development services we provide to third parties, including process and assay development and production and testing of clinical trial material.

UK Supply Agreement Termination

In September 2020, we entered into a supply agreement, or the UK Supply Agreement, with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom, or the UK Authority, pursuant to which we were to develop, manufacture, and supply a COVID-19 vaccine to the UK Authority in the United Kingdom of Great Britain and Northern Ireland, or the UK. As part of the UK Supply Agreement, it was agreed that a significant amount of the government advance funding to be provided by the UK Authority would be used to upgrade our manufacturing facilities in Scotland.

We received notice of the UK Authority's intent to terminate the UK Supply Agreement in September 2021, and the termination became effective on October 10, 2021. The UK Supply Agreement provides that, in the case of termination for convenience by the UK Authority, we shall not be obliged to refund or repay any amount paid by the UK Authority.

The impact of the termination of the UK Supply Agreement was assessed as at December 31, 2021. Payments received, where the likelihood of repayment is remote, totaled €253.3 million and were recognized as revenue in 2021. For amounts with uncertainties and a repayment likelihood which was more than remote, a refund liability of €166.9 million was recognized for the royalty on sales and certain other obligations which survive the termination of the UK Supply Agreement.

In June 2022, we and the UK Authority signed a settlement agreement. The settlement agreement resolves certain matters relating to the obligations of the Company and UK Authority following the termination of the UK Supply Agreement and in relation to the separate agreement relating to clinical trials of VLA2001 in the UK, which remains in place. We continue to have certain other obligations pursuant to provisions of the UK Supply Agreement that survive its termination.

The UK Supply Agreement (including the settlement agreement) was assessed in the context of the preparation of the financial statements as at and for the year ended December 31, 2022. For payments received, where judgement was necessary and we assessed the likelihood of repayment to be remote, we recognized as other revenue in the year ended December 31, 2022 an amount of €169.2 million, which related to uncertain restrictions and repayment obligations. The revenue recognition of €169.2 million led to a de-recognition of the corresponding refund liabilities in 2022 to nil for the year ended December 31, 2022. There was no impact on the financial position of the Group for the year ended December 31, 2023.

Advance Purchase Agreement with the European Commission in 2021 and Amendment in 2022

In November 2021, we signed an Advance Purchase Agreement (APA) with the European Commission (EC) to supply up to 60 million doses of VLA2001 over two years. Under the terms of the APA, Valneva was to deliver 24.3 million doses in 2022 (starting in April 2022), subject to approval of VLA2001 by the European Medicines Agency (EMA). The EC had an option to purchase a further 35.7 million doses for delivery in 2023. During 2021, no revenue was recognized, as the deliveries were to start in the second quarter of 2022. Advanced payments of €116.9 million were included as contract liabilities as at December 31, 2021.

In May 2022, Valneva received a notice from the EC of its intent to terminate the APA on the basis of a right to terminate the APA if VLA2001 had not received a marketing authorization from the EMA by April 30, 2022. Based on the terms of the APA, Valneva had 30 days from May 13, 2022, to obtain a marketing authorization, which Valneva did not obtain within this period. Valneva did, however, obtain a marketing authorization in June 2022. Following the receipt of the EC's notice to terminate the APA, both parties entered into negotiations for a remediation plan. In July 2022, the EC and the Company signed an amendment to the APA. Under this amendment the order quantity was reduced to 1.25 million doses of VLA2001 in 2022, with the option to purchase an equivalent quantity later in 2022. In 2022, 1.25 million doses were delivered. Under the terms of the APA, the pre-payments received in connection with the original order volume are not

required to be reimbursed. Of the total amount of pre-payments, Valneva recognized €110.8 million as other revenue in 2022. Product sales were €6.0 million in the year ended December 31, 2022.

In light of reduced order volume from EU Member States, we suspended manufacturing of VLA2001 in July 2022. Our remaining VLA2001 inventories were fully written-down as of December 31, 2022, as explained further in the Notes to our financial statements.

There was no impact on the financial position of the Group for the year ended December 31, 2023.

Key Cost Drivers

Research and Development

We generate a significant amount of research and development expenses due to the nature of our business. Research and development expenses were €59.9 million, €104.9 million, and €173.3 million for the years ended December 31, 2023, 2022, and 2021, respectively. Research and development expenses generally track development of our underlying product candidate portfolio. Investment in research and development is required to support advancing programs through increasingly expensive stages of clinical development.

We have seen decreased research and development costs in 2022 and 2023 mainly due to the phasing of clinical trial expenses and accelerated wind-down of VLA2001-related activities in 2022. Our research and development costs in 2023 mainly comprised expenses relating to the Phase 3 clinical trial for our chikungunya vaccine candidate (VLA1553) progressing to BLA submission and ultimately obtaining FDA licensure in November 2023, the Lyme program (partnered with Pfizer), the development of our Zika vaccine candidate and work on pre-clinical projects. We expect R&D expenses to increase in the medium/long term as we advance other candidates in our pipeline.

Marketing and Distribution

We have developed an established commercial infrastructure that is dedicated to promoting and selling our products and educating physicians and travelers about our products and the diseases they target. We are continually investing in our commercial infrastructure and have identified markets where we can increase our sales and marketing efforts and market penetration. We have also been able to leverage our commercial infrastructure for third-party product distribution.

Marketing and distribution expenses were €48.8 million for the year ended December 31, 2023, compared to €23.5 million in 2022 and €23.6 million in 2021. In 2023, advertising and promotional spend increased in line with a significant resumption of international travel and as a result of launch preparation spend following the FDA licensure of IXCHIQ in November 2023. We expect that marketing and distribution expenses will continue to increase, though at much lower rates, driven by incremental spend in creating awareness for IXCHIQ and by further building our commercial infrastructure.

Cost of Goods and Services

Historically, manufacturing costs have experienced limited cost increases. Manufacturing costs comprise site infrastructure, employees to operate the manufacturing, and the bill of materials. Incremental cost increase is driven by the variable cost in the bill of materials. We are manufacturing our chikungunya vaccine at our facilities in Livingston, Scotland. We need limited additional infrastructure and employees for this program, and we incur relatively low raw materials costs.

The bulk drug substance for our COVID-19 vaccine was manufactured at our facility in Livingston and by IDT Biologika in Germany, and fill-finish activities took place at our facilities in Solna, Sweden. As part of our broader COVID-19 response, we invested in both our Livingston and Solna manufacturing facilities, including through an expansion of the Livingston facility financed by the UK Supply Agreement. We stopped manufacturing of the COVID-19 vaccine in 2022.

Cost of goods and services were €100.9 million in the year ended December 31, 2023 (2022: €324.4 million, 2021: €187.9 million), of which €5.5 million (2022: €159.4 million, 2021: €121.4 million) related to VLA2001. The considerably higher amounts in 2022 and 2021 stem from costs of goods of the VLA2001 doses sold, write-downs for materials which cannot be used, failed batches, and batches at risk of failure as well as product which is not expected to be sold. €66.6 million of costs of goods and services in 2022 related to onerous agreements provision and settlement costs of which €5.3 million have been released in 2023.

General and Administrative Expenses

General and administrative expenses have increased in the year ended December 31, 2023 compared to the year ended in December 31, 2022, as we have become a more complex organization, requiring additional corporate support. Corporate support increased as a result of our Nasdaq listing. In 2022, employee-related expenses profited from a favorable effect of our share price development on the employee share-based compensation programs.

Grants

We seek grants from governmental agencies and non-governmental organizations to partially offset our increasing research and development costs. Grant income also includes research and development tax credits. Grants, which are recorded in other income, increased to €18.1 million for the year ended December 31, 2023 from €15.5 million for the year ended December 31, 2022, mainly due to the recognition of an €11.1 million grant income received from Scottish Enterprise, Scotland's national economic development agency, for developing non-COVID-19 vaccines (the chikungunya vaccine and IXIARO). In 2023, the amount of research and development tax credit executed in Austria was €5.7 million. In 2022 and

2021, the amounts recognized were €13.9 million and €20.2 million, respectively, mainly related to the then COVID-19 and chikungunya vaccine candidates.

In July 2019, we entered into a funding agreement with CEPI pursuant to which we are eligible to receive up to \$23.4 million (paid in a series of six-month tranches) for vaccine manufacturing and late-stage clinical development of a single-dose live attenuated vaccine against chikungunya (VLA1553) in return for equitable access to project results. In 2022, CEPI agreed to increase our funding to up to \$24.6 million. We are obligated to pay CEPI up to \$7.0 million in commercial and related milestones. See “Item 10.C—Material Contracts—CEPI Funding Agreement” for more details on the terms of this grant. We plan to continue evaluating and pursuing grant opportunities.

In February 2022, we received two grants worth up to £20 million (approximately €23.9 million) from Scottish Enterprise to support research and development relating to the manufacturing processes of the COVID-19 vaccine and other vaccine candidates. Following the termination of the COVID-19 vaccine program, in May 2023 the grant relating to this program was amended, reducing the available funding by £0.7 million and adjusting how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. If we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date.

International Operations and Foreign Currency Exchange Risks

We operate on a global basis with facilities, sales, and activities throughout the world and our global operations subject our financial results to fluctuations in foreign currency exchange rates. Because a substantial part of sales are generated in the United States for IXIARO, with production costs in the British Pound, or GBP, and in Canada for DUKORAL, with production costs in Swedish Krona, or SEK, and proceeds in USD from the capital raises in May 2021, October 2021, June 2022, and October 2022, we are exposed to foreign exchange risks, principally with respect to the U.S. Dollar, or USD, GBP, SEK and the Canadian dollar, or CAD. Our results of operations continue to be impacted by exchange rate fluctuations.

Impact of COVID-19

The COVID-19 pandemic had a number of significant impacts on our business since March 2020. Notably, we initiated development of a COVID-19 vaccine, VLA2001, and sold VLA2001 to certain European countries and Bahrain. Other than recording sales related to shipment of VLA2001 doses to Bahrain and residual costs for VLA2001 clinical studies, the COVID-19 pandemic had no further impact on the income statement for the year ended December 31, 2023.

Our primary commercial products, IXIARO and DUKORAL, are aimed at diseases that primarily threaten travelers to particular regions (e.g. Asia). Sales of these vaccines remained lower in 2021 compared to pre-pandemic levels, adversely impacting our financial results. For the year ended December 31, 2021, €5.4 million of the write-down we included in our income statement was due to lower sales expectations and limited shelf life of finished goods. A significant resumption of international travel occurred in the years ended December 31, 2022 and 2023, resulting in higher sales of our travel vaccines and a release of €1.5 million of this write-down provision. Furthermore, as a result of a COVID-related manufacturing halt for IXIARO and DUKORAL in the third quarter of 2020, idle capacity costs were not capitalized. The manufacturing for IXIARO and DUKORAL re-started during 2022.

Financial Operations Overview

Revenue

Our product revenue is primarily derived from the sale of our commercialized products IXIARO and DUKORAL in their approved markets and sales of third-party products pursuant to distribution partnerships. We distribute products both directly and through the use of third-party distributors. We primarily sell IXIARO in the United States (private market as well as to the U.S. Department of Defense for military personnel being deployed to endemic areas), Canada, Germany, the Nordics (being Denmark, Finland, Norway and Sweden together), France, and Benelux. We primarily sell DUKORAL in Canada and the Nordics. We derived product revenues from the sale of our COVID-19 vaccine to certain European countries in 2022 and to the Kingdom of Bahrain in 2022 and 2023.

Our other revenue (from collaboration, licensing, and services) consists of milestone payments, upfront licensing payments, and reimbursement of services. Certain of these payments are initially recorded on our statement of financial position and subsequently recognized as revenue in accordance with our accounting policy as described further under “Critical Accounting Estimates and Judgments” and Note 5.2 to our consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included elsewhere in this Annual Report. We generate revenues from licensing and service agreements for our product candidates and proprietary technologies. We contract with third parties to provide a variety of services such as manufacturing services, leases arrangements, research licenses, commercial licenses and research and development services. The terms of such licenses include license fees payable as initial fees, annual license maintenance fees and fees to be paid upon achievement of milestones, as well as license option fees and fees for the performance of research services. In addition, our licensing arrangements generally provide for royalties payable on the licensee’s future sales of products developed within the scope of the license agreement.

In the years ended December 31, 2022 and 2021, our other revenues included certain amounts from the agreements relating to our COVID-19 vaccine: a) the UK Supply Agreement executed in September 2020 and b) the EC APA executed in October 2021.

For more detailed information, see Note 5.5 to the financial statements included elsewhere in this Annual Report.

Operating Expenses

Cost of Goods and Services

Cost of goods and services consist primarily of personnel costs, costs for materials, royalties, and costs for third-party services, as well as building and energy costs, depreciation and amortization, impairment charges of tangible assets, and other direct and allocated costs incurred in connection with the production of our products. Costs of goods and services also include costs of product sales from inventory produced in the prior year, idle production costs, and costs related to expired and faulty products which have been written off. Cost of goods and services also include costs relating to our revenue-generating collaboration, services, and licensing agreements.

Research and Development Expenses

The nature of our business and the primary focus of our activities generate a significant amount of research and development expenses. Research and development expenses include the costs associated with research and development conducted by us or for us by outside contractors, research partners, or clinical study partners, and expenses associated with research and development carried out by us in connection with strategic collaboration and licensing agreements. Our research and development expenses are primarily incurred as a result of the following activities:

- discovery efforts leading to product candidates,
- development efforts for our clinical programs, and
- development of our manufacturing technology and infrastructure.

The costs of the above activities driving research and development expenses comprise the following categories:

- expenses related to our research and development personnel, including salaries, social security expense, share-based compensation expense, and other related expenses,
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our pre-clinical studies and clinical trials, and in-licensing arrangements,
- costs of acquiring, developing, and manufacturing materials for pre-clinical studies and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs,
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process, and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

The substantial majority of our direct expenses incurred for the years ended December 31, 2023, 2022, and 2021, including for CROs, other contracted research and development activities, and raw materials, related to our chikungunya vaccine candidate, COVID-19 vaccine (in 2022 and 2021), and our Lyme disease vaccine candidate. We also incur indirect research and development expenses primarily related to facilities, energy, and office costs as well as the cost of research and development personnel.

Research and development expenses are generally recognized in the period in which they are incurred. However, research and development expenses of €7.0 million related to VLA2001 for which no future benefit is expected were provisioned as of December 31, 2022 and fully released, against the incoming invoices received, in the period ended December 31, 2023. Research and development expenses incurred in connection with product candidates are capitalized and recorded as intangible assets when the following criteria are met: the technical feasibility of completing the asset has been achieved so that it will be available for use or sale; the intention to complete the asset and use or sell it; the ability to use or sell the asset; the asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally; the availability of adequate technical, financial, and other resources to complete the development and to use or sell it; and the ability to reliably measure the expenditure attributable to the intangible asset. In the years ended December 31, 2023, 2022, and 2021, no research and development expenses were recorded as intangible assets. As of December 31, 2023 and 2022, we had previously capitalized research and development costs recorded as intangible assets in an aggregate amount of €1.2 million and €1.4 million, respectively.

Research and development activities are a key component of our business model. The successful development and commercialization of a product candidate involves significant costs, which may vary from year to year depending upon factors such as the progress of clinical trials and other research and development activities, the timing of regulatory approvals, the duration of the regulatory approvals process and the possibility of, and potential expenses related to, filing, prosecuting, defending, or enforcing any patent claims or other intellectual property or proprietary rights. The most expensive stages in the regulatory approval process in the United States and the European Union are late-stage clinical trials, which are the longest and largest trials conducted during the approval process. The significant cost factors in our clinical trials include manufacturing compounds for product candidates, organizing clinical trials, including participant enrollment, production and testing of product candidates involved in clinical trials, and laboratory testing and analysis of clinical parameters. By contrast, pre-clinical research and development expenses primarily depend on the number of scientific staff employed. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate and progress clinical trials for our vaccine candidates.

Marketing and Distribution Expenses

Marketing and distribution expenses consist primarily of expenses relating to marketing and distribution personnel, including salaries, social security contributions, share-based compensation expense, and other employee-related expenses, advertising, media, and public relations expenses, warehousing and distribution costs, costs related to third-party services and other direct and allocated expenses incurred in connection with our own commercial sales infrastructure, business development, and other marketing and distribution activities. We have incurred incremental costs for preparation of market access and launch activities of IXCHIQ following licensure of the vaccine in the U.S. in November 2023.

General and Administrative Expenses

General and administrative expenses consist primarily of non-research and development personnel-related costs, including salaries, social security contributions, share-based compensation expense, and other employee-related expenses for general management, finance, legal, human resources, investor relations, internal audit, and other administrative and operational functions, fees for professional services, such as consulting, legal, and financial services, information technology, and facility-related costs. These costs relate to the operation of our business and are unrelated to our research and development function or any individual product candidate program.

We anticipate that our general and administrative expenses in the near term will remain comparable to the costs incurred in the year ended December 31, 2023. We also anticipate continued material expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with U.S. exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs. In particular, we will continue to incur additional accounting expenses to comply with the Sarbanes-Oxley Act of 2002 in the United States that require us to test the effectiveness of our internal controls over financial reporting. We also anticipate increased expenses associated with new sustainability reporting requirements applicable to us as a publicly listed company in both France and the United States.

Other Income (Expenses)

Our other income results principally from grants and research tax credits. We expect to continue to be eligible for these tax credits and subsidies for so long as we incur eligible expenses.

Grants

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and that we will comply with all conditions.

In 2019, we entered into a funding agreement with CEPI. Under this funding agreement, we are eligible to receive up to \$23.4 million (paid in a series of six-month tranches) for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine against chikungunya (VLA1553). In 2022, the amount of funding we are eligible to receive under the agreement was increased to \$24.6 million. We will be obligated to repay up to \$7.0 million to CEPI if and when certain commercial and related milestones are reached. See “Item 10.C—Material Contracts” for more details on the terms of this grant. The difference between the proceeds from CEPI and the carrying amount of the loan is treated under IAS 20 and presented as “Borrowings”. The amount from the CEPI grant which benefits Instituto Butantan is recognized as revenue. In the year ended December 31, 2023, €0.2 million of grant income (2022: €0.2 million) and €5.0 million of other revenue (2022: €3.9 million) related to CEPI were recognized.

In February 2022, we received two grants worth up to £20.0 million (approximately €23.9 million) from Scottish Enterprise to support research and development relating to the manufacturing processes of the COVID-19 vaccine and other vaccine candidates. Following the termination of the COVID-19 vaccine program, in May 2023 the grant relating to this program was amended, reducing the available funding by £0.7 million and adjusting how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. If we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date. In the year ended December 31, 2023, €11.1 million (£9.6 million) of grant funds from Scottish Enterprise were recognized.

Research Tax Credits

We benefit from Austrian research tax credit and French tax credit (known as *Crédit d'Impôt Recherche*, or CIR). The qualifications for the Austrian and French tax credits are similar, as both the Austrian and French tax authorities encourage companies to conduct technical and scientific research. To be eligible, companies need to demonstrate that they have expenses that meet certain required criteria, including research expenses located within the European Union. The main differences between the Austrian and French tax credits are the applicable percentage of and the basis for the tax credit.

For the CIR, companies need to demonstrate that expenses taken into account for the calculation of the CIR only involve certain eligible research and development expenses. Subcontracting expenses are limited to an amount equal to €10 million.

The main characteristics of the CIR are the following:

- the CIR results in a cash inflow to us from the tax authorities, either through an offset against the payment of corporate tax or through a direct payment to us for the portion that remains unused;
- our income tax liability does not limit the amount of the CIR, as a company that does not pay any income tax in France can request direct cash payment of the CIR; and

- the CIR is not included in the determination of the corporate income tax.

For the Austrian tax credit, there is no limit for subcontracting expenses, but contract research expenses are limited to €1.0 million per year. The Austrian research tax credit results in a cash inflow from the tax authorities paid to us and is not included in the determination of the corporate income tax.

We have concluded that research tax credits in both countries meet the definition of a government grant, as defined in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, and, as a result, it has been classified as other income within operating income in our statement of operations.

Finance Income (Expenses)

Finance income relates primarily to interest income received from cash and cash equivalents deposits. Our cash and cash equivalents have been deposited primarily into cash accounts and term deposit accounts with short maturities and therefore generate only a modest amount of interest income.

Finance expenses relate primarily to interest expense paid to banks and government agencies and on other loans as well as to interest expense on lease liabilities and refund liabilities.

We also incur foreign exchange gains and losses related to our international operations, primarily with respect to the U.S. Dollar, the British Pound, the Swedish Krona, and the Canadian Dollar, which amounts are recorded as finance income or expenses.

Income Tax

Income tax income or expense reflects our current income tax, as well as our deferred tax income (expense).

Adjusted EBITDA

To provide investors with additional information regarding our financial results, we have provided within this Annual Report Adjusted EBITDA, a non-IFRS financial measure, which is defined as earnings (loss) from the period before income taxes, finance income/expense, foreign currency gain/(loss) – net, result from investments in associates, amortization, depreciation, and impairment. Adjusted EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management uses Adjusted EBITDA as a supplemental measure for assessing operating performance in conjunction with related GAAP amounts. It also uses Adjusted EBITDA in connection with matters such as strategic planning, annual budgeting, operating decision making, evaluating company performance, and comparing operating results with historical periods and with industry peer companies.

Management uses and presents IFRS results as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand our current performance, performance trends, and financial condition.

We have provided reconciliations in “Item 5A—Operating Results—Results of Operations” to operating loss, which is the most directly comparable IFRS measure, for the years ended December 31, 2023, 2022, and 2021. Our use of Adjusted EBITDA has limitations as an analytical tool, and you should not consider it in isolation or as a substitute for analysis of our results as reported under IFRS. For example:

- Although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and Adjusted EBITDA does not reflect cash capital expenditure requirements for such replacements or for new capital expenditure requirements.
- Adjusted EBITDA does not reflect changes in, or cash requirements for, our working capital needs.
- Adjusted EBITDA does not reflect interest expense or income tax payments that may represent a reduction in cash available to us.

Item 5A. Operating Results

Results of Operations

Overview

Results of Operations—Consolidated

Our results of operations for the years ended December 31, 2023, 2022, and 2021 are summarized in the table below.

	Year ended December 31,		
in € thousand	2023	2022	2021
Product sales	144,624	114,797	62,984
Other revenues	9,088	246,506	285,101
REVENUES	153,713	361,303	348,086
Cost of goods and services	(100,875)	(324,441)	(187,920)
Research and development expenses	(59,894)	(104,922)	(173,283)
Marketing and distribution expenses	(48,752)	(23,509)	(23,643)
General and administrative expenses	(47,799)	(34,073)	(47,606)
Other income and expense, net	21,520	12,199	22,976
OPERATING PROFIT/(LOSS)	(82,087)	(113,443)	(61,390)
Finance income	1,210	260	249
Finance expenses	(23,325)	(19,054)	(16,964)
Foreign exchange gain/(loss), net	5,574	(12,587)	8,130
Result from investments in associates	—	9	(5)
PROFIT/(LOSS) BEFORE INCOME TAX	(98,629)	(144,815)	(69,979)
Income tax income/(expense)	(2,800)	1,536	(3,446)
PROFIT/(LOSS) FOR THE PERIOD	(101,429)	(143,279)	(73,425)

Results of Operations—By Segment

Our Management Board (since December 20, 2023, our Executive Committee) as our chief operating decision maker (“CDM”), considers our operating business in its entirety to allocate resources and assess performance. The CDM evaluates all vaccine candidates and vaccine products together as a single operating segment, “development and commercialization of prophylactic vaccines”. Therefore, the split used to allocate resources and assess performance is based on a functional view, thus correlating to the income statement format.

As a consequence, we have changed our internal reporting process as at January 1, 2023 to present a single operating segment instead of the previously disclosed product-based segments.

Comparisons for the Years Ended December 31, 2023 and 2022

Revenue

Consolidated Revenue

	Year ended December 31,	
in € thousand	2023	2022
Product sales	144,624	114,797
Other revenues from contracts with customers	8,075	245,709
Other non-IFRS 15 revenue	1,014	797
REVENUES	153,713	361,303

Revenue decreased by €207.6 million, or 57%, to €153.7 million for the year ended December 31, 2023 compared to €361.3 million for the year ended December 31, 2022. The decrease is mainly related to one-off revenues recorded in the prior year linked to our COVID-19 program which has been suspended.

Our total product sales reached €144.6 million for the year ended December 31, 2023, compared to €114.8 million in the same period of 2022. This 26% increase was driven by the continued recovery of travel vaccine sales. Currency fluctuations of €2.8 million adversely impacted product sales.

Product sales

in € thousand	Year ended December 31,	
	2023	2022
IXIARO	73,483	41,349
DUKORAL	29,775	17,334
Third party products	35,675	26,545
COVID VLA2001	5,691	29,568
PRODUCT SALES	144,624	114,797

IXIARO/JESPECT product sales were €73.5 million in the year ended December 31, 2023 compared to €41.3 million in 2022. The 78% increase in sales is primarily the result of the continued travel market recovery, as well as price increases. The increase in IXIARO/JESPECT product sales included an adverse €1.5 million foreign currency impact.

DUKORAL sales were €29.8 million in the year ended December 31, 2023 compared to €17.3 million in the same period of 2022. This 72% increase is also a result of the significant recovery in the private travel markets and price increases. Foreign currency fluctuations reduced DUKORAL sales by €0.9 million.

Third party product sales were €35.7 million in the year ended December 31, 2023 compared to €26.5 million in the comparison period of 2022, a 34% increase which was mainly driven by sales of Rabipur/RabAvert and Encepur under the distribution agreement with Bavarian Nordic.

COVID-19 vaccine sales in 2023 amounted to €5.7 million compared to €29.6 million in 2022, which was a result of our decision to suspend the program.

Product Sales—By Geography

We also monitor product sales generated in the countries and regions where we operate. The following table presents product sales by geography and is based on the final location where our distribution partner sells the product or where the customer or partner is located.

in € thousand	Year ended December 31,	
	2023	2022
United States	32,606	21,992
Canada	28,193	18,904
United Kingdom	20,216	10,901
Austria	13,915	13,749
Germany	13,238	20,341
Nordics	12,426	8,560
France	5,303	2,625
Other Europe	8,168	6,245
Rest of World	10,560	11,480
PRODUCT SALES	144,624	114,797

Total product sales in the United States increased by €10.6 million, or 48%, to €32.6 million in the year ended December 31, 2023, compared to €22.0 million in the year ended December 31, 2022. They increased primarily as a result of higher sales to the DLA and higher demand in private markets.

Product sales in Canada increased by €9.3 million, or 49%, from €18.9 million in the year ended 2022, to €28.2 million in 2023 as a result of the significant recovery in the private travel markets.

Sales in the United Kingdom increased by €9.3 million, or 85%, to €20.2 million in the year ended December 31, 2023 due to continued resumption of travel positively impacting sales of our travel vaccines and of product distributed for third parties.

Other revenues from contracts with customers

The following table presents our other revenues (from collaboration, licensing, and services) for the years ended December 31, 2023 and 2022.

in € thousand	Year ended December 31,	
	2023	2022
IXCHIQ	2,733	5,565
COVID VLA2001	1,973	280,010
Lyme VLA15	—	(45,869)
Services related to clinical trial material	275	3,205
Others	3,093	2,798
OTHER REVENUES FROM CONTRACTS WITH CUSTOMERS	8,075	245,709

In the year ended December 31, 2023, total other revenues were €8.1 million, a decrease of €237.6 million compared to €245.7 million in the year ended December 31, 2022. The amount in the year ended December 31, 2022 included recognition of COVID-related revenues stemming from previous COVID-19 vaccine supply agreements with the UK Authority and the EC.

In the year ended December 31, 2022, €45.9 million of negative revenue were recorded for the Lyme disease vaccine candidate, primarily resulting from a reversal of revenue from amendments of the Collaboration and License Agreement with Pfizer.

Operating Income and Expenses**Cost of Goods and Services**

Cost of goods and services (COGS) decreased by €223.6 million, or 69%, to €100.9 million for the year ended December 31, 2023. The significant reduction in cost of goods was primarily due to impairment and scrap of short-dated or expired product in 2022 related to the wind down of COVID-19 manufacturing.

The gross margin on commercial product sales amounted to 46.0% in the year ended December 31, 2023 compared to 45.5% in the year ended December 31, 2022. COGS of €35.1 million related to IXIARO product sales, yielding a product gross margin of 52.3%. The IXIARO gross margin was impacted by batch write-offs in the Scottish manufacturing site. COGS of €17.1 million related to DUKORAL product sales, yielding a product gross margin of 42.4%. Of the remaining COGS in 2023, €22.8 million related to the third-party products distribution business, €5.3 million to VLA2001 and €10.2 million to cost of services. In 2022, overall COGS were €324.4 million, of which €314.7 million related to cost of goods and €9.7 million related to cost of services. In 2022, COGS of the COVID-19 vaccine program amounted to €267.1 million and included effects from the significant reduction of sales volumes to the European Union Member States which resulted in impairment of fixed assets and inventories.

Research and Development Expenses

Research and development expenses decreased by €45.0 million, or 43%, to €59.9 million for the year ended December 31, 2023 from €104.9 million in the year ended December 31, 2022. Research and development expenses were 23% of our total operating expenses for the year ended December 31, 2023. This decrease was exclusively driven by the lower spend on our COVID-19 vaccine, VLA2001 due to discontinuation of the program while we intensified our work on IXCHIQ leading in sum to 25% increased expenses of €32.0 million for IXCHIQ as of December 31, 2023. Further, costs related to the Zika vaccine candidate increased as we have been working towards re-initiation of clinical development.

For the year ended December 31, 2023, research and development expenses consisted primarily of i) €20.2 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €30.1 million external research and development services, including costs for clinical studies and external manufacturing, and iii) €3.5 million of material consumption.

For the year ended December 31, 2022, research and development expenses consisted primarily of i) €12.5 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €59.1 million of external research and development services, including costs for clinical studies and external manufacturing, and iii) €7.8 million of material consumption. In 2022, employee-related expenses profited from a favorable effect of our share price development on the employee share-based compensation programs.

We track our research and development expenses by product or development program. The following table sets forth our research and development expenses by product or development program for the periods indicated:

(In € thousand)	Year ended December 31	
	2023	2022
IXCHIQ	31,953	25,558
Zika vaccine candidate (VLA1601)	12,828	2,143
COVID-19 Vaccine (VLA2001)	5,796	72,762
IXIARO	1,175	504
DUKORAL	875	563
Human metapneumovirus vaccine candidate (VLA1554)	739	1,562
Lyme borreliosis vaccine candidate (VLA15)	277	1,016
Other research projects (*)	6,250	815
TOTAL RESEARCH AND DEVELOPMENT EXPENSES	59,894	104,922

* In 2023 and 2022, other research projects included €1.4 million of expenses and €1.3 million of income respectively, related to IFRS 2 (share-based and cash-based compensation) programs, which have not been allocated to the projects.

VLA1553. Our research and development expenses related to our chikungunya vaccine IXCHIQ increased by €6.4 million, or 25.0%, to €32.0 million in the year ended December 31, 2023 from €25.6 million in the year ended December 31, 2022. This increase relates to the progress of the chikungunya vaccine towards BLA submission and ultimately U.S. licensure in November 2023.

VLA1601. Our research and development expenses related to our Zika vaccine candidate program increased in the year ended December 31, 2023 by €10.7 million, or 498.6%, to €12.8 million from €2.1 million in the year ended December 31, 2022. The increase was caused by our re-initiation of clinical development of the program in 2023.

VLA2001. Our research and development expenses related to our COVID-19 vaccine program decreased by €67.0 million, or 92.0%, to €5.8 million in the year ended December 31, 2023 from €72.8 million in the year ended December 31, 2022. This decrease was primarily driven by reduced clinical study costs due to the progress of the program as well as wind-down activities.

VLA15. Our research and development expenses related to our Lyme disease vaccine candidate program decreased by €0.7 million, or 72.8%, to €0.3 million in the year ended December 31, 2023 from €1.0 million in the year ended December 31, 2022. This decrease was primarily driven by the completion of our Phase 2 clinical studies. In 2023, Lyme disease clinical studies for Phase 2 and Phase 3 of €8.2 million were included in COGS, as these studies were related to the Pfizer partnership.

Our research and development expenses for our commercial products and the rest of our development pipeline increased by €5.6 million, or 162.5%, to €9.0 million in the year ended December 31, 2023 from €3.4 million in the year ended December 31, 2022. This increase was primarily related to increased expenses related to our pre-clinical stage programs as well as IFRS 2.

Marketing and Distribution Expenses

Marketing and distribution expenses for the year ended December 31, 2023 amounted to €48.8 million compared to €23.5 million in 2022, which mainly related to €20.7 million of expenses for the launch preparations for the chikungunya vaccine candidate, VLA1553, compared to €7.3 million in the year ended December 31, 2022. The employee-related expenses were positively affected in 2022 by the release of the employer contribution provision and therefore an income to the social security contributions. Marketing and distribution expenses comprised 19% of our total operating expenses for the year ended December 31, 2023, compared to 5% of our total operating expenses for the year ended December 31, 2022.

For the year ended December 31, 2023, marketing and distribution expenses consisted primarily of €13.1 million of employee-related expenses, including salaries, social security contributions, share-based compensation income/expense, and other employee-related expenses, €13.4 million of advertising expenses, including media and public relations expenses, €3.9 million of warehousing and distribution costs, and €11.2 million of expenses related to third-party services.

For the year ended December 31, 2022, marketing and distribution expenses consisted primarily of €3.4 million of employee-related expenses, including salaries, social security contributions, share-based compensation expense and other employee-related expenses, €7.3 million of advertising expenses, including media and public relations expenses, €1.9 million of warehousing and distribution costs, and €5.4 million of costs related to third-party services. The employee-related expenses were positively affected in 2022 by the release of the employer contribution provision and therefore an income to the social security contributions.

General and Administrative Expenses

General and administrative expenses increased by €13.7 million, or 40%, to €47.8 million for the year ended December 31, 2023 from €34.1 million for the year ended December 31, 2022. General and administrative expenses comprised 19% of

our total operating expenses for the year ended December 31, 2023 compared to 7% of our total operating expenses for the year ended December 31, 2022. This increase was primarily driven by a positive effect in 2022 from the release of an employer contribution provision on share-based compensation plans due to the decrease of the share price.

For the year ended December 31, 2023, general and administrative expenses consisted primarily of €21.1 million of employee-related expenses (salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees), as well as of €21.8 million in costs and fees for professional services, such as consulting, legal and financial services. For the year ended December 31, 2022, general and administrative expenses consisted primarily of €11.6 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense, and other employee-related expenses paid to employees in general and administrative functions, as well as of €18.5 million in costs and fees for professional services, such as consulting, legal, and financial services. The employee-related expenses were positively affected in 2022 by the release of the employer contribution provision and therefore an income to the social security contributions.

Expenses by Nature

The table below summarizes our cost of goods and services, research and development expenses, marketing and distribution expenses, and general and administrative expenses by nature of cost:

in € thousand	Year ended December 31,	
	2023	2022
Consulting and other purchased services	80,988	141,631
Cost of services and change in inventory	11,417	190,086
Employee benefit expense other than share-based compensation	72,997	56,393
Share-based compensation expense	6,276	(5,215)
Raw materials and consumables used	14,113	12,723
Depreciation and amortization and impairment	16,853	44,285
Building and energy costs	13,088	14,696
Supply, office and IT costs	11,663	11,739
License fees and royalties	5,492	6,830
Advertising costs	13,361	7,343
Warehousing and distribution costs	3,939	1,898
Travel and transportation costs	2,700	2,208
Other expenses	4,432	2,329
OPERATING EXPENSES	257,320	486,945

Note: As of December 31, 2022, the position “employee benefit expense other than share-based compensations” includes an amount of €23.2 million resulting from the release of the provision of employer contribution charges, which are payable at the exercise of the share-based payment programs.

The decrease in operating expenses of €229.6 million from €486.9 million in the year ended December 31, 2022 to €257.3 million in the year ended December 31, 2023 primarily resulted from one-off expenses recorded in the prior year related to the suspended COVID-19 program. These expenses included the write-down of COVID-19 vaccine inventory of €159.4 million (presented under “cost of services and change in inventory”) as well as impairment charges of fixed assets, leading to a total expense of €44.3 million for depreciation, amortization, and impairment charges.

Expenses for “consulting and other purchased services” reduced substantially in the year ended December 31, 2023, as the comparison period of 2022 included considerable expenses for COVID-19 related to research and development and external manufacturing costs.

Expenses for “cost of services and change in inventory” strongly decreased in 2023, as in the year ended December 31, 2022 effects from the significant changes to the ordered volumes and the expected future demand for VLA2001, in particular a write-down of inventory of €159.4 million, were recorded.

The expense position “depreciation and amortization and impairment” contains a reversal of a fixed asset impairment in the amount of €1.9 million related to production equipment in the year ended December 31, 2023, whereas 2022 included one-off charges of €14.8 million for the impairment of COVID-19 related fixed assets including idle manufacturing equipment, leasehold improvements and Right of Use assets.

“Employee benefit expenses other than share-based compensation” increased in the year ended December 31, 2023 compared to December 31, 2022 because of a €23.2 million release of the employer contribution provision and therefore an income to the social security contributions in 2022. In the same year “Share-based compensation expense” showed an income due to share-based payment program valuations resulting from the reduction in the share price.

Other Income (Expenses)

The table below summarizes the other operating income (expenses), net for the years ended December 31, 2023 and 2022:

in € thousand	Year ended December 31,	
	2023	2022
Research and development tax credit	6,797	15,348
Grant income	11,350	191
Profit/(loss) on disposal of fixed assets and intangible assets, net	(21)	(38)
Profit/(loss) from revaluation of lease agreements	45	(32)
Taxes, duties, fees, charges, other than income tax	(475)	(217)
Miscellaneous income/(expenses), net	3,824	(3,054)
OTHER INCOME AND EXPENSES, NET	21,520	12,199

Other operating income and expenses, net increased by €9.3 million, or 76%, to €21.5 million for the year ended December 31, 2023 from €12.2 million for the year ended December 31, 2022.

In the year ended December 31, 2023, grant income increased due to the recognition of grant income received from Scottish Enterprise in the amount of €11.1 million. The research and development tax credit decrease was linked to the decrease of our research and development expenses. As in 2022, €13.9 million related to the research and development programs executed in Austria, mainly for the COVID-19 and chikungunya vaccine (candidates), were recognized.

In the "Miscellaneous income/(expenses), net", in the year ended December 31, 2023, a gain from a final settlement with a supplier in connection with COVID-19 activities was recognised in the amount of €4.7 million, partly offset by a loss of €1.4 million from the divestment of the CTM Unit in Solna. A €0.3 million gain from the sale of our equity investment BliNK Biomedical SAS was recorded. In the year ended December 31, 2022, this position was negatively impacted by an increase in a litigation provision in the amount of €3.1 million.

Financial Income (Expense)

The table below summarizes our financial income (expense) for the years ended December 31, 2023 and 2022:

in € thousand	Year ended December 31,	
	2023	2022
Interest income from other parties	1,210	260
Fair value gains on derivative financial instruments	—	—
TOTAL FINANCE INCOME	1,210	260
Interest expense on loans	(13,681)	(8,238)
Interest expense on refund liabilities	(8,419)	(9,597)
Interest expenses on lease liabilities	(1,183)	(955)
Other interest expense	(42)	(264)
Fair value losses on derivative financial instruments	—	—
TOTAL FINANCE EXPENSES	(23,325)	(19,054)
FOREIGN EXCHANGE GAIN/(LOSSES), NET	5,574	(12,587)
FINANCE INCOME/(EXPENSES), NET	(16,541)	(31,381)

Finance expenses, net were €16.5 million for the year ended December 31, 2023 compared to net expenses of €31.4 million for the year ended December 31, 2022. This decrease in finance income/expenses, net was mainly due to foreign exchange gains in the year ended December 31, 2023, primarily related to the depreciation of the USD and GBP exchange rates against the Euro affecting our corresponding balance sheet accounts (liabilities and borrowings denominated in USD), whereas in the year ended December 31, 2022, the appreciation of the USD and the GBP against the Euro resulted in losses incurred during that period.

Income Tax

We recorded €2.8 million of income tax expenses for the year ended December 31, 2023 compared to €1.5 million of income tax gains for the year ended December 31, 2022. This change in income tax was primarily driven by deferred tax income in 2022 due to high impairment charges.

Profit/(Loss) for the Period

Our loss for the period ended December 31, 2023 was €101.4 million, decreased from a loss of €143.3 million for the period ended December 31, 2022. The higher loss in 2022 was primarily driven by one-off expenses of goods and services related to valuation of inventory and onerous agreement provisions for material in connection with our COVID-19 vaccine and its program suspension.

Adjusted EBITDA

Our Adjusted EBITDA loss was €65.2 million for the year ended December 31, 2023 compared to a loss of €69.2 million for the year ended December 31, 2022. The Adjusted EBITDA loss decreased by €3.9 million, which was primarily driven by a lower net loss largely offset by high impairment losses in 2022. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure, is set forth below:

in € thousand	Year ended December 31,	
	2023	2022
PROFIT/(LOSS) FOR THE PERIOD	(101,429)	(143,279)
Add:		
Income tax expense	2,800	(1,536)
Total finance income	(1,210)	(260)
Total finance expense	23,325	19,054
Foreign currency gain/(loss) - net	(5,574)	12,587
Result from investments in associates	—	(9)
Amortization	5,831	7,024
Depreciation	11,753	14,012
Impairment	(731)	23,249
ADJUSTED EBITDA	(65,234)	(69,159)

Comparisons for the Years Ended December 31, 2022 and 2021**Revenue****Consolidated Revenue**

Revenue increased by €13.2 million, or 3.8%, to €361.3 million for the year ended December 31, 2022 compared to €348.1 million for the year ended December 31, 2021. For VLA2001 in the year ended December 31, 2022, the increase was mainly driven by revenues from previous COVID-19 vaccine supply agreements with the UK Authority in the amount of €169.2 million (previously recognized as refund liabilities) and the EC in the amount of €116.8 million. The product sales from commercialized products increased mainly due to the continued recovery of travel vaccine sales in the year ended December 31, 2022. The other revenues from contracts with customers in the year ended December 31, 2022, included a reversal of revenue of €45.9 million from amendments of the Collaboration and License Agreement with Pfizer. In 2021 and 2022, several amendments to the transaction price took place via amendments to the Collaboration and License Agreement. As at December 31, 2022, it is no longer highly likely that the revenue will not reverse, therefore the previously realized revenue was reversed to zero. In the year ended December 31, 2021, the VLA15 Lyme disease vaccine candidate (non-product sales) revenues amounted to €14.3 million.

in € thousand	Year ended December 31,	
	2022	2021
Product sales	114,797	62,984
Other revenues from contracts with customers	245,709	284,202
Other non-IFRS 15 revenue	797	899
REVENUES	361,303	348,086

Product sales

(In € thousand)	Year ended December 31,	
	2022	2021
IXIARO	41,349	45,118
DUKORAL	17,334	2,440
COVID	29,568	—
Third-party products	26,545	15,426
TOTAL PRODUCT SALES	114,797	62,984

Product sales increased by €51.8 million, or 82.3%, to €114.8 million in the year ended December 31, 2022 compared to €63.0 million for the year ended December 31, 2021.

In the year ended December 31, 2022, IXIARO product sales were €41.3 million, a decrease of €3.8 million, or 8.4%, compared to €45.1 million in the year ended December 31, 2021. In the year ended December 31, 2022, IXIARO product sales were largely driven by demand in the United States, mainly for use by military personnel through our supply agreement with the DLA. This decrease was partly offset by the significant recovery of the private travel markets.

In the year ended December 31, 2022, DUKORAL product sales were €17.3 million, an increase of €14.9 million, or 610%, compared to €2.4 million in the year ended December 31, 2021, driven by demand in European countries, and, to a lesser extent, product sales in Canada, also benefiting from the significant recovery in the private travel markets.

In the year ended December 31, 2022, third-party product sales increased by €11.1 million, or 72.1%, to €26.5 million, compared to €15.4 million in the year ended December 31, 2021. This increase was primarily due to the marketing and distribution partnership with Bavarian Nordic.

Product Sales—By Geography

We also monitor product sales generated in the countries and regions where we operate. The following table presents product sales by geography and is based on the final location where our distribution partner sells the product or where the customer or partner is located.

(In € thousand)	Year ended December 31,	
	2022	2021
United States (military)	12,544	38,048
United States (non-military)	9,448	2,291
Canada	18,904	4,226
Austria	13,749	9,341
United Kingdom	10,901	2,707
Nordics	8,560	2,436
Germany	20,341	726
France	2,625	1,000
Other Europe	6,245	2,075
Rest of World	11,480	134
TOTAL PRODUCT SALES	114,797	62,984

Total product sales in the United States decreased by €18.3 million, or 45%, to €22.0 million in the year ended December 31, 2022, compared to €40.3 million in the year ended December 31, 2021. Sales in the United States decreased primarily as a result of lower sales to the DLA. Product sales in Canada increased by €14.7 million, or 77.6%, from €4.2 million in the year ended December 31, 2021, to €18.9 million in the year ended December 31, 2022. Sales in Canada increased primarily as a result of the significant recovery in the private travel markets.

Other revenues from contacts with customers

The following table presents our other revenues (from collaboration, licensing, and services), for the years ended December 31, 2022 and 2021.

in € thousand	Year ended December 31,	
	2022	2021
IXCHIQ	5,565	3,257
COVID VLA2001	280,010	253,314
Lyme VLA15	(45,869)	14,265
Services related to clinical trial material	3,205	10,001
Others	2,798	3,364
OTHER REVENUES FROM CONTRACTS WITH CUSTOMERS	245,709	284,202

In the year ended December 31, 2022, total other revenues were €245.7 million, compared to €284.2 million in the year ended December 31, 2021. The amount in the year ended December 31, 2022 included recognition of COVID-related revenues related to previous COVID-19 vaccine supply agreements with the UK Authority and the EC.

Lyme VLA15 revenues decreased from €14.3 million in the year ended December 31, 2021 to €45.9 million of negative revenue in the year ended December 31, 2022, primarily resulting from a reversal of revenue from amendments of the Collaboration and License Agreement with Pfizer. In the year ended December 31, 2021, this collaboration contributed €14.3 million of revenues.

Operating Income and Expenses

Cost of Goods and Services

Cost of goods and services, or COGS, increased by €136.5 million, or 72.6%, to €324.4 million with a gross margin on product sales of 45.5% within the commercialized products for the year ended December 31, 2022, as compared to COGS of €187.9 million and gross margin on product sales of 36.5% within the commercialized products for the year ended December 31, 2021. The increase in the gross margin was primarily due to reduced impairment and scrap of short-dated or expired product.

COGS was €324.4 million, or 68.3% of our total operating expenses, for the year ended December 31, 2022. Of this total COGS, €267.1 million related to VLA2001, whereas €15.6 million related to IXIARO sales, yielding a product gross margin of 62.2%, and €14.2 million related to DUKORAL sales, yielding a product gross margin of 18.2%. In the year ended December 31, 2022, COGS related to the third-party product distribution business was €16.7 million, yielding a product gross margin of 37.3%, and cost of services was €9.7 million.

COGS was €187.9 million, or 45.9% of our total operating income (expenses), for the year ended December 31, 2021. Of this total COGS, €22.6 million related to IXIARO sales, yielding a product gross margin of 50.0%, and €7.6 million related to DUKORAL sales, yielding a product gross margin of negative 209.8%. Gross margin for DUKORAL sales was negatively impacted by idle capacity costs and impairment of short-dated or expired products, resulting from the decreased demand due to the COVID-19 pandemic. In 2021, COGS related to the third-party product distribution business was €9.9 million, yielding a product gross margin of 36.1%, and cost of services was €25.1 million. The increase in cost of services from €12.2 million to €25.1 million was mainly due to the fact that the Lyme disease vaccine candidate had been out-licensed to Pfizer by the end of 2020.

Research and Development Expenses

Research and development expenses decreased by €68.4 million, or 39.5%, to €104.9 million for the year ended December 31, 2022 from €173.3 million in the year ended December 31, 2021. Research and development expenses were 22.1% of our total operating expenses for the year ended December 31, 2022, as compared to 42.3% of our total operating expenses for the year ended December 31, 2021. This decrease was driven primarily by a reduction of expenses relating to the COVID-19 and chikungunya vaccine candidates, as the main costs of the Phase 3 studies were recorded in 2021. For our Lyme disease vaccine candidate, research and development expenses decreased, primarily driven by the completion of the VLA15-201 and VLA15-202 clinical studies. €7.2 million and €3.4 million related to the Pfizer partnership were recognized as cost of service in 2022 and 2021, respectively.

For the year ended December 31, 2022, research and development expenses consisted primarily of i) €12.5 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €59.1 million external research and development services, including costs for clinical studies and external manufacturing and iii) €7.8 million of material consumption.

For the year ended December 31, 2021, research and development expenses consisted primarily of i) €30.6 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €117.6 million of external research and development services, including costs for clinical studies and external manufacturing and iii) €5.0 million of material consumption.

We track our research and development expenses by product or development program. The following table sets forth our research and development expenses by product or development program for the periods indicated:

(In € thousand)	Year ended December 31,	
	2022	2021
COVID-19 Vaccine (VLA2001)	(72,762)	(113,907)
Chikungunya vaccine candidate (VLA1553)	(25,558)	(43,975)
Zika vaccine candidate (VLA1601)	(2,143)	(120)
Lyme borreliosis vaccine candidate (VLA15)	(1,016)	(3,761)
hMPV (VLA1554)	(1,562)	(2,111)
IXIARO	(504)	(1,125)
DUKORAL	(563)	(969)
Other research projects (*)	(815)	(7,314)
TOTAL RESEARCH AND DEVELOPMENT EXPENSES	(104,922)	(173,283)

* In 2022 and 2021, other research projects included €1.3 million of income and €3.7 million of expenses respectively, related to IFRS 2 (share-based and cash-based compensation) programs, which have not been allocated to the projects.

VLA2001. Our research and development expenses related to our COVID-19 vaccine candidate program decreased by €41.1 million, or 36.1%, to €72.8 million in the year ended December 31, 2022 from €113.9 million in the year ended December 31, 2021. This decrease was primarily driven by reduced clinical study costs due to the progress of the program as well as wind-down activities.

VLA1553. Our research and development expenses related to our chikungunya vaccine candidate program decreased by €18.4 million, or 41.9%, to €25.6 million in the year ended December 31, 2022 from €44.0 million in the year ended December 31, 2021. This decrease was primarily driven by the progress of the chikungunya vaccine candidate.

VLA1601. Our research and development expenses related to our Zika vaccine candidate program increased by €2.0 million to €2.1 million in the year ended December 31, 2022 from €0.1 million in the year ended December 31, 2021. This increase was primarily driven by process development activities after this program had previously been on hold, including assay development, preclinical experiments, clinical study planning, and process-scale-up activities.

VLA15. Our research and development expenses related to our Lyme disease vaccine candidate program decreased by €2.7 million, or 73.0%, to €1.0 million in the year ended December 31, 2022 from €3.8 million in the year ended December 31, 2021. This decrease was primarily driven by the completion of our VLA15-201 and VLA15-202 clinical studies. In 2022 and 2021, Lyme disease clinical studies of €7.2 million and €3.4 million were included in COGS, as these studies were related to the Pfizer partnership.

Our research and development expenses related to our commercial products and the rest of our development pipeline decreased by €8.1 million, or 70.1%, to €3.4 million in the year ended December 31, 2022 from €11.5 million in the year ended December 31, 2021. This decrease was primarily related to decreased expenses related to our pre-clinical stage programs.

Marketing and Distribution Expenses

Marketing and distribution expenses were almost stable and decreased by €0.1 million, or 0.6%, to €23.5 million in the year ended December 31, 2022 from €23.6 million in the year ended December 31, 2021. Marketing and distribution expenses comprised 5.0% of our total operating expenses for the year ended December 31, 2022, compared to 5.8% of our total operating expenses for the year ended December 31, 2021.

For the year ended December 31, 2022 marketing and distribution expenses consisted primarily of €3.5 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation income/expense, and other employee-related expenses, €7.3 million of advertising expenses, including media and public relations expenses, €1.9 million of warehousing and distribution costs, and €5.4 million of costs related to third-party services.

For the year ended December 31, 2021 marketing and distribution expenses consisted primarily of €13.9 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense, and other employee-related expenses, €2.2 million of advertising expenses, including media and public relations expenses, €1.4 million of warehousing and distribution costs, and €3.0 million of costs related to third-party services.

General and Administrative Expenses

General and administrative expenses decreased by €13.5 million, or 28.4%, to €34.1 million for the year ended December 31, 2022 from €47.6 million for the year ended December 31, 2021. General and administrative expenses comprised 7.2% of our total operating expenses for the year ended December 31, 2022 compared to 11.6% of our total operating expenses for the year ended December 31, 2021. This decrease was primarily driven by a positive effect from the release of an employer contribution provision on share-based compensation plans due to the decrease of the share price.

For the year ended December 31, 2022, general and administrative expenses consisted primarily of €11.6 million of employee-related expenses (salaries, social security contributions, share-based compensation expense, and other employee-related expenses paid to employees), as well as of €18.5 million in costs and fees for professional services, such as consulting, legal, and financial services. For the year ended December 31, 2021, general and administrative expenses consisted primarily of €24.3 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense, and other employee-related expenses paid to employees in general and administrative functions, as well as of €20.6 million in costs and fees for professional services, such as consulting, legal, and financial services.

Expenses by Nature

The table below summarizes our cost of goods and services, research and development expenses, marketing and distribution expenses, and general and administrative expenses by nature of cost:

in € thousand	Year ended December 31,	
	2022	2021
Consulting and other purchased services	141,631	169,158
Cost of services and change in inventory	190,086	105,648
Employee benefit expense other than share-based compensation	56,393	85,334
Share-based compensation expense	(5,215)	14,678
Raw materials and consumables used	12,723	14,676
Depreciation and amortization and impairment	44,285	14,281
Building and energy costs	14,696	10,960
Supply, office and IT costs	11,739	7,409
License fees and royalties	6,830	4,865
Advertising costs	7,343	2,176
Warehousing and distribution costs	1,898	1,419
Travel and transportation costs	2,208	538
Other expenses	2,329	1,309
OPERATING EXPENSES	486,945	432,452

* As of December 31, 2022, the position "employee benefit expense other than share-based compensations" includes an amount of €23.2 million resulting from the release of the provision of employer contribution charges fees, which are payable at the exercise of the share-based payment programs (December 31, 2021: expense of €26.5 million).

The increase in operating expenses of €54.5 million in the year ended December 31, 2022 compared to the prior year primarily resulted from the write-down of COVID-19 vaccine inventory of €159.4 million as well as increased depreciation charges of fixed assets including impairment charges of idle manufacturing equipment, leasehold improvements, and Right of Use assets, leading to a total expense of €44.3 million for depreciation, amortization, and impairment charges. This was partially offset by a reduction of employee-related expenses including non-cash income from the revaluation of share-based compensation programs resulting from a year-over-year reduction of Valneva's share price.

Other Income (Expenses)

The table below summarizes the other operating income (expenses) for the years ended December 31, 2022 and 2021:

(In € thousand)	Year ended December 31,	
	2022	2021
Research and development tax credit	15,348	21,949
Grant income	191	1,684
Profit/(loss) on disposal of fixed assets and intangible assets, net and from revaluation of lease agreements	(70)	(42)
Taxes, duties, fees, charges, other than income tax	(217)	(212)
Miscellaneous income/(expenses), net	(3,054)	(403)
TOTAL OTHER OPERATING INCOME (EXPENSES), NET	12,199	22,976

Other operating income and expenses decreased by €10.8 million, or 46.9%, to €12.2 million for the year ended December 31, 2022 from €23.0 million for the year ended December 31, 2021. This decrease was mainly driven by decreased

research and development tax credits directly resulting from decreased qualifying research and development expenses. For the years ended December 31, 2022 and 2021, of the research and development tax credit, €13.9 million and €20.2 million, respectively, related to the research and development programs executed in Austria, mainly for the COVID-19 and chikungunya vaccine candidates, whereas the remainder of €1.5 million and €1.8 million, respectively, related to the R&D tax credit in France. For the year ended December 31, 2021, a negative grant income of €0.9 million was recognized due to the increase of the probability of achieving one milestone under the CEPI funding agreement. This negative grant income was offset by €2.6 million of grants from government authorities related to the COVID-19 pandemic to cover fixed costs of commercial activities. For the years ended December 31, 2022 and 2021, CEPI and COVID-19-pandemic related grants totaled €0.2 million and €1.7 million, respectively.

Financial Income (Expense)

The table below summarizes our financial income (expense) for the years ended December 31, 2022 and 2021:

(In € thousand)	Year ended December 31,	
	2022	2021
FINANCE INCOME		
Interest income from other parties	260	249
TOTAL FINANCE INCOME	260	249
FINANCE EXPENSE		
Interest expenses on loans	(8,238)	(7,273)
Interest expense on refund liabilities	(9,597)	(8,478)
Interest expenses on lease liabilities	(955)	(903)
Other interest expense	(264)	(309)
TOTAL FINANCE EXPENSES	(19,054)	(16,962)
FOREIGN EXCHANGE GAIN/(LOSSES), NET	(12,587)	8,130
FINANCE INCOME/(EXPENSES), NET	(31,381)	(8,584)

Finance expenses, net were €31.4 million for the year ended December 31, 2022 compared to €8.6 million for the year ended December 31, 2021. This increase in finance expenses, net was mainly due to negative foreign expense losses. The foreign exchange losses in the year ended December 31, 2022 are related to the development of the USD and GBP exchange rates and our corresponding balance sheet accounts (mainly due to an increase of refund liabilities and borrowings denominated in USD).

Income Tax

We recorded €1.5 million of income tax benefit for the year ended December 31, 2022 compared to €3.4 million of income tax expense for the year ended December 31, 2021. This change in income tax benefit (expense) was primarily driven by a change in deferred income tax.

Profit/(Loss) for the Period

Our loss for the period ended December 31, 2022 was €143.3 million, increased from a loss of €73.4 million for the period ended December 31, 2021. The increased loss in the 2022 period was primarily driven by increased cost of goods and services related to valuation of inventory, and onerous agreement provisions for material in connection with our COVID-19 vaccine, partly offset by decreased research and development expenses and decreased general and administrative expenses.

Adjusted EBITDA

Our Adjusted EBITDA loss was €69.2 million for the year ended December 31, 2022 compared to a loss of €47.1 million for the year ended December 31, 2021. The increased Adjusted EBITDA loss was primarily driven by a higher net loss. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure, is set forth below:

(In € thousand)	Year ended December 31,	
	2022	2021
Loss for the period	(143,279)	(73,425)
Add:		
Income tax expense	(1,536)	3,446
Total finance income	(260)	(249)
Total finance expense	19,054	16,964
Foreign currency gain/(loss) - net	12,587	(8,130)
Result from investments in associates	(9)	5
Amortization	7,024	6,600
Depreciation	14,012	7,681
Impairment	23,249	—
ADJUSTED EBITDA	(69,159)	(47,108)

B. Liquidity and Capital Resources.

Overview

We have financed our operations primarily through a combination of equity offerings, secured debt, and revenues from product sales. As at December 31, 2023, we had €126.1 million in cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2023 will fund our current operating plans for at least the next 12 months following the publication of the full-year 2023 financial statements. In addition, we received gross proceeds of \$103 million for the sale of our PRV in February 2024.

Sources and Uses of Cash

We have financed our operations through revenue from product sales, payments under historical collaborative research alliances, as well as research tax credits and subsidies granted by various public institutions. In addition, we have borrowed secured debt to finance our operations.

In May 2021, we announced the closing of a global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares, after full exercise of the overallotment option granted to the underwriters. The public offering consisted of 2,850,088 American Depositary Shares, or ADSs, each representing two ordinary shares, in the United States at an offering price of \$26.41 per ADS and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option were €89.6 million, whereas related expenses of €6.8 million incurred.

In November 2021, we announced the closing of a global offering to specified categories of investors of an aggregate of 5,175,000 new ordinary shares, after full exercise of the overallotment option granted to the underwriters. The public offering consisted of an offering of 354,060 ADSs, each representing two ordinary shares, in the United States at an offering price of \$39.42 per ADS and a concurrent private placement of 4,466,880 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €17.00 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option were approximately €88.0 million, whereas related expenses of €6.7 million incurred.

In June 2022, we signed an Equity Subscription Agreement with Pfizer. Pursuant to the Equity Subscription Agreement, Pfizer invested €90.5 million (\$95 million) in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share. The per share purchase price was determined based on the average closing price of the Company's shares on Euronext Paris during the 10 trading days preceding the date of the Equity Subscription Agreement.

On August 12, 2022, we entered into an Open Market Sale Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, pursuant to which we may issue and sell ADSs, each representing two ordinary shares, having an aggregate offering price of up to \$75,000,000 (subject to French regulatory limits), from time to time, in one or more at-the-market offerings, for which Jefferies will act as sales agent and/or principal. The at-the-market facility has been registered under the Securities Act pursuant to our Registration Statement on Form F-3 (File No. 333-266839). As of December 31, 2023, no issuances or sales had been made pursuant to the Sales Agreement.

In October 2022, we announced the closing of our global offering to specified categories of investors of an aggregate 21,000,000 new ordinary shares, consisting of a public offering of 375,000 ADSs, each representing two ordinary shares, in

the United States at an offering price of \$9.51 per ADS, and a concurrent private placement of 20,250,000 ordinary shares in Europe (including France) and other countries outside of the United States at the corresponding offering price of €4.90 per ordinary share. Gross proceeds of this global offering were €102.9 million, whereas related expenses of €7.4 million incurred.

As of December 31, 2023, we had borrowings and lease liabilities of €208.8 million, of which €176.8 million were other loans and €32.0 million were lease liabilities.

In February 2020, we entered into a debt financing agreement, or the Financing Agreement, with Deerfield and OrbiMed. The intended use of proceeds was to repay existing borrowings from the European Investment Bank and allow us to continue to advance our Lyme and chikungunya development programs in the short term. We have amended the Financing Agreement several times, most recently in March 2024. For further information about these amendments, refer to “Item 3.D—Risk Factors” and the Notes to our consolidated financial statements. As of December 31, 2023, \$200.0 million (€180.0 million) was outstanding under the Financing Agreement of which a total of \$100.0 million was drawn in two installments, in August and December 2023. The loan bears interest at 9.95%. Due to the quarterly interest calculation method, the aggregate annual interest actually paid is an amount equivalent to 10.09%. The interest-only period for the initial tranches amounting to \$100.0 million extends until the first quarter of 2026, and this portion of the loan will mature in the first quarter of 2027. The interest-only period for the tranches drawn in 2023 amounting to \$100.0 million extends until the first quarter of 2027, and this portion of the loan will mature in the fourth quarter of 2028. The loan is secured by substantially all of our assets, including our intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. The Financing Agreement contains covenants, including a minimum liquidity in the amount of €35.0 million and minimum consolidated net revenue in the amount of €115.0 million on a consecutive twelve month basis. If our consolidated liquidity or net revenues were to fall below the covenant minimum values, we would be in default, which may trigger various consequences. For example, the interest rate on the loans could increase by up to 10 additional interest points if the duration of the default is longer than 15 days, or we could be required to immediately repay the full principal amount of the loans, including all fees and interest associated with repayment. We do not expect the limitations of these covenants to affect our ability to meet our cash obligations.

In February 2022, we announced that Valneva Scotland had received two grants worth up to £20 million (approximately €23.9 million) from Scottish Enterprise to support research and development relating to the manufacturing processes of our COVID-19 vaccine and our other vaccine candidates. Following the termination of our COVID-19 vaccine program, in May 2023 we amended the grant relating to this program to reduce the available funding by £0.7 million and to adjust how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. Valneva SE has provided a parent guarantee in connection with these grants, and if we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date. As of the date of this Annual Report, we have received €11.1 million (€9.6 million) of grant funds from Scottish Enterprise.

In November 2023, we obtained licensure of VLA1553, our chikungunya vaccine candidate, in the United States and consequently were awarded a Priority Review Voucher (PRV) from the US Food and Drug Administration (FDA). The PRV was sold in February 2024 and generated proceeds of \$103 million.

As we continue to develop and commercialize our products and product candidates in the coming years, we will likely continue relying on some or all of these sources of financing, as well as potential milestone payments and royalties that may result from licensing agreements for our products and product candidates.

Cash Flows

Comparisons for the Years Ended December 31, 2023 and 2022

The table below summarizes our cash flows for the years ended December 31, 2023 and 2022:

(In € thousand)	Year ended December 31,	
	2023	2022
Net cash generated from/(used in) operating activities	(202,744)	(245,343)
Net cash generated from/(used in) investing activities	(20,585)	(29,054)
Net cash generated from/(used in) financing activities	63,081	215,116
NET CHANGE IN CASH AND CASH EQUIVALENTS	(160,248)	(59,282)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was €202.7 million compared to €245.3 million of net cash used in the year ended December 31, 2022. Net cash used in operating activities for the year ended December 31, 2023 was primarily derived from the loss for the period amounting to €101.4 million and from decreases in working capital in the amount of €145.6 million, which largely were related to payments to Pfizer in conjunction with Valneva’s contribution to the Phase 3 costs of the Lyme VLA15 R&D program, reducing the refund liability. These amounts have been partly offset by adjustments for non-cash transactions of €45.0 million mostly for depreciation and amortization of tangible and intangible assets of €17.6 million and interest expenses of €23.3 million.

Net cash used in operating activities for the year ended December 31, 2022 was primarily derived from the loss for the period amounting to €143.3 million and from changes in non-current assets and liabilities in the amount of minus €147.7

million (which mainly related to refund liabilities recorded in line with the Pfizer agreement amendments as they are no longer non-current). These amounts have been partly offset by depreciation and amortization of €21.0 million as well as impairment of tangible and intangible assets of €23.2 million, interest expenses of €19.1 million, share-based compensation of minus €8.7 million, and by other non-cash expenses amounting to minus €9.2 million. Changes in working capital amounted to €1.7 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was €20.6 million, compared to €29.1 million for the year ended December 31, 2022 and was comprised primarily of €14.2 million purchases for property, plant and equipment as well as of the acquisition of the VBC3 building in Vienna.

Financing Activities

Net cash generated from financing activities was €63.1 million for the year ended December 31, 2023 compared to €215.1 million for the year ended December 31, 2022. Net cash generated from financing activities during the year ended December 31, 2023 was primarily due to €81.1 million of net proceeds from borrowings, namely the additional tranches from the financing agreement with Deerfield and OrbiMed drawn in the second half of the year. Interest payments amounting to €12.6 million reduced the net cash generated from financing activities.

Net cash generated from financing activities for the year ended December 31, 2022 consisted primarily of €189.8 million net proceeds from the Equity Subscription Agreement signed with Pfizer in June 2022 and closing of a global offering in October 2022 as well as €39.3 million of proceeds mainly from disbursements from the Deerfield and OrbiMed Financing Agreement during 2022, partially offset by €9.2 million of interest payments and lease payments amounting to €3.0 million.

Comparisons for the Years Ended December 31, 2022 and 2021

The table below summarizes our cash flows for the years ended December 31, 2022 and 2021:

(In € thousand)	Year ended December 31,	
	2022	2021
Net cash generated from/(used in) operating activities	(245,343)	76,901
Net cash generated from/(used in) investing activities	(29,054)	(93,117)
Net cash generated from/(used in) financing activities	215,116	154,504
NET CHANGE IN CASH AND CASH EQUIVALENTS	(59,282)	138,288

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was €245.3 million compared to €76.9 million of net cash generated for the year ended December 31, 2021.

Net cash used in operating activities for the year ended December 31, 2022 was primarily derived from the loss for the period amounting to €143.3 million and from changes in non-current assets and liabilities in the amount of minus €147.7 million (which mainly related to refund liabilities recorded in line with the Pfizer agreement amendments as they are no longer non-current). These amounts have been partly offset by depreciation and amortization of €21.0 million as well as impairment of tangible and intangible assets of €23.2 million, interest expenses of €19.1 million, share-based compensation of minus €8.7 million and by other non-cash expenses amounting to minus €9.2 million. Changes in working capital amounted to €1.7 million.

Net cash generated from operating activities for the year ended December 31, 2021 was primarily derived from payments of €299.2 million received from the UK Government in connection with the UK Supply Agreement and advance payments of €100.8 million received from the European Commission member states in connection with the EC APA signed in November 2021. These payments were partially offset by expenditures related to the development and production mainly of our COVID-19 vaccine and other cash expenses.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was €29.1 million, compared to €93.1 million for the year ended December 31, 2021 and was comprised primarily of €29.2 million purchases for property, plant and equipment.

Financing Activities

Net cash generated from financing activities was €215.1 million for the year ended December 31, 2022 compared to €154.5 million for the year ended December 31, 2021. The increase was primarily due to €96.7 million of net proceeds from the issuance of ordinary shares mainly resulting from the global offering in October 2022, the Equity Subscription Agreement signed with Pfizer in June 2022 amounting to €90.6 million, as well as the additional tranches drawn from the financing agreement with Deerfield and OrbiMed in the amount of €39.3 million. Interest payments amounting to €9.2 million reduced the net cash generated from financing activities.

Net cash generated from financing activities for the year ended December 31, 2021 consisted primarily of €166.6 million net proceeds from the issuance of ordinary shares mainly resulting from the U.S. public offerings and the European private placements in May 2021 and November 2021, partially offset by interest payments amounting to €8.4 million and lease payments amounting to €2.8 million.

Operating and Capital Expenditure Requirements

We have previously incurred significant operating losses, including in the years discussed in this annual report. As of December 31, 2023 and 2022, we had accumulated a net loss of €551.7 million and €450.3 million, respectively. Our net loss was €101.4 million, €143.3 million, and €73.4 million for the years ended December 31, 2023, 2022, and 2021, respectively. We expect to continue to incur significant expenses, and we may incur substantial operating losses over the next several years as we market our approved products, advance clinical development of our product candidates and continue our research and development efforts in the United States, Europe, and endemic markets. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We anticipate that our expenses will increase in connection with our ongoing activities, as we:

- invest in our vaccine candidate programs, including VLA1601, and our other pre-clinical and research programs;
- invest into fulfilling Phase 4 post-marketing obligations and progress commercial launch activities related to IXCHIQ, our chikungunya vaccine; and
- invest in our working capital and general corporate purposes.

Our present and future funding requirements will depend on many factors, including, among other things:

- costs of continued commercial activities, including product sales, marketing, manufacturing and distribution, for our approved products;
- the scope, progress, timing, and successful completion of our clinical trials of our current or future product candidates, especially the Phase 3 clinical trial for VLA15 and the Phase 4 clinical trials of IXCHIQ;
- the number of potential new product candidates we identify and decide to develop;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates; and
- the amount of revenues, if any, we may derive either directly, or in the form of royalty payments from any current or future collaboration agreements.

For more information as to the risks associated with our future funding needs, see “Item 3.D—Risk Factors”.

We expect to finance these expenses and our operating activities through a combination of revenue from sales of our products and third-party products, grants, milestone and service payments from our collaboration with Pfizer regarding our Lyme disease vaccine candidate, and our existing liquidity. If we are unable to generate sufficient revenue from product sales and through our collaboration agreements in accordance with our expected timeframes, we will need to raise additional capital through the issuance of our shares, through other equity or debt financings or through collaborations with other companies. However, we may be unable to raise additional funds or enter into other funding arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant others rights to develop or market drug candidates that we would otherwise prefer to develop and market ourselves. Our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents as of December 31, 2023 will be sufficient to fund our operations through at least 12 months after publication of this document.

Contractual Obligations

The following table discloses aggregate information about our material long-term contractual obligations as of December 31, 2023 and the periods in which payments are due. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

in € thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Over 5 years	Total
Borrowings	44,079	62,378	70,390	—	176,847
Lease liabilities	2,879	5,313	5,414	18,362	31,969
Refund liabilities	33,637	6,303	—	—	39,941
TOTAL	80,595	73,994	75,804	18,362	248,757

The amounts disclosed in the table above are the contractual undiscounted cash flows.

Borrowings

As of December 31, 2023, the carrying amount of bank borrowings and other loans was €176.8 million. Of this, €167.5 million related to the Financing Agreement with Deerfield and OrbiMed. Following amendments to the Financing Agreement, most recently in March 2024, the interest-only period on the initial \$100 million tranche extends until the first quarter of 2026, and this portion of the loan will mature in the first quarter of 2027. The interest-only period for the tranches drawn in 2023 amounting to \$100.0 million extends until the first quarter of 2027, and this portion of the loan will mature in the fourth quarter of 2028. The interest rate is 9.95% (equivalent to 10.09% on an annual basis). Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €3.6 million and the CEPI loan in the amount of €5.7 million, which relates to advanced payments received which are expected to be paid back in the future.

As of December 31, 2022, the carrying amount of bank borrowings and other loans was €98.8 million. Of this, €89.2 million related to the Financing Agreement with Deerfield and OrbiMed. Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €4.4 million and the CEPI loan in the amount of €5.2 million, which relates to advanced payments received which are expected to be paid back in the future.

Lease Liabilities

As of December 31, 2023, the outstanding, discounted amount of lease liabilities was €32.0 million. Of this, €28.3 million related to the lease agreements for two premises in Sweden, which we expect will terminate in 2031 and 2037, respectively. Base rent will increase based on an inflation index. In October 2023, the lease agreement for premises in Vienna, Austria, expired whereby the lease liability at the end of September 2023 amounted to €22.5 million. We acquired the premises via takeover of the legal entity VBC 3, which possessed the premises. For further information, see Note 5.12 of our financial statements. Regular installment payments are variable and based on EURIBOR. Other lease liabilities of €3.6 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of December 31, 2022, the outstanding, discounted amount of lease liabilities was €53.6 million. Of this, €27.2 million related to the lease agreements for two premises in Sweden. Base rent will increase based on an inflation index. €23.2 million related to the lease agreements for premises in Vienna, Austria. Other lease liabilities of €3.2 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

Refund Liabilities

As of December 31, 2023, the carrying amount of refund liabilities was €39.9 million. Of this, €33.1 million related to the collaboration with Pfizer, as we will fund 40% of Phase 3 clinical trial costs performed by Pfizer, and €6.5 million (all non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreement in 2019, and €0.3 million (all current) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products.

As of December 31, 2022, the carrying amount of refund liabilities was €143.1 million. Of this, €135.5 million related to the collaboration with Pfizer, as we will fund 40% of Phase 3 clinical trial costs performed by Pfizer, and €6.6 million (all non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreement in 2019, and €0.9 million (all current) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products. Revenue recognized and the corresponding de-recognition of refund liabilities in 2022 related primarily to the de-recognition of the previously included royalty obligation towards the UK Authority in the amount of €89.2 million and the de-recognition of the previously included CAPEX obligation towards the UK Authority in the amount of €80.0 million (£70.8 million).

C. Research and Development, Patents and Licenses

For a discussion of our research and development activities, see “Item 4.B—Business Overview” and “Item 5.A—Operating Results.”

D. Trend Information

For a discussion of trends, see “Item 4.B—Business Overview,” “Item 5.1—Operating Results” and “Item 5.B—Liquidity and Capital Resources.”

E. Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. Some of the accounting methods and policies used in preparing our consolidated financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. Critical accounting policies and practices are tailored to specific events in the current year, and the accounting policies and practices that are considered critical might change from year to year. The actual value of our assets, liabilities, and shareholders’ equity and of our accumulated deficit could differ from the value derived from these estimates if conditions change and these changes had an impact on the assumptions adopted.

Our management applied judgement and estimates on the following critical accounting topics:

Revenue Recognition of Other Revenue

Management’s judgement is required to determine the identification of performance obligations (especially when determining whether the license is distinct, which is the case when the customer can benefit from the license without further involvement), the determination of the transaction price (including the judgement of payables to customers), and allocation of the transaction price to the performance obligations on relative standalone selling price. The standalone selling price is sometimes not available or are hard to value intangible assets, so various valuation techniques are used. In addition, management’s judgement is required whether revenue from collaborations and licensing is recognized over time or at a point in time.

In April 2020, we entered into a collaboration to co-develop and commercialize our Lyme disease vaccine candidate with Pfizer. This agreement included a \$130.0 million (€116.9 million) upfront payment from Pfizer, which we received in June 2020 and booked in an amount of €116.9 million, and a \$10.0 million milestone payment from Pfizer, which we received in April 2021 and booked in an amount of €8.4 million. While we are obligated to contribute 40% (before May 2022: 30%) of all ongoing and future development costs through completion of the development program, as of December 31, 2023, 2022 and 2021, €33.1 million, €135.5 million and €79.6 million, respectively, have been recognized as discounted refund liabilities to reflect the requirement to pay 40% (before May 2022: 30%) of Pfizer’s research and development costs. As of December 31, 2022, revenue recognition for 2022 amounting to €4.6 million was deferred and recorded as refund liability and trade receivable in the financial statements. For closing as per December 31, 2023 the amount further increased to an accumulated €10.7 million.

Accounting for Grants

In February 2022 Valneva Scotland received two grants worth up to £20 million (approximately €23.9 million) from Scottish Enterprise to support research and development relating to the manufacturing processes of our COVID-19 vaccine and our other vaccine candidates. Following the termination of our COVID-19 vaccine program, in May 2023 we amended the grant relating to this program to reduce the available funding by £0.7 million and to adjust how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. Valneva SE has provided a parent guarantee in connection with these grants, and if we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date. As of the date of this report, we have received €11.1 million (£9.6 million) of grant funds from Scottish Enterprise.

Valuation of Intangibles and Tangibles / Impairment tests

As of December 31, 2023, impairment tests were performed on the IXIARO, DUKORAL and IXCHIQ cash-generating units (CGUs). The impairment tests resulted in no additional impairment charges. However, the headroom of the value in use is very low for DUKORAL and an increase in the WAC or reduction in revenue may result in further impairment charges. In 2022, impairment charges of €8.3 million for DUKORAL have been allocated. In addition, in the same year COVID related assets, which will be no longer used, caused impairment charges of €14.8 million.

Management estimates are applied on the long range business plan, on the revenue as well as on the expense side. A reduction in revenues of 10.0% would result in no additional impairment loss in the year ended December 31, 2023, for IXIARO and IXCHIQ, whereas it would result in an additional impairment loss for DUKORAL in the amount of €6.5 million.

Valuation of Inventories / Impairment tests

In 2023, inventory-related COGS were €106.2 million (2022: €257.8 million), of which €6.0 million (2022: €157.7 million) related to inventory which cannot be used, failed batches which were written down, and product which is not expected to be sold. In 2023, €5.5 million (2022: €159.4 million) of these expenses related to VLA2001, mostly related to product which is not expected to be sold due to the discontinuation of the program. The valuation of commercialized products resulted in write-downs of €1.5 million. These expenses stem from write-downs due to lower sales expectations and limited shelf life of the products. In 2022, a reversal of write-downs from prior periods of €2.8 million was recorded due to higher sales expectations.

Measurement of Contingencies and Loss Provision

As part of our activities, we may be exposed to contractual commitment risk. Management exercises its judgment to estimate the probability and amount of cash outflows, as well as the information to disclose regarding contingent liabilities. For the litigation related to the Vivalis-Intercell merger, a provision has been included for potential settlement costs, but not for the maximum amount that could be claimed by the plaintiffs. This could be material if the exchange ratio between Intercell and Valneva shares used in the merger is amended as this could be applied to all outstanding Intercell shareholders. Management considers having to pay the maximum amount that could be claimed by the plaintiffs to be remote.

Share-based Compensation and Related Expected Employer Contribution Costs

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our Executive Committee and Board of Directors members (prior to December 2023, our Management Board and Supervisory Board) and our employees, including stock options (ESOPs), Free Convertible Preferred Shares, Free Ordinary Shares, and Equity Warrants (BSAs). We also established Phantom Stock Option Programs, with terms and conditions similar to ESOPs, for employees who are U.S. citizens.

The fair value of such share-based compensation is recognized as an expense for employee services received in exchange for the grant of the options. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted, excluding the impact of any non-market vesting conditions. Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Annually, we revise our estimates of the number of options that are expected to become exercisable. We recognize the impact of the revision of original estimates, if any, in the income statement and make a corresponding adjustment to equity.

While assumptions in measuring fair values on the share-based compensations have been taken into account, management has considered the likelihood of an event of change of control remote, therefore the accelerated vesting was not taken into account. Further information is explained in Note 5.23 to our consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included elsewhere in this Annual Report.

Employer contribution costs will occur at the exercise of share-based payment programs. Therefore, these costs have been accounted for and spread over the vesting period of the various programs. This provision has been assessed at the share price as of the balance sheet date and has been updated on each balance sheet date to reflect the potential payment amount. The latest share price in 2023 was €4.46, therefore the provision taken as at December 31, 2023 amounted to €1.7 million, whereas the latest share price in 2022 was €6.22, and the respective provision amounted to €3.3 million as at December 31, 2022. The employer contribution to be paid is depending on the date and the amount of the exercise in the future.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Until December 20, 2023, we had a two-tier corporate governance system consisting of a Management Board (*Directoire*), which was responsible for managing the Company, and a Supervisory Board (*Conseil de Surveillance*), which oversaw the Management Board. On December 20, 2023, our shareholders approved the Supervisory Board’s recommendation to change to a one-tier governance system under which the Company is led by a Board of Directors. We refer to our senior management as the Executive Committee, which includes the members of our former Management Board.

The following table sets forth information concerning the members of our Executive Committee and Board of Directors as of the date of this annual report.

Name	Age	Position
Executive Committee		
Thomas Lingelbach	60	Director, President & Chief Executive Officer
Peter Bühler	54	Chief Financial Officer
Franck Grimaud	57	Chief Business Officer
Juan Carlos Jaramillo	53	Chief Medical Officer
Dipal Patel	50	Chief Commercial Officer
Frédéric Jacotot	60	General Counsel, Corporate Secretary
Vincent Dequenne	57	Chief Operating Officer
Petra Pesendorfer	38	Chief People Officer
Non-Employee Directors		
Anne-Marie Graffin	62	Chair of the Board of Directors
James Sulat	73	Vice Chair of the Board of Directors
James Connolly	59	Member of the Board of Directors
Mailys Ferrère	61	Representative of Bpifrance Participations SA, member of the Board of Directors
Kathrin Jansen	65	Member of the Board of Directors

Executive Committee

The members of our Executive Committee are appointed by the Board of Directors and are responsible for the day-to-day management of the Company. Certain members of the Executive Committee were also appointed as Associate Managing Officers (*Directeurs Généraux Délégués*), as described further in this Item 6.

Thomas Lingelbach has served as our President and Chief Executive Officer since 2013. He served as Chairman of our Management Board until December 2023, and in connection with the change to a one-tier governance structure, he was appointed as a member of our Board of Directors and as the *Directeur Général* of the Company. He serves as the Chairman of the Executive Committee. Prior to joining us, Mr. Lingelbach served in a variety of increasingly senior roles, most recently as President and Chief Executive Officer at InterCell AG from 2006 until its merger with Vivalis SA in 2013. He has held a variety of positions of increasing international responsibility in his twenty years in the pharma and vaccine industry. He has served as Managing Director of Chiron Behring GmbH & Co KG and Vice President, Global Industrial Operations-Vaccines of Chiron Corporation. Upon Chiron’s acquisition by Novartis Vaccines & Diagnostics GmbH & Co KG, he served as Managing Director and General Manager Germany until joining InterCell. Prior to joining InterCell, he was the General Manager and Managing Director for Novartis’ German operations. Mr. Lingelbach holds an M.S. in Engineering from Technische Hochschule Gießen / THM.

Peter Bühler has served as our Chief Financial Officer since January 2022. Mr. Bühler previously served as Chief Financial Officer of Quotient Limited, a position he held from February 2020 until December 2021. From May 2017 to March 2019, Mr. Bühler served as Group Chief Financial Officer at Zaluvida Corporate AG. From April 2013 to April 2017, Mr. Bühler served as Group Chief Financial Officer at Stallergenes Greer SA. Mr. Bühler is a Swiss Chartered Accountant, a member of the Swiss Institute of Certified Accountants and Tax Consultants and received an MBA from SBS Swiss Business School.

Franck Grimaud has served as our Chief Business Officer since 2013. Prior to joining us, he served as Chief Executive Officer of Vivalis SA from 1999 until its merger with InterCell AG in 2013. Mr. Grimaud has served as Chair of the Governing Board of Fonds Pays de la Loire Participations since September 2016 and as President of the Board of Directors of Atlanpole Biothérapies since February 2018, where he served as Treasurer from January 2015 to February 2018. Mr. Grimaud holds an M.B.A. from University of Ottawa and received his Licence AES from Université de Poitiers.

Juan Carlos Jaramillo, M.D., has served as our Chief Medical Officer since October 2020. Prior to joining us, Dr. Jaramillo served as Senior Vice President, Market Access & Medical Affairs and then as Senior Vice President, Head of Global Market Access & Pricing at Daiichi Sankyo, GmbH from April 2013 to September 2020. Prior to Daiichi Sankyo, Dr. Jaramillo served as Senior Vice President, Medical Affairs & Clinical Development at Grünenthal, Inc. and prior to that held a variety of positions at GlaxoSmithKline plc. Dr. Jaramillo received his M.D. and B.S. in Pre-Medicine from Universidad Central Del Este.

Dípal Patel has served as our Chief Commercial Officer since November 2022. Ms. Patel has over 23 years' experience in the pharmaceutical industry. Prior to joining us, Ms. Patel served as Vice President, Vaccines Commercialization Lead at GlaxoSmithKline, a position she held from January 2020, and as Vice President, Commercial Head (Respiratory) Emerging Markets from August 2017 to January 2020. Prior to that Ms. Patel held multiple roles at GlaxoSmithKline covering commercial strategy, execution, market access and lifecycle management. Over her career, she has held roles of increasing responsibilities across multiple countries including the United States, Australia, Belgium, Singapore, Thailand, and the European and emerging markets regions. Ms. Patel graduated with a B.Sc. (Honors) from Macquarie University, Sydney in 1998 followed by an M.B.A. from Macquarie Graduate School of Management in 2006.

Frédéric Jacotot has served as our General Counsel and Corporate Secretary since 2013. Prior to joining us, he served as counsel at Abbott Laboratories from 2010 to 2013. Mr. Jacotot received his *Diplôme d'études approfondies* in business law from Paris 1 Panthéon-Sorbonne University.

Vincent Dequenne has served as our Chief Operating Officer since June 2022 and as a member of our Executive Committee since January 2024. Prior to this position, he served as our Senior Vice President of Global Industrial Operations from July 2021 to May 2022. Prior to that, he served as Site Head Biologics at Eurogentec from January 2020 to June 2021 and as CDMO Site Head at Pierre Fabre from October 2017 to January 2020. Before that, he served in roles of increasing responsibility at GSK for more than 10 years and at Eli Lilly for more than 15 years. Mr. Dequenne holds a Master of Engineering, Electromechanical Engineering from *L'institut Supérieur Industriel* in Mons, Belgium.

Petra Pesendorfer has served as our Chief People Officer and as a member of our Executive Committee since January 2024. She has more than 18 years' experience in strategic and operational Human Resources, leading large teams across different countries and regions in rapidly growing business environments. During her career, she has held a variety of positions with increasing international responsibilities. Prior to joining us, Ms. Pesendorfer served as Vice President & Global HR Business Unit & Functional Head (2019 - 2023), Regional HR Head for USA and Canada (2022-2023) and Global Head of Human Capital Development & Talent Acquisition (2016-2019) at ams OSRAM. Prior to that, Ms. Pesendorfer held multinational HR leadership roles at Rentokil Initial and Soravia Group from 2006 to 2016. Ms. Pesendorfer holds an International Master of Business Administration from FH Wien University of Applied Sciences, Vienna, and the University of Texas at Brownsville.

Board of Directors

The Board of Directors is composed of a minimum of three and a maximum of eighteen members. Directors are appointed for a renewable term of three years at the general meeting of shareholders. The general meeting of shareholders may revoke the appointments of directors at any time during the meeting by a simple majority vote. The appointees are selected by the shareholders and may be individuals or entities (represented by a designated individual).

The age limitation for directors is 80 years old, and no more than 20% of the directors may be over 75 years old. The limitations on holding such an appointment concurrently with an appointment in another company are those set forth in the applicable statutory and regulatory provisions.

Our Board of Directors is currently composed of the following non-employee directors, in addition to Thomas Lingelbach:

Anne-Marie Graffin joined our Supervisory Board in 2013 and was appointed to the new Board of Directors in December 2023. She was elected Chair of our Board of Directors in December 2023. She served as Chief Executive Officer of the Big Booster Acceleration Program, an international non-profit acceleration program for startups, from 2011 to May 2017. Prior to that, she served in a variety of positions, most recently as Executive Vice President and member of the Executive Committee at Sanofi Pasteur MSD, a European vaccine company, from 1998 to 2011. Ms. Graffin currently serves as the President of SMAG Consulting SAS. Ms. Graffin has served on the supervisory board of Nanobiotix S.A. (Nasdaq: NBTX) since January 2014, on the board of Sartorius Stedim Biotech SA since April 2015, and on the Board of Directors of Vetoquinol SA since 2022. Ms. Graffin received her MBA from ESSEC Business School Paris. We believe Ms. Graffin's experience in the vaccine space and her experience advising biotech companies qualifies her to serve on our Supervisory Board.

James Sulat joined our Supervisory Board in 2013 and was appointed to the new Board of Directors in December 2023. He is currently Vice Chairman of our Board of Directors. Previously, he served on the Supervisory Board of Intercell AG from 2005 until its merger with Vivalis SA in 2013. From 2009 to 2013, Mr. Sulat served as Chief Executive Officer and Chief Financial Officer of Maxygen, Inc., and as a member of Maxygen's Board of Directors from 2003 to 2013. From 2005 to 2009, Mr. Sulat served in a variety of roles at Memory Pharmaceuticals Corp., including as President and Chief Executive Officer from 2005 to 2008 and as a member of Memory's Board of Directors from 2005 to 2009. Previously, Mr. Sulat served as Chief Financial Officer for Chiron Corporation and Stanford Health Services. Mr. Sulat has served on the Board of GS Holdings, Inc. since October 2021. He previously served on the Board of Directors of Excure, Inc. from 2021 until December 2022, on the Board of Directors of Arch Therapeutics, Inc. from 2015 until December 2021 and on the Board of Directors of AMAG Pharmaceuticals, Inc. from 2014 to November 2020. Mr. Sulat received an MBA and an M.S. in Health Services Administration from Stanford University and a B.S. in Administrative Sciences from Yale University. We

believe Mr. Sulat’s experience in the pharmaceutical industry, expertise in corporate finance and public company board experience qualifies him to serve on our Board of Directors.

James Connolly joined our Supervisory Board in June 2022 and was appointed to the new Board of Directors in December 2023. Since 2013, Mr. Connolly has been providing broad based consulting and advisory services to a variety of vaccine, biopharmaceutical and investment organizations. From 2010 to 2013, Mr. Connolly was President and CEO of Aeras (now IAVI). Prior to this, he spent 24 years at Wyeth (now Pfizer) in a series of increasingly senior roles, including Executive Vice President and General Manager, Wyeth Vaccines and President, Wyeth Canada. Mr. Connolly currently serves on the Board of Directors of IAVI. He previously served on the Board of Directors of Vaxess Technologies (2013-19), Aeras (2013-18), PaxVax (2014-18), Tivorsan Pharmaceuticals (2015-20) and Ambulatus Robotics (2020-21). Mr. Connolly earned a B.S. in Business Administration from Washington University in St Louis. We believe Mr. Connolly’s experience in the vaccines and pharmaceutical industries and his experience advising biotech companies qualifies him to serve on our Board of Directors.

Mailys Ferrère joined our Supervisory Board in June 2022 as representative of Bpifrance Participations, member of the Supervisory Board, and now continues to represent Bpifrance Participations on our Board of Directors. Ms. Ferrère has served as a Director, Head of the Large Venture Investment Activity at Bpifrance, France’s public investment bank, since October 2013. Ms. Ferrère serves on the board of directors of Sequans Communications S.A., a publicly traded French designer, developer and supplier of cellular semiconductor solutions, and on the Board of DBV Technologies, a publicly traded French company that develops a treatment against peanut allergy. Ms. Ferrère served on the board of directors of Innate Pharma SA., a French global oncology-focused biotech company, from 2017 to 2021. Ms. Ferrère served on the board of directors at Gensight Biologics S.A., a French publicly traded biotechnology company, from 2016 to 2019. She graduated from Institut d’Etudes Politiques Paris and began her career with the General Inspectorate of Société Générale before working for multiple French banks in the equity capital markets origination department. We believe that Ms. Ferrère’s experience in the banking industry and her knowledge of capital markets qualify her to serve on our Board of Directors.

Kathrin Jansen joined our Supervisory Board in June 2023 and was appointed to our new Board of Directors in December 2023. Dr. Jansen has over 30 years of vaccine R&D experience focused on the development of vaccines addressing large unmet medical needs. From 2015 to 2022 she served as Senior Vice President and Head of Vaccine Research and Development at Pfizer Inc, and as a member of Pfizer’s Worldwide Research, Development and Medical leadership team. She led a fully integrated, global vaccines research and development organization, with responsibilities ranging from discovery to clinical development, registration, and postmarketing commitments of all of Pfizer’s vaccines, including partnered ones. Most notably she led the development of several highly successful and licensed vaccines such as Pfizer/BioNtech’s SARS-CoV-2 (COMIRNATY), the first-ever licensed mRNA vaccine, Pfizer’s Streptococcus pneumoniae (Pneumovax 23), Respiratory syncytial virus (Abrysvo), and Meningococcal B Group B (Trumenba) vaccines. From 2006 to 2015, Dr. Jansen served as Senior Vice President at Wyeth Pharmaceuticals and then Pfizer and was responsible for vaccine discovery, early development, and clinical testing operations. Prior to Wyeth, Dr. Jansen spent 12 years at Merck Research Laboratories supporting several vaccine efforts and leading the R&D activities of Gardasil, the world’s first cervical cancer vaccine. Dr. Jansen received her Ph.D. in microbiology, biochemistry & genetics from Phillips Universität, Marburg, Germany, in 1984 followed by postdoctoral training at Cornell University. Dr. Jansen was appointed an Adjunct Professor at the University of Pennsylvania School of Medicine in 2010 and has authored and co-authored over 200 publications. She is a member of the National Academy of Medicine, National Academy of Engineering, a Fellow of the Royal Society of Medicine and recipient of the Albert E Sabin Gold Medal. We believe that Dr. Jansen’s experience in the vaccines industry qualifies her to serve on our Board of Directors.

Diversity of the Board of Directors

Board of Directors Diversity Matrix (as of January 1, 2024)

Country of Principal Executive Offices:				France
Foreign Private Issuer:				Yes
Disclosure Prohibited under Home Country Law:				No
Total Number of Directors:				6
Part I: Gender Identity				
	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	3	3	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction				0
LGBTQ+				0
Did Not Disclose Demographic Background				1

Family Relationships

There are no family relationships among any of the members of our Board of Directors and Executive Committee.

B. Compensation

Compensation of Members of the Board of Directors

The members of the Board of Directors receive compensation for serving on the Board and, as applicable, each of the Committees set up by the Board of Directors. At our General Meeting of shareholders held on December 20, 2023, shareholders approved the compensation shown in the table below. Fees are fixed but may be reduced if meeting attendance is under 75%. The following table shows the compensation payable to our directors in 2024:

Member Role	Maximum Allowable Compensation (per year)
Chair of the Board	€90,000
Other Board members	€45,000
Vice-Chair supplement	€15,000
Lead Independent Member supplement	€15,000
Committee Chair supplement (includes membership of the chaired Committee)	€15,000
Committee membership supplement (per Committee)	€7,500

The following table sets forth information regarding the compensation earned by members of the Board during the year ended December 31, 2023 for their service on our Board (including as previous members of the Supervisory Board):

Member	Compensation
Anne-Marie Graffin	€74,300.00
James Sulat	€74,073.97
James Connolly	€66,109.93
Kathrin Jansen	€28,247.96

Ms. Maïlys Ferrère did not receive any compensation in connection with her representation of Bpifrance Participations on the Supervisory Board or Board of Directors during the year ended December 31, 2023, as Bpifrance Participations waived its right to receive such compensation. In addition, in accordance with the decision of the Board of Directors held on December 20, 2023, Mr. Thomas Lingelbach will not receive any compensation for his role on the Board of Directors.

Note: In 2023, €236,620.89 in total was also earned by former members of the Supervisory Board who served until December 20, 2023 (namely Frédéric Grimaud, Sharon Tetlow and Johanna Pattenier).

Compensation of CEO and Associate Managing Officers (former Members of the Management Board)—2023

The Company's general management is currently represented by Mr. Thomas Lingelbach, CEO. The following Associate Managing Officers (*Directeurs Généraux Délégués*) were also appointed in order to assist the CEO in the performance of his duties:

- Franck Grimaud, Chief Business Officer;
- Peter Bühler, Chief Financial Officer;
- Frédéric Jacotot, General Counsel & Corporate Secretary;
- Juan Carlos Jaramillo, Chief Medical Officer; and
- Dipal Patel, Chief Commercial Officer.

The current term of office of Mr. Lingelbach will end at the 2026 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2025.

The current terms of office of Mr. Grimaud, Mr. Jacotot, Mr. Jaramillo, Mr. Bühler and Ms. Patel will end at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 2024.

The method and amount of compensation for the CEO and each Associate Managing Officer is determined by the Board of Directors, after recommendation by the Nomination, Governance and Compensation Committee.

The following tables set forth compensation earned by the CEO and Associate Managing Officers (former Members of the Management Board) with respect to the year ended December 31, 2023.

Mr. Thomas Lingelbach – Chief Executive Officer and member of the Management Board since December 20, 2023 (previously Chief Executive Officer and Chair of the Management Board)

Mr. Lingelbach's compensation is set in accordance with (a) the provisions of the Management Agreement executed between Mr. Lingelbach and Valneva Austria GmbH, and (b) our Supervisory Board or Board of Directors decisions, as applicable.

Type of Compensation	Amount of compensation earned	Description
Fixed compensation	€540,750	As per Supervisory Board decision of January 30, 2023.
Annual variable compensation	€240,093	60% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 74% of the objectives set with respect to the year 2023, on February 23, 2024.
Exceptional compensation	€87,500 (inventor's compensation)	
Compensation in connection with Board membership	€0	In accordance with the decision of the Board of Directors of December 20, 2023
Fringe benefits :		
– Car rental	Lease fee: €15,840 Insurance: €3,440.16 Other car related expenses (except fuel) : €7,444.63	Maximum €1,500 per month for the lease fee as per Mr. Lingelbach's Management Agreement.
– Death and endowment insurance policy	€18,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement of home workplace journeys made by flights, and associated costs	€6,494.94	The current Management Agreement executed between Mr. Lingelbach and our subsidiary, Valneva Austria GmbH, provides that Mr. Lingelbach be reimbursed for the costs of weekend flights between hometowns in Germany and Austria and sites of Valneva, these costs including the transfers from and to the airport.
Total compensation	€919,562.73	

Mr. Franck Grimaud – Chief Business Officer and Associate Managing Officer since December 20, 2023 (previously Chief Business Officer, Management Board member, and Managing Director)

Mr. Grimaud’s compensation is set in accordance with (a) the provisions of the Management Agreements executed between Mr. Grimaud and Valneva SE, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€283,250	As per Supervisory Board decision of January 30, 2023.
Annual variable compensation	€92,056.25	50% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 65% of the objectives set with respect to the year 2023, on February 23, 2024.
Fringe benefits :		
– Car rental	Lease fee: €15,840 Insurance: €1,635.30	Maximum €1,320 per month for the lease fee as per Mr. Grimaud’s Management Agreement.
– Garantie Sociale des Chefs et Dirigeants d’Entreprises	€8,559	An unemployment insurance contract for Company Directors and Managers (Convention Garantie Sociale des Chefs et Dirigeants d’Entreprise) has been granted to Mr. Grimaud. The purpose of this contract is to guarantee the payment of compensation in case of unemployment (up to 70% of the last professional net income filed with the tax authorities). This GSC was set up pursuant to an authorization of the Supervisory Board of October 26, 2000.
Total compensation	€401,340.55	

Mr. Peter Bühler – Chief Financial Officer and Associate Managing Officer since December 20, 2023 (previously Chief Financial Officer and Management Board member)

Mr. Bühler’s compensation is set in accordance with (a) the provisions of the Management Agreement executed between Mr. Bühler and Valneva Austria GmbH, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€391,400	As per Supervisory Board decision of January 30, 2023.
Annual variable compensation	€135,033	50% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 69% of the objectives set with respect to the year 2023, on February 23, 2024.
Fringe benefits :		
– Car allowance	€14,400.00	Maximum €1,200 per month as per Mr. Bühler’s Management Agreement (or €14,400 per year).
– Death and endowment insurance policy	€18,000	Long-term life insurance policy as a retirement savings product.
Total compensation	€558,833.00	

Mr. Frédéric Jacotot – General Counsel & Corporate Secretary, Associate Managing Officer since December 20, 2023 (previously General Counsel & Corporate Secretary, Management Board member)

Mr. Jacotot’s compensation is set in accordance with (a) the provisions of the Management Agreements executed between Mr. Jacotot and Valneva SE, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€221,450	As per Supervisory Board decision of January 30, 2023.
Annual variable compensation	€70,864	50% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 64% of the objectives set with respect to the year 2023, on February 23, 2024.
Fringe benefits :		
– Garantie Sociale des Chefs et Dirigeants d’Entreprises	€12,887.28	Unemployment insurance contract for Company Directors and Managers (Convention Garantie Sociale des Chefs et Dirigeants d’Entreprise) has been granted to Mr. Jacotot with effect as from January 1, 2020. The purpose of this contract is to guarantee the payment of compensation in case of unemployment (up to 70% of the last professional net income filed with the tax authorities).
Total compensation	€305,201.28	

Dr. Juan Carlos Jaramillo – Chief Medical Officer and Associate Managing Officer since December 20, 2023 (previously Chief Medical Officer and Management Board member)

Dr. Jaramillo’s compensation is set in accordance with (a) the provisions of the Management Agreement executed between Dr. Jaramillo and Valneva Austria GmbH, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€326,510	As per Supervisory Board decision of January 30, 2023.
Annual variable compensation	€117,543.60	50% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 72% of the objectives set with respect to the year 2023, on February 23, 2024.
Exceptional compensation	€54,418 (inventor’s compensation)	
Fringe benefits:		
– Car allowance	€14,400	€1,200 per month as per Dr. Jaramillo’s Management Agreement.
– Death and endowment insurance policy	€18,000	€1,500 per month as per Dr. Jaramillo’s Management Agreement.
– Reimbursement of home workplace journeys made by flights, and associated costs	€8,885.61	The current Management Agreement executed between Dr. Jaramillo and the subsidiary Valneva Austria GmbH provides that Dr. Jaramillo be reimbursed for the costs of weekend flights between hometown in Spain and site of Valneva Austria, these costs including the transfers from and to the airport.
Total compensation	€539,757.21	

Ms. Dipal Patel – Chief Commercial Officer and Associate Managing Officer since December 20, 2023 (previously Chief Commercial Officer and Management Board member)

Ms. Patel’s compensation is set in accordance with (a) the provisions of the Management Agreement executed between Ms. Patel and Valneva UK Ltd, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned (*)	Description
Fixed compensation	£305,000, or €353,959.75	As per Supervisory Board decision of August 10, 2022.
Annual variable compensation	£105,225, or €122,113.26	50% of 2023 gross annual salary set by the Supervisory Board on January 30, 2023. Validation by the Board of Directors of 69% of the objectives set with respect to the year 2023, on February 23, 2024.
Fringe benefits:	£12,180 or €14,134.85	£1,015 per month per Ms. Patel’s Management Agreement.
– Car allowance		
– Contribution to UK pension plan	£22,875, or €26,546.36	7.5% of the gross annual salary
Total compensation	€516,754.22	

(*) Exchange rate applied: €1 for £0.8617 (average rate for December 2023). This rate will be updated, in particular with regard to the annual variable compensation, at the time of the bonus payment expected in July 2024 (subject to prior approval by the Company's Annual Ordinary General Meeting to be held in June 2024).

Compensation of the CEO and Associate Managing Officers —2024

The Board of Directors, during its meeting held on December 20, 2023, confirmed the following base salaries for the current CEO and Associate Managing Officers with respect to the year ended December 31, 2024:

General Management	2024 Base Salary
Thomas Lingelbach	€573,195.00
Franck Grimaud	€291,747.50
Peter Bühler	€410,970.00
Frédéric Jacotot	€228,093.50
Juan Carlos Jaramillo	€375,486.50
Dipal Patel	£314,150.00

Adoption of Clawback Policy

In November 2023, in accordance with Rule 10D-1 promulgated under the Exchange Act and Nasdaq Listing Rule 5608, we adopted an incentive compensation recoupment policy which is filed herewith as Exhibit 97.1.

Limitations on Liability and Indemnification Matters

Under French law, provisions of bylaws that limit the liability of the members of the Board of Directors, the Chief Executive Officer and Deputy Chief Executive Officer(s) (together with the Chief Executive Officer, the “Executive Officers”) are prohibited. However, French law allows *sociétés européennes* to contract for and maintain liability insurance against civil liabilities incurred by members of the Board and Executive Officers involved in a third-party action, provided that they acted in good faith and within their capacities as members of such board or management of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We have liability insurance for our Board members, Executive Officers and other members of our Executive Committee and have obtained insurance coverage for liability under the Securities Act. We also have entered into agreements with our Board members and Executive Officers to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements provide for indemnification for damages and expenses including, among other things, attorneys’ fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified Board members and Executive Officers.

These agreements may discourage shareholders from bringing a lawsuit against our Board members and Executive Officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our Board members and Executive Officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder’s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our Board members and Executive Officers pursuant to these insurance agreements.

Equity Incentives

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. In accordance with French corporate law, we have historically granted several different equity incentive instruments to our management and our employees, including stock options and free ordinary shares.

Our Board of Directors’ authority to grant these stock options and free ordinary shares and the aggregate amount authorized to be granted must be approved by two-thirds of the shareholders voting in the relevant extraordinary shareholders’ meeting. Once approved by our shareholders, our Board of Directors can continue to grant such awards for a specified period.

We currently have various long-term incentive plans for our management and employees that have been approved by our shareholders. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the conversion ratio and/or the exercise price of the outstanding stock options.

Stock Options

Since 2013, we have granted stock options to employees and management pursuant to seven successive plans.

Since 2015, our employee stock option plans, or ESOPs, have primarily been for the benefit of non-executive employees, while members of the Management Board and the Management Committee, as well as the Manufacturing Site Heads (since 2017), had the opportunity to participate in four-year free share programs (convertible preferred shares or ordinary shares).

The beneficiaries receive a number of options, depending notably on their job functions, that they can convert into ordinary shares during specific exercise periods that are announced by the management and subject to applicable vesting periods.

Typically, each option converts into one ordinary share. However, under our 2013 stock option plan, the Management Board determined that, in accordance with applicable legal requirements and following a public offering with subscription rights, one option under this plan would convert into 1.099617653 ordinary shares.

With the exception of our 2013 stock option plan, our ESOPs do not include a discount on the exercise price. Our 2013 stock option plan provided for a 10% discount on the average Euronext Paris closing share price over the twenty trading days immediately preceding the option grant date.

All stock options not exercised within ten years of the grant date lapse without compensation.

The following table sets forth the stock options outstanding as of December 31, 2023 (or which were in force during 2023):									
Plan name	ESOP 2013	ESOP 2015	ESOP 2016	ESOP 2017	ESOP 2019	SLG SOP 2022	ESOP 2022	SLG SOP 2023	ESOP 2023
General Meeting date	June 28, 2013	June 26, 2014	June 30, 2016	June 30, 2016	June 28, 2018	June 23, 2022	June 23, 2022	June 21, 2023	June 21, 2023
Grant date	October 2, 2013	July 28, 2015	October 7, 2016	December 7, 2017	September 30, 2019	October 10, 2022	October 10, 2022	December 15, 2023	December 15, 2023
Subscription price	€2.919	€3.92	€2.71	€2.85	€3.05	€6.47	€6.47	€5.25	€5.25
Option/share conversion ratio	1: 1.099617653 (then rounded-up for each beneficiary)	1: 1	1: 1	1: 1	1: 1	1: 1	1: 1	1: 1	1: 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	1,052,950	712,000	584,250	1,269,500	2,670,010	1,159,751	2,154,500	1,284,519	2,156,750
Vesting dates	October 2, 2015 (for 50% of the options) October 2, 2017 (for the remaining 50%)	July 28, 2017 (for 50% of the options) July 28, 2019 (for the remaining 50%)	October 7, 2018 (for 50% of the options) October 7, 2020 (for the remaining 50%)	December 7, 2019 (for 50% of the options) December 7, 2021 (for the remaining 50%)	September 30, 2020 (for 1/3 of the options) September 30, 2021 (for another 1/3 of the options) September 30, 2022 (for the remainder)	October 10, 2023 (for 1/3 of the options) October 10, 2024 (for another 1/3 of the options) October 10, 2025 (for the remainder)	October 10, 2023 (for 1/3 of the options) October 10, 2024 (for another 1/3 of the options) October 10, 2025 (for the remainder)	December 15, 2024 (for 1/3 of the options) December 15, 2025 (for another 1/3 of the options) December 15, 2026 (for the remainder)	December 15, 2024 (for 1/3 of the options) December 15, 2025 (for another 1/3 of the options) December 15, 2026 (for the remainder)
Stock options exercised as of December 31, 2023	630,050	478,845	383,250	427,025	0	0	0	0	0
Shares resulting from exercise of stock options	692,888	478,845	383,250	427,025	0	0	0	0	0
Outstanding stock options as of December 31, 2023	0	43,655	14,500	551,475	1,770,676	1,159,751	1,617,500	1,284,519	2,135,500
Of which outstanding stock options held by corporate officers	0	0	0	0	0	790,236	0	949,029	0
Shares potentially resulting from stock option exercise after December 31, 2023	0	43,655	14,500	551,475	1,770,676	1,132,977	1,617,500	1,284,519	2,135,500
Stock options having lapsed as of December 31, 2023	422,900	189,500	186,500	291,000	899,334	26,774	537,000	0	21,250

Free Ordinary Shares

Free ordinary shares (*actions ordinaires gratuites*) are employee equity incentive instruments pursuant to which the beneficiaries are granted, for free, the possibility to receive our ordinary shares under certain conditions.

As of December 31, 2023, the number of unvested outstanding free shares that have been granted by the Company to the CEO (formerly Chairman of the Management Board) is 260,696 shares and a total of 465,796 for the Associate Managing Officers (former members of the Management Board).

The following table shows the free ordinary shares outstanding as of December 31, 2023:

Plan name	Free ordinary share plan 2019-2023
General Meeting date	June 27, 2019
Management Board decision	December 19, 2019
Free ordinary shares granted by the Management Board	2,191,947 allocated in three tranches, each amounting to one third of the total individual allocation. If one third is not a whole number, the number of free ordinary shares will be rounded down for the first two tranches and rounded up for the third tranche.
Duration of vesting period	The vesting period is set at two (2) years as from December 19, 2019 for the first tranche, three (3) years as from December 19, 2019 for the second tranche, and four (4) years as from December 19, 2019 for the third tranche. The vesting (<i>attribution définitive</i>) of each tranche is subject to performance and employment conditions.
Date of availability	Following free ordinary shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (fourth paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on November 21, 2019, the Supervisory Board decided that the beneficiaries that are corporate officers should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.
Free ordinary shares fully vested as of December 31, 2023	1,186,280
Free ordinary shares being vested as of December 31, 2023	536,124
Free ordinary shares lapsed as of December 31, 2023	469,543

Performance and employment conditions	<p>Concerning non-corporate officers employees, the vesting of each tranche will be contingent upon the beneficiary's performance in the Relevant Year having been rated not lower than "Meets Expectations" (regardless of any qualifying sign), as assessed by his/her supervisor under the Company's employee performance appraisal rules.</p> <p>Concerning corporate officers, the vesting of each tranche will be contingent upon the level of achievement of the Management Board member's collective and individual goals in the Relevant Year (as defined below), as assessed by the Supervisory Board (or the Board of Directors), starting above 60% (60% = no vesting) and increasing in a linear way, so that 80% goal achievement will result in vesting of 50% of the relevant tranche and 100% goal achievement will result in vesting of 100% of the relevant tranche.</p> <p>Relevant Year means 2021 for the first tranche, 2022 for the second tranche and 2023 for the third tranche. If a vesting period expires before the performance has been assessed for the Relevant Year, the vesting of the relevant tranche will be postponed until all Participants have been assessed.</p> <p>Additionally, each of the beneficiaries must continuously remain a corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting, subject to the retirement exception below.</p>
Provisions relating to retirement	<p>The beneficiaries who, prior to the vesting of all or part of the free ordinary shares granted to them, retire in accordance with the age requirements of their pension plan, will retain a portion of their free ordinary shares, and this applies to each of the tranches that have not yet vested. The number of shares thus retained will be calculated according to the period elapsed between the date of the initial allocation of free ordinary shares until the date of the executive's retirement, in relation to the total duration of the tranche in question (two, three or four years) – provided, however, that the performance condition defined in the plan is declared satisfied during the performance appraisal immediately preceding the retirement of the beneficiary in question. For beneficiaries that are corporate officers, the level of performance will also affect the amount of shares kept.</p>
Provisions relating to a change of control	<p>If (a) a Change of Control (as defined below) occurs not earlier than December 19, 2021, and (b) the performance condition stated above was met for the calendar year immediately preceding the year of Change of Control (or for the year of Change of Control if already assessed), all tranches will vest immediately. For beneficiaries that are corporate officers, their level of performance will also affect the amount of shares that will be the subject of accelerated vesting.</p> <p>Change of Control means that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L 233-3 of the French Commercial Code.</p>

Plan name	Free ordinary share plan 2022-2025
General Meeting date	June 23, 2021
Management Board decision	October 10, 2022
Free ordinary shares granted by the Management Board	374,390 allocated in three tranches, each amounting to one third of the total individual allocation. If one third is not a whole number, the number of free ordinary shares will be rounded down for the first two tranches and rounded up for the third tranche.
Duration of vesting period	The vesting period is set at two (2) years as from October 10, 2022 for the first and the second tranches, and three (3) years as from October 10, 2022, for the third tranche. The vesting (<i>attribution définitive</i>) of each tranche of ordinary shares will be subject to employment conditions.
Date of availability	Following free shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (fourth paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on June 22, 2022, the Supervisory Board decided that the beneficiaries that are corporate officers should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.
Free ordinary shares fully vested as of December 31, 2023	0
Free ordinary shares being vested as of December 31, 2023	374,390
Free ordinary shares lapsed as of December 31, 2023	0
Performance and employment conditions	No performance condition. However, the beneficiaries of the plan must, on an ongoing basis, remain corporate officers or employees (full time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the grant of the free ordinary shares allocated to them.
Provisions relating to retirement	The beneficiaries who retire in accordance with the age requirements of their pension plan prior to full vesting will be entitled to a pro rata number of shares for each unvested tranche based on the period from the date of grant to retirement in relation to the total term of the tranche in question, provided, however, that for purposes of this calculation, the term of the first tranche shall be considered to be one year.
Provisions relating to a change of control	If a Change of Control takes place before October 10, 2024, and Article L.225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however for the beneficiaries that are corporate officers to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable plan rules will apply to this calculation mutatis mutandis. “ Change of Control ” shall mean that a person or entity other than the Company’s current shareholders has taken control of the Company, “control” having the meaning set forth in Article L.233-3 of the French Commercial Code.

Plan name	Second Special 2022-2024 free ordinary share plan
General Meeting date	June 23, 2021
Management Board decision	December 6, 2022
Free ordinary shares granted by the Management Board	December 6, 2022
Duration of vesting period	The vesting period for the shares is set at two (2) years from December 6, 2022. The vesting (<i>attribution définitive</i>) of each tranche of ordinary shares will be subject to employment conditions.
Date of availability	No holding period is applicable to ordinary shares vested. However, in accordance with section II (fourth paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on May 4 and October 12, 2022, the Supervisory Board decided that the beneficiary should keep not less than 10% of the vested free shares of each tranche until termination of his office as Management Board member or corporate officer.
Free ordinary shares fully vested as of December 31, 2023	0
Free ordinary shares being vested as of December 31, 2023	27,521
Free ordinary shares lapsed as of December 31, 2023	0
Performance and employment conditions	The beneficiary of the plan must, on an ongoing basis, retain the status of corporate officer or employee (full-time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the vesting of the free ordinary shares allocated to him. There is no performance condition.
Provisions relating to a change of control	<p>If (a) a Change of Control takes place before December 6, 2024, and (b) the above-mentioned employment conditions is satisfied until the Change of Control, and (c) Article L.225-197-1, III of the French Commercial Code does not apply, the plan will be cancelled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the cancelled plan, subject however to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control.</p> <p>“<i>Change of Control</i>” shall mean that a person or entity other than the Company’s current shareholders has taken control of the Company, “control” having the meaning set forth in Article L.233-3 of the French Commercial Code.</p>

Plan name	Free ordinary share plan 2023-2026
General Meeting date	June 23, 2021
Management Board decision	December 15, 2023
Free ordinary shares granted by the Management Board	445,320 allocated in three tranches, each amounting to one third of the total ordinary shares granted by the Management Board. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche.
Duration of vesting period	The vesting period is set at two (2) years as from December 15, 2023 for the first and the second tranches, and three (3) years as from December 15, 2023, for the third tranche. The vesting (attribution définitive) of each tranche of ordinary shares will be subject to employment conditions.
Date of availability	Following free shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (fourth paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on March 9, 2023 (confirmed on June 21, 2023), the Supervisory Board decided that the beneficiaries that are corporate officers should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.
Free ordinary shares fully vested as of December 31, 2023	0
Free ordinary shares being vested as of December 31, 2023	445,320
Free ordinary shares lapsed as of December 31, 2023	0
Performance and employment conditions	No performance conditions. However, the beneficiaries of the plan must, on an ongoing basis, remain corporate officers or employees (full time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the grant of the free ordinary shares allocated to them, except for the retirement provisions described below.
Provisions relating to retirement	The beneficiaries who retire in accordance with the age requirements of their pension plan prior to full vesting will be entitled to a pro rata number of shares for each unvested tranche based on the period from the date of grant to retirement in relation to the total term of the tranche in question, provided, however, that for purposes of this calculation, the term of the first tranche shall be considered to be one year.
Provisions relating to a change of control	If a Change of Control takes place before December 14, 2025, and Article L.225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however for the beneficiaries that are corporate officers to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable plan rules will apply to this calculation mutatis mutandis. “ Change of Control ” shall mean that a person or entity other than the Company’s current shareholders has taken control of the Company, “control” having the meaning set forth in Article L.233-3 of the French Commercial Code.

Phantom Shares

In recent years, we established Phantom Stock Option Programs with terms and conditions similar to the then-existing ESOPs described above, for employees who are U.S. tax citizens.

The Phantom Stock Option Programs are based on our share price and entitle the participants to a potential cash bonus if there has been an increase in our share price compared to the strike price at the grant date. Each employee participating in the program has phantom stock options potentially giving right to a certain number of phantom shares, which will be settled in cash instead of equity.

The overall objectives of the Phantom Stock Option Programs were (i) to retain certain employees who are U.S. citizens, (ii) to create long-term incentive for the participants, because they were not eligible for the ESOPs, and consequently (iii) to align the interests of our employees who are U.S. citizens and our employees eligible for the ESOPs.

The strike price per phantom share for each program is calculated on the basis of the volume-weighted average closing price of our shares on Euronext Paris during a period of 20 trading days prior to the grant of options under the parallel ESOP. Current strike prices are set in a range from €2.71 to €3.92. The phantom shares will be settled in cash until 2030 by subtracting the entry price per share from the market price per share and multiplying the result by the total number of granted phantom shares, but only if our market price per share at that date exceeds the strike price. The market price per share will be based on the closing price of our shares on Euronext Paris on the date of receipt of the exercise notice.

In 2020, we established a Phantom Free Share Plan for the benefit of senior managers who could not receive free ordinary shares under the free ordinary share plan 2019-2023 because they were not members of the Management Committee. This plan includes vesting and performance conditions similar to those of the free ordinary share plan 2019-2023, but provides for a settlement in cash instead of equity.

As of December 31, 2023, the Phantom Stock Option Programs and Phantom Free Share plan consisted of an aggregate of 410,500 phantom shares.

The Phantom Stock Option Programs and Phantom Free Share plan do not have any dilutive effect on our shareholders, as the phantom shares do not constitute or qualify for our ordinary shares.

The liability for the phantom plans is measured (initially at the end of each reporting period until settled) at the fair value of the share options rights, by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

C. Board Practices

On December 20, 2023, our shareholders approved the change from a two-tier governance system under which we were governed by a Supervisory Board and Management Board to a one-tier governance system led by a Board of Directors, with our senior management comprising an Executive Committee. Responsibility for the general management of the Company rests with our Executive Committee, notably our Chief Executive Officer (*Directeur Général*) and five other members of the Executive Committee appointed as Associate Managing Officers (*Directeurs Généraux Délégués*).

We present the details of both the Supervisory Board and the Board of Directors below.

Composition

The Supervisory Board was composed of a minimum of three and a maximum of eighteen members, each appointed for a renewable term of three years at the general meeting of shareholders. The age limit for the members of the Supervisory Board was 80. The terms of Ms. Sharon Tetlow and Dr. Johanna Pattenier were renewed at the general meeting of shareholders in June 2023, and at this meeting shareholders also approved the appointment of Dr. Kathrin Jansen to the Supervisory Board for a three-year term. The terms of Mr. James Connolly, Ms. Anne-Marie Graffin, Mr. Frédéric Grimaud, and Mr. James Sulat were to expire at the end of the general meeting of shareholders in 2025. The term of Bpifrance Participations, represented by Ms. Mailys Ferrère, was to expire at the end of the general meeting of shareholders in 2025. The appointees were selected by the shareholders.

The Board of Directors is composed of a minimum of three and a maximum of eighteen members. Directors are appointed for a renewable term of three years at the general meeting of shareholders. The age limit for the members of the Supervisory Board is 80, and no more than 20% of the directors may be over 75 years old. The limitations on holding such an appointment concurrently with an appointment in another company are subject to the applicable legal and regulatory provisions. All of our directors were appointed by our shareholders during the combined general meeting on December 20, 2023. The terms of Mr. Connolly, Ms. Graffin, Dr. Jansen, and Mr. Lingelbach will expire at the end of the general meeting of shareholders in 2026. The terms of Mr. Sulat and Bpifrance Participations, represented as of the date of this annual report by Ms. Mailys Ferrère, will expire at the end of the general meeting of shareholders in 2025. The general meeting of shareholders may revoke the appointments of directors at any time during the meeting by a simple majority vote. The directors are selected by the shareholders and may be individuals or companies (represented by a designated individual). With the exception of Mr. Lingelbach, our Chief Executive Officer and member of the Board of Directors who has a management agreement with our subsidiary Valneva Austria GmbH, none of our directors serve pursuant to a service contract providing benefits upon termination of service as a director.

Role of the Board in Risk Oversight

Our Supervisory Board was, and the Board of Directors is, primarily responsible for the oversight of our risk management activities and has delegated to the Audit and Committee (as defined below) the responsibility to assist the Board in this task. While our Board oversees our risk management, our management, through the Executive Committee, is responsible for day-to-day risk management processes. Our Board expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Committees

The Supervisory Board had established three committees that operated during the year ended December 31, 2023 pursuant to rules of procedure adopted by the Supervisory Board. These committees were the Nomination and Compensation Committee, the Audit and Governance Committee, and the Environmental, Social, and Governance (ESG) Committee.

Two of these committees were renamed in the rules of procedures adopted by our Board of Directors in connection with our governance change on December 20, 2023. The committee descriptions below refer to the committees as of January 1, 2024 but are accurate with respect to the Supervisory Board committees unless otherwise noted.

The Board of Directors has established four committees, each of which operates pursuant to rules of procedure adopted by the Board. These committees are the Audit, Compliance and Risk Committee, the Nomination, Governance and Compensation Committee, the Scientific Committee, and the ESG Committee. The respective responsibilities of the Audit, Compliance and Risk Committee and the ESG Committee will be reviewed during 2024 to take account of the latest legislation on sustainability reporting.

Subject to available exemptions, the composition and functioning of all of our committees will comply with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq listing rules and SEC rules and regulations.

In accordance with French law, committees of our Board will only have an advisory role and can only make recommendations to our Board of Directors. As a result, decisions will be made by our Board of Directors taking into account non-binding recommendations of the relevant Board committee.

Audit and Governance Committee (as of December 20, 2023: Audit, Compliance and Risk Committee)

We refer in this section to the “Audit Committee”, and this description applies to both the committee of the Supervisory Board and the committee of the Board of Directors unless otherwise noted.

The Audit Committee assists our Board in its oversight of our corporate accounting and financial reporting and oversees the selection of our auditors, their remuneration and independence and keeps the Board informed on control systems, key processes and procedures, security and risks. As of December 20, 2023, the charter of the Audit Committee also specifically includes oversight of risks relating to cybersecurity. The Audit Committee previously had oversight of these risks in practice, but this was not specifically noted in its charter.

The members of our Audit Committee prior to December 20, 2023 were Sharon Tetlow (chair), James Sulat, and James Connolly. The Supervisory Board determined that Ms. Tetlow, Mr. Sulat and Mr. Connolly were independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. The Supervisory Board further determined that Ms. Tetlow was an “audit committee financial expert” as defined by the Nasdaq listing rules and that each of the members qualified as financially sophisticated under the Nasdaq listing rules.

The members of our Audit Committee as of the date of this annual report are James Sulat (chair), James Connolly, and Bpifrance Participations, represented by Maïlys Ferrère. Our Board has determined that Mr. Connolly, Mr. Sulat, Mr. Connolly, and Bpifrance Participations, represented by Ms. Ferrère are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Board has further determined that Mr. Sulat is an “audit committee financial expert” as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

The principal responsibility of our Audit Committee is to monitor the existence and efficacy of our financial audit and risk control procedures on an ongoing basis.

Our Supervisory Board assigned, and our Board of Directors has assigned, the following duties specifically to the Audit Committee:

- oversight of the statutory auditors’ work in relation to their review of the interim condensed consolidated financial statements, and their audit of the annual Company and consolidated financial statements;
- oversight of the statutory auditors and monitoring of the independence of the statutory auditors; and
- oversight of internal audit procedures and monitoring the efficiency of internal and risk management procedures.

Nomination and Compensation Committee (as of December 20, 2023: Nomination, Governance and Compensation Committee)

We refer in this section to the “Nomination Committee”, and this description applies to both the committee of the Supervisory Board and the committee of the Board of Directors unless otherwise noted.

Our Nomination Committee assists our Board with respect to the appointment and the compensation of the members of our Board and Executive Committee (previously, the Supervisory Board and Management Board). In accordance with operating rules adopted by the Board, the Nomination Committee is composed of at least three members (or their permanent representatives) appointed by the Board.

The members of our Nomination Committee prior to December 20, 2023 were Anne-Marie Graffin (chair), James Sulat and Johanna Pattenier, all of whom were independent.

The members of our Nomination Committee as of the date of this annual report are Anne-Marie Graffin (chair), James Sulat and James Connolly, all of whom are independent.

Our Supervisory Board assigned, and our Board of Directors has assigned, the following duties specifically to the Nomination Committee:

- reviewing our compensation policy, in particular the description of our collective objectives (applicable company-wide) and individual objectives (for members of the Management Board or, since December 20, 2023, the Executive Committee),
- reviewing the compensation of the members of our Management Board or, since December 20, 2023, Executive Committee,
- examining and making proposals with respect to the various components of corporate officers' compensation, the policy concerning the distribution of equity such as warrants, stock options, grants and capital increases reserved for members of our savings plan the allocation of incentive bonuses and all the provisions relating to retirement benefits and any other kind of benefit,
- examining the amount of attendance fees among Board members,
- assisting the Board in the selection of directors, the members of the Executive Committee, and the members of Board committees, and
- making recommendations with respect to the independence of the members of the Board and committees.

Scientific Committee

Our Scientific Committee was established on December 20, 2023 and assists our Board in oversight of the Company's research and development programs, portfolio strategy and scientific and technological expertise. In accordance with operating rules adopted by the Board, the Scientific Committee is composed of at least two members (or their permanent representatives) appointed by the Board. The members of our Scientific Committee are Kathrin Jansen and Thomas Lingelbach. Dr. Jansen is the chair of the committee.

Environmental, Social and Governance (ESG) Committee

Our Environmental, Social, and Governance Committee, or the ESG Committee, assists our Board in fulfilling its responsibilities relating to ESG matters under applicable law and as the Board may otherwise determine, including review of the Company's ESG strategy and public disclosures on ESG matters. In accordance with operating rules adopted by the Board, the ESG Committee is composed of at least three members (or their permanent representatives) appointed by the Board. The members of the ESG Committee prior to December 20, 2023 were Frédéric Grimaud (chair), Kathrin Jansen and Bpifrance Participations, represented by Mailys Ferrère. The members of our ESG Committee as of the date of this annual report are Thomas Lingelbach, Kathrin Jansen and Bpifrance Participations, represented by Mailys Ferrère. Mr. Lingelbach is the chair of the committee.

D. Employees

As of December 31, 2023, we had a headcount of 676 employees located in Austria, Canada, France, Sweden, the United Kingdom and the United States. The table below shows the number of employees employed by us and each of our subsidiaries:

Location	Number of Employees
Valneva Austria GmbH	271
Valneva Canada Inc.	8
Valneva France SAS	11
Valneva Scotland Ltd	167
Valneva SE	56
Valneva Sweden AB	124
Valneva UK Ltd	11
Valneva USA, Inc.	28
Total	676

Of these employees, approximately 33% were primarily engaged in manufacturing, 31% in research and development, 26% in general and administrative functions, and 10% in commercial operations.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. The principal purposes of our equity incentive plans are to attract, retain, and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Pursuant to local laws, including the laws of France and Austria, some of our employees are covered by collective bargaining agreements. We consider our relationship with our employees to be good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “Item 6.B—Compensation” and “Item 7.A—Major Shareholders.”

F. Disclosure of Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table and accompanying footnotes sets forth, as of December 31, 2023, information regarding beneficial ownership of our ordinary shares by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our ordinary shares;
- each of the members of our Board of Directors (including the former Chair of the Management Board) and our Associate Managing Officers (former Management Board members), individually or as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including free ordinary shares that vest within 60 days of December 31, 2023 and options that are currently exercisable or exercisable within 60 days of December 31, 2023. Ordinary shares subject to free ordinary shares that vest within 60 days of December 31, 2023, and options currently exercisable or exercisable within 60 days of December 31, 2023 are deemed to be outstanding for computing the percentage ownership of the person holding these free ordinary shares or options and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all ordinary shares shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

Unless otherwise indicated in the notes under the table, the address of each beneficial owner listed in the table below is c/o Valneva SE, 6 rue Alain Bombard, 44800 Saint-Herblain, France.

	Number of Ordinary Shares Owned	Percentage of Ordinary Shares Beneficially Owned
5% Shareholders:		
Groupe Grimaud La Corbière SAS ⁽¹⁾	13,204,831	9.51
Bpifrance Participations SA and affiliated entities ⁽³⁾	12,801,207	9.22
Pfizer Inc. ⁽²⁾	9,549,761	6.87
Deep Track Capital ⁽⁴⁾	7,526,807	5.42
Members of the Board of Directors ⁽⁵⁾ :		
Mr. Thomas Lingelbach	385,545	*
Ms. Anne-Marie Graffin	14,250	*
Mr. James Connolly	—	*
Mr. James Sulat	30,367	*
Ms. Kathrin Jansen	—	—
Bpifrance Participations (represented by Maïlys Ferrère)	8,639,886	6.22
Associate Managing Officers (members of the Management Board until December 20, 2023) ⁽⁵⁾ :		
Mr. Franck Grimaud	635,218	*
Mr. Frederic Jacotot	276,158	*
Mr. Peter Bühler	44,744	*
Mr. Juan Carlos Jaramillo	44,744	*
Ms. Dipal Patel	—	—
All members of our Board of Directors and Associate Managing Officers as a group	14,232,233	10.25 %

* Represents beneficial ownership of less than 1%.

- (1) Consists of 13,204,831 ordinary shares held by Groupe Grimaud La Corbière SAS (“Groupe Grimaud”). The majority shareholder of Groupe Grimaud is La Financière Grand Champ, a French company. Voting and investment control over the shares is held in Groupe Grimaud La Corbière by a strategic shareholders committee (Comité Stratégique des Actionnaires) comprised of Frédéric Grimaud, Joseph Grimaud, Claire Grimaud-Mandin, Odile Grimaud-Chateigner, Patrick Neaume, Unigrains (represented by Nicolas Mülle), Idia Participations (represented by Manuel Leal) and Bpifrance Participations (represented by Louis Molis). The principal business address of Groupe Grimaud and La Financiere Grand Champ is 3 La Corbière – Roussay – 49450 Sevremonoine, France. Frédéric Grimaud, a member of our former Supervisory Board, is the President and Chief Executive Officer of Groupe Grimaud.
- (2) As reported in a Schedule 13G filed with the SEC on June 29, 2022. The principal address for Pfizer Inc. is 235 E. 42nd Street, New York, NY 10017.
- (3) As reported in a Schedule 13D filed with the SEC on June 30, 2023. Bpifrance Participations SA (f/k/a Fonds Stratégique d’Investissement, “Bpifrance”) is a French public investment fund specializing in the business of equity financing via direct investments or fund and is a wholly owned subsidiary of Bpifrance S.A., a French financial institution (“Bpifrance S.A.”). Caisse des Dépôts (“CDC”) and EPIC Bpifrance (“ÉPIC”) each hold 49.2% of the share capital of Bpifrance S.A. and jointly control Bpifrance S.A. CDC is principally engaged in the business of long-term investments. EPIC is principally engaged in the business of banking finance. As of June 29, 2023, (i) Bpifrance Participations SA held directly 8,639,886 ordinary shares and 17,247,792 voting rights, and (ii) CDC Croissance S.A., a wholly-owned subsidiary of CDC (“CDC Croissance”), held, through CDC PME CROISSANCE & CDC TECH CROISSANCE, 4,161,321 ordinary shares and 4,161,321 voting rights. Neither Bpifrance S.A. nor EPIC held any ordinary shares directly. Bpifrance S.A. may be deemed to be the beneficial owner of 8,639,886 ordinary shares and 17,247,792 voting rights indirectly through its 99.99% ownership of Bpifrance Participations. EPIC may be deemed to be the beneficial owner of 8,639,886 ordinary shares and 17,247,792 voting rights, indirectly through its joint ownership and control of Bpifrance S.A. CDC may be deemed to be the beneficial owner of (x) 8,639,886 ordinary shares and 17,247,792 voting rights, indirectly through its joint ownership and control of Bpifrance S.A. and (y) 4,161,321 ordinary shares and 4,161,321 voting rights, indirectly through its ownership of CDC Croissance. The board of directors of Bpifrance holds voting and investment power over these shares and is comprised of Bpifrance’s chief executive officer, three directors appointed by the French State, three directors appointed by CDC and three independent directors. The principal address for CDC is 56, rue de Lille, 75007 Paris, France and for Bpifrance, Bpifrance S.A. and EPIC is 27-31 avenue du Général Leclerc, 94700 Maisons-Alfort Cedex, France.

- (4) As reported in a Schedule 13G filed with the SEC on February 14, 2024. Voting and dispositive power over the shares is shared by Deep Track Capital, LP, Deep Track Biotechnology Master Fund, Ltd. and David Kroin. The principal business address of Deep Track Capital, LP is 200 Greenwich Avenue, 3rd Floor, Greenwich CT 06830. The principal business address of Deep Track Biotechnology Master Fund, Ltd. is c/o Walkers Corporate Limited, 190 Elgin Avenue, George Town, KY1-9001, Cayman Islands. The principal business address of David Kroin is c/o Deep Track Capital, LP, 200 Greenwich Avenue, 3rd Floor, Greenwich CT 06830.
- (5) The business address of Messrs. Thomas Lingelbach, Juan Carlos Jaramillo and Peter Bühler is located at Valneva Austria GmbH, Campus Vienna Biocenter 3, 1030, Vienna (Austria). The business address of Ms. Dipal Patel is located at: Valneva UK Ltd, Centaur House, Ancells Business Park, Ancells Road, Fleet, Hampshire, U51 2UJ (United Kingdom).

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2021 were primarily the result of (i) our issuance and sale of 8,145,176 ordinary shares (including in the form of ADSs) in our May 2021 U.S. public offering and European private placement, (ii) our issuance and sale of 5,175,000 ordinary shares (including in the form of ADSs) in our November 2021 U.S. public offering and European private placement, (iii) our issuance and sale of 9,549,761 ordinary shares to Pfizer in June 2022 and (iv) our issuance and sale of 21,000,000 ordinary shares (including in the form of ADSs) in our October 2022 U.S. public offering and European private placement.

Voting Rights

A double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years, starting from the registration of the Company in the form of a European company.

Shareholders in the United States

To our knowledge, as of December 31, 2023, approximately 36,552,062 shares, or 26% of our ordinary shares outstanding at that date, were held of record by 45 residents of the United States.

B. Related Party Transactions

Since January 1, 2023, we have engaged in the following transactions with members of our Management and Supervisory Boards and holders of more than 5% of our outstanding voting securities, and their respective affiliates, which we refer to as our related parties.

Transactions With Groupe Grimaud and Affiliates

In September 2018, we entered into a collaboration and research license agreement, or CRLA, with Groupe Grimaud La Corbière SA (now Groupe Grimaud Corbière SAS), or Groupe Grimaud, which was subsequently assigned to Vital Meat SAS, or Vital Meat, a French company and affiliate of Groupe Grimaud, for the purpose of collaborating with Groupe Grimaud to explore the possibility of using our avian cell lines to produce nutritional meat-like substances. Under this agreement, which was renewed and extended until April 30, 2022, we granted Groupe Grimaud non-exclusive research license to use our EBx platform (excluding EB66), provided Groupe Grimaud with certain assistance and provided office space and certain equipment to Groupe Grimaud in connection with such research. Groupe Grimaud and affiliates made payments relating to the CRLA totaling €189.0 thousand excluding tax in 2022. Vital Meat continues to rent certain of our office space and equipment pursuant to a premises and equipment provision agreement dating to September 2018 which was last amended in November 2022. Groupe Grimaud and affiliates paid €129.3 thousand under this agreement in 2023 (2022: €0 thousand).

Following expiration of the CRLA, in May 2022 we entered into a sale and licensing agreement, or EBx Agreement, with Vital Meat, pursuant to which we agreed to sell our “Cleanmeat” patent and the EBx platform (excluding EB66) to Vital Meat and granted Vital Meat an exclusive commercial license to use certain Valneva know-how and patents in the context of developing nutritional meat-like substances. The EBx Agreement provides for upfront and milestone payments to Valneva of €4.0 million, royalties equal to three percent of net sales of products developed using the EBx platform, and sublicensing revenues ranging from 25% to 75%. We received €1.0 million pursuant to the EBx Agreement in 2022 and €0 in 2023. In July 2023, we amended certain non-financial terms of the EBx Agreement, including to allow for sublicensing and subcontracting relating to development activities.

Sale of Shares of BliNK Biomedical SAS

We previously held a 48.9% equity interest in BliNK Biomedical SAS, Marseille (BliNK), a private company not listed on a stock exchange that qualified as a related party because our Chief Business Officer was a member of BliNK’s supervisory board. On September 8, 2023, we sold this equity interest, and the proceeds of the sale amounted to €2.4 million. For the year ended December 31, 2023, the final sale resulted in a profit of €0.2 million. The transaction stipulates an earn-out component which entitles us to receive 0.006491% for each equity interest share of BliNK’s net revenue over a period of seven years. BliNK is no longer a related party as of October 12, 2023.

Arrangements with the Members of our Board of Directors and Executive Committee

Management and Board of Directors Compensation

See Item 6B of this Annual Report for information regarding compensation of the members of our Board of Directors and Executive Committee. We executed new management agreements with each member of our Executive Committee in 2023.

Indemnification Agreements

In connection with our global offerings in 2021 and 2022, we entered into indemnification agreements with each of our Management Board and Supervisory Board members. With certain exceptions and subject to limitations on indemnification under French law, these agreements provide for indemnification for damages and expenses including, among other things, attorneys’ fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We have liability insurance for the members of our Executive Committee and Board of Directors. We believe that this insurance and these agreements are necessary to attract qualified members of the Executive Committee and Board of Directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related Person Transaction Policy

We comply with French law regarding approval of transactions with related parties. In May 2021, our Supervisory Board adopted a related person transaction policy that was re-adopted by the new Board of Directors in December 2023. This policy sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and the amount involved in the transaction exceeds \$120,000, with the exception of usual transactions concluded under normal conditions. A related person is any member of the Board of Directors, a *Directeur Général Délégué* (certain members of our Executive Committee), or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to the Board of Directors for review, consideration, and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction, and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our Board of Directors and Executive Committee and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

In addition, under our Code of Conduct, our employees and the members of our Board of Directors and Executive Committee have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, the Board of Directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on the independence of a member of the Board of Directors or Executive Committee in the event that the related person is a member of the Board of Directors or Executive Committee, immediate family member of a member of the Board of Directors or Executive Committee or an entity with which a member of the Board of Directors or Executive Committee is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a related person transaction, the Board of Directors must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as the Board of Directors determines in the good faith exercise of its discretion.

Certain of the transactions described above were entered into prior to the adoption of the written policy, but our Board of Directors (or, prior to December 20, 2023, our Supervisory Board) evaluated and approved all transactions that were considered to be related party transactions under French law at the time at which they were consummated.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated Statements

Our consolidated financial statements are included as part of this Annual Report, starting at page F-1.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For a description of certain legal matters, see the Notes to our consolidated financial statements included elsewhere in this Annual Report.

Dividend Policy

We have never declared or paid any dividends on our ordinary shares. Under our credit facility, except with respect to certain permitted dividend distributions, we are generally not permitted to declare or make any dividend with respect to our share capital. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business, given our state of development.

Subject to the requirements of French law and our bylaws, dividends may only be distributed from our distributable profits, plus any amounts held in our available reserves which are reserves other than legal and statutory and revaluation surplus. Dividend distributions, if any in the future, will be made in euro and converted into U.S. dollars with respect to the ADSs, as provided in the deposit agreement.

B. Significant Changes

Not applicable.

Item 9. The Offer and Listing

A. Offer and Listing Details

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol “VALN” since May 6, 2021. Our ordinary shares have been trading on Euronext Paris under the symbol “VAL” since May, 2013. Prior to that date, there was no public trading market for our ADSs or our ordinary shares.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs have been listed on Nasdaq under the symbol “VALN” since May 6, 2021. Our ordinary shares have been trading on Euronext Paris under the symbol “VAL” May, 2013.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth in Exhibit 2.3 “Description of Securities” is incorporated herein by reference.

C. Material Contracts

Agreements Relating to Product Sales

Department of Defense Contracts

In September 2020, the U.S. Department of Defense, Defense Logistics Agency, or DLA, awarded us a new contract for the supply of IXIARO, following previous contracts we have had with DLA since January 2019. The terms of the agreement contemplated an initial base year followed by two option years, each with a range of minimum and maximum potential dose orders. The base year had a minimum value of approximately \$53 million for 370,000 doses, and the first option year, which DLA exercised, had a minimum value of approximately \$28.8 million for 200,000 doses. The second option year, which DLA did not exercise, had a minimum value of approximately \$36 million for 250,000 doses. We also agreed to provide additional inventory after September 2023 to mitigate the potential impact of unused stock that may expire. This replacement inventory will be provided without cost to DLA and resulted in a contract liability amounting to \$5.2 million (€4.7 million) recognized as of December 31, 2023.

In September 2023, the DLA awarded us a new one-year contract for the supply of IXIARO. The contract has a minimum value of approximately \$32.3 million for approximately 200,000 doses.

Since 2009, we have also had a Federal supply schedule contract with the Department of Veterans Affairs listing IXIARO.

Bavarian Nordic Distribution Agreements

In November 2020, Valneva Austria GmbH, or Valneva Austria, entered into a distribution agreement, or the IXIARO Distribution Agreement, with Bavarian Nordic A/S, or BN, pursuant to which Valneva Austria granted BN an exclusive right to import, market, promote, distribute, and sell IXIARO in Germany. In parallel, Valneva Sweden AB, or Valneva Sweden, entered into a distribution agreement, or the DUKORAL Distribution Agreement, with BN pursuant to which Valneva Sweden granted BN an exclusive right to import, market, promote, distribute, and sell DUKORAL in Germany. The IXIARO Distribution Agreement and the DUKORAL Distribution Agreement together are referred to as the BN Distribution Agreements.

In connection with BN’s purchase of the Vaxchora cholera vaccine, the DUKORAL Distribution Agreement was amended with effect in May 2023 to convert BN’s exclusive right to distribute DUKORAL to a non-exclusive distribution right and to terminate the agreement on December 31, 2025. The IXIARO Distribution Agreement will also terminate on December 31, 2025.

The BN Distribution Agreements include sub-distribution rights. Each of Valneva Austria and Valneva Sweden has a co-exclusive right to deliver, distribute, market, sell, promote, and import IXIARO and DUKORAL, as applicable, in Germany solely with respect to certain non-profit organizations. Pursuant to the BN Distribution Agreements, BN is required to use reasonable commercial efforts to promote, sell and distribute IXIARO and DUKORAL in Germany and is required to purchase an agreed upon minimum quantity of IXIARO and DUKORAL doses during each year of the BN Distribution Agreements. The DUKORAL Distribution Agreement, as amended, maintains this requirement for a minimum quantity but provides that this condition will lapse automatically if Valneva appoints another distributor of DUKORAL in Germany.

VBI Distribution Agreement

In December 2022, Valneva Austria GmbH entered into an agreement, or the VBI Distribution Agreement, with VBI Vaccines B.V., or VBI, relating to Valneva’s distribution of VBI’s hepatitis B vaccine PreHevbri, or the Product. The VBI Distribution Agreement has an initial term until December 31, 2025 and may be renewed for an additional two years and then thereafter as may be mutually agreed. Pursuant to the VBI Distribution Agreement, Valneva has an exclusive license to distribute, market, promote, and sell the Product in Sweden, Norway, Denmark, Finland, the United Kingdom, Belgium, and the Netherlands, collectively the Territory. Valneva also has a first right of refusal to enter into an agreement to provide the same services in Austria, Canada, and/or France. Valneva is obligated to purchase annually a progressively higher minimum number of doses of the Product within each country in the Territory at a price per dose to be calculated as a percentage of the estimated average net selling price annually, above a certain minimum price floor.

Either party may terminate the VBI Distribution Agreement in its entirety or with respect to a particular part of the Territory if the other party breaches and fails to cure a material obligation or certain compliance obligations, enters into certain insolvency proceedings, or undergoes a change of control, or in case of force majeure or withdrawal of the marketing

authorization for the Product in the Territory. VBI may also terminate in case Valneva fails to exercise diligent efforts to promote, sell, and distribute the Product within the Territory, if Valneva fails to purchase the minimum annual purchase quantity for a certain number of consecutive years, or if Valneva loses its wholesale license in any country within the Territory.

GSK Distribution Agreement

In December 2015, we entered into a distribution agreement, or the GSK Distribution Agreement, with GlaxoSmithKline GmbH (as a successor in interest to Novartis Vaccines and Diagnostics, Inc.), or GSK, pursuant to which we granted GSK an exclusive right to import, market, promote, distribute and sell IXIARO in Germany, including sub-distribution rights in accordance with the terms of the GSK Distribution Agreement. The GSK Distribution Agreement expired on December 31, 2021 as part of our planned transition of these distribution services to Bavarian Nordic, as described further above.

Under the GSK Distribution Agreement, we had a co-exclusive right to deliver, distribute, market, sell, promote, and import IXIARO in Germany solely with respect to certain non-profit organizations. Pursuant to the GSK Distribution Agreement, GSK was required to use reasonable commercial efforts to promote, sell and distribute IXIARO in Germany and was required to purchase an agreed upon minimum quantity of IXIARO doses during each year of the agreement. In connection with the GSK Distribution Agreement, we were obligated to supply (or designate a third-party entity to supply) GSK with all of its IXIARO supply requirements, subject to our reserved right to modify or discontinue manufacture and sale of IXIARO at our discretion. The GSK Distribution Agreement further provided that GSK must not manufacture, market, file applications for regulatory approval, distribute, sell or promote, in Germany a directly competing product that is a generic substitute for IXIARO.

Agreements Relating to Product Development and Manufacturing

Pfizer License Agreement

In April 2020, we entered into a research collaboration and license agreement, or the Pfizer License, with Pfizer. In June 2022, Valneva Austria and Pfizer amended the Pfizer License. In connection with the Pfizer License, as amended, we granted to Pfizer (a) an exclusive, worldwide, sublicensable license under certain patents, know-how, and materials and (b) a non-exclusive, worldwide, sublicensable license under all patents, know-how or other intellectual property rights controlled by us, in each case to use, have used, develop, have developed, manufacture, have manufactured, commercialize, have commercialized and otherwise exploit VLA15 and related products for all therapeutic, diagnostic and prophylactic human and veterinary use. Under the Pfizer License, we also obtained, during the development term, a non-exclusive, royalty-free, fully paid-up, worldwide license with the right to sublicense to subcontractors under certain patents and know-how controlled by Pfizer and patents and know-how developed under the Pfizer License to perform development activities relating to VLA15 and related products.

We are obligated to grant licenses or sublicenses that are consistent with the Pfizer License directly to affiliates of Pfizer upon Pfizer’s written request. Each party also granted the other a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up worldwide license for research purposes with the right to sublicense to affiliates under its know-how, materials, and confidential information disclosed under the agreement.

In connection with the Pfizer License, we may not develop or exploit a competing product, and we must use commercially reasonable efforts to perform assigned obligations under a development plan. As partial consideration for the license grant, Pfizer paid us a one-time upfront payment of \$130 million on June 15, 2020. We and Pfizer will each contribute towards development costs, and Pfizer is obligated to pay us up to \$178 million in development milestones and low double-digit tiered royalties starting at 14% on net sales of licensed products, subject to specified offsets and reductions. Of this \$178 million, (i) \$143 million is comprised of additional payments related to the first stages of commercialization of VLA15 in the United States and Europe as well as the approval of the vaccine, (ii) \$10 million is comprised of payments linked to development milestones related to the initiation of the VLA15-221 clinical study and was received in 2021, and (iii) \$25 million related to the initiation of the Phase 3 clinical trial and was received in 2022. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country and ending on the last to occur of the date on which the sale, offer for sale or importation of such licensed product in such country would infringe, but for the license granted here, a valid claim covering such licensed product in such country and fifteen years after the first commercial sale of such licensed product in such country. In addition, the royalties will be supplemented by milestone payments of up to \$100 million, payable to Valneva based on cumulative sales.

The Pfizer License expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term for any licensed product in such country. Pfizer may terminate the agreement (a) on a licensed product-by-licensed product and country-by-country basis or in its entirety for convenience or any uncured material breach by us, (b) in whole or relevant part for certain violations of global trade control laws prior to the first regulatory approval of a licensed product, or (c) for our breach of certain representations and warranties or other failure to comply with specified laws. We may terminate the agreement on a licensed product-by-licensed product and country-by-country basis for any uncured material breaches by Pfizer of any of its diligence obligations, or in its entirety for any uncured material breach of the agreement by Pfizer.

Following the signature of the amendment to the Pfizer License in June 2022, Valneva will finance 40% of the costs of Phase 3 costs, compared to 30% in the initial agreement, resulting in €45.9 million negative revenue in the year ended

December 31, 2022. In addition, Pfizer is paying Valneva royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement.

On June 22, 2022, Pfizer invested €90.5 million (\$95 million), or 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase designed to strengthen the strategic partnership between the two companies in Lyme disease. Valneva used the proceeds of this investment to finance a portion of its contribution to the Phase 3 Lyme program.

CEPI Funding Agreement

In July 2019, we entered into a funding agreement, or the CEPI Agreement, with CEPI. In connection with the CEPI Agreement, we were awarded up to \$23.4 million in funding (paid in a series of six-month tranches) to further develop a chikungunya vaccine, or the product, and we are obligated to provide equitable access to project results on the terms and conditions of the CEPI Agreement. In 2022, the amount of funding we are eligible to receive under the CEPI Agreement was increased to \$24.6 million. Under the CEPI Agreement, equitable access means the regular supply of chikungunya vaccines in all Non-Traveler's Market Countries (as defined in the CEPI Agreement, covering mostly low and middle income countries) that have a demand for the vaccines at an affordable price (as defined in the CEPI Agreement) and, in the context of an outbreak or increased outbreak preparation need, means that vaccines are first available to populations in the affected territory when and where they are needed. In addition, we granted CEPI a limited non-exclusive, fully paid-up, sublicensable license, referred to as the Public Health License, under the project results and other intellectual property necessary to enable CEPI or a third party designated by CEPI to develop, manufacture, market, and/or supply the product worldwide solely to end users in an affected territory in preparation for or response to an outbreak. Such Public Health License shall only be effective upon specified license triggers.

We are obligated to pay CEPI up to \$7.0 million in commercial and related milestones and to supply CEPI with specified quantities of the chikungunya drug product or investigational product in case of an outbreak or increased outbreak preparation need. This includes maintaining at our cost a one-year rolling safety stock comprised of not less than 200,000 doses of chikungunya vaccines, referred to as the Safety Stock. In case the Safety Stock is used to address an outbreak or increased outbreak preparation need, and CEPI wishes to replenish such Safety Stock, CEPI shall pay us the related production costs.

Either party may terminate the CEPI Agreement upon an uncured material breach of the agreement or insolvency of the other party. CEPI may also terminate the agreement if we are unable to discharge our obligations, for safety, regulatory, or ethical issues, if we do not satisfy specified criteria for funding, if there are material changes to the development plan without CEPI's prior written consent, or during the term any affiliate to whom we have assigned or transferred the agreement ceases to be our affiliate. We may also terminate the agreement (in whole or with respect to certain markets) for convenience at any time after 10 years following the grant of U.S. marketing approval for the product, at any time after three years following the grant of U.S. marketing approval for the product if we are unable to sell the product at a viable price, or if CEPI transfers or assigns the agreement other than to specified entities. Following the last to occur of (a) the granting of U.S. marketing approval for the product and (b) such approval in the first low income country, in the event we undergo a change of control or sell the entire chikungunya business, we may also terminate the agreement. In each of these terminations by Valneva, we have obligations to collaborate with CEPI for two years to find a third party supplier to whom our obligations under the CEPI Agreement will be assigned and to transfer the drug substance and drug product technology and related intellectual property (with the exception of trademarks) to such third party supplier. In lieu of such transfer, after two years following termination, the CEPI Agreement will be suspended, except for certain continuing obligations, until we and CEPI agree to continue the program appropriate to the circumstances.

In connection with our obligations under the CEPI Agreement, and following the execution of a binding term sheet in May 2020, in January 2021 we entered into definitive agreements with Instituto Butantan, a Brazilian public institute, and Fundação Butantan, a Brazilian non-profitable private foundation of the Instituto Butantan, which we refer to jointly as Butantan, engaged in the research, development, manufacture, and commercialization of vaccines in Brazil, pursuant to which we and Butantan intend to collaborate to transfer our drug product technology to Butantan, to enable Butantan to develop, manufacture, and commercialize our chikungunya vaccine in Latin America and in certain low and middle income countries and obtain WHO prequalification. In turn, Butantan will provide certain clinical and Phase 4 observational studies that we will use to meet regulatory requirements with the FDA. Butantan will also have to comply with certain CEPI requirements, among others, equitable access to the product and outbreak related obligations, including maintaining a Safety Stock.

IDT Commercial Manufacturing Services Agreement and VLA1553 Product Schedule

In November 2021, Valneva Austria GmbH entered into a non-exclusive commercial manufacturing services agreement, or the IDT Agreement, with IDT Biologika GmbH, or IDT, pursuant to which IDT would provide contract manufacturing services under separate product schedules. For a description of the now-terminated product schedule relating to VLA2001, see “—Agreements Relating to Our COVID-19 Vaccine Program—IDT Product Schedule for VLA2001”. The IDT Agreement will expire in November 2026 unless previously terminated. Valneva may terminate the IDT Agreement for convenience. Either party may terminate the IDT Agreement or the separate product schedules, in whole or in part, in case of material breach, insolvency, or certain compliance failures.

Valneva and IDT entered into a product schedule pertaining to the manufacturing of VLA1553, or the VLA1553 Product Schedule, in December 2022. Pursuant to the VLA1553 Product Schedule, IDT will perform the lyophilization process on a specified number of bulk drug substance batches of VLA1553 received from Valneva. The VLA1553 Product Schedule will remain in place until December 31, 2029 and will automatically renew thereafter unless previously terminated.

Manufacturing Agreement with Vetter Pharma International

In April 2023, Valneva Austria GmbH entered into a non-exclusive commercial manufacturing services agreement, or the Vetter Agreement, with Vetter Pharma International GmbH, or Vetter, pursuant to which Vetter will provide syringes pre-filled with sterilized water in connection with the manufacturing of IXCHIQ. The maximum estimated value of the Vetter Agreement during the initial term is approximately €26.9 million. The Vetter Agreement will expire in April 2028 unless previously terminated and may be renewed for subsequent terms. Either party may terminate the Vetter Agreement in case of breach or insolvency on the part of the other party, and Vetter may terminate in case of a change of control of Valneva involving a Vetter competitor or in case the parties cannot agree on changes to manufacturing processes or prices that may be requested by Valneva.

Agreements Relating to Our COVID-19 Vaccine Program

EC Advance Purchase Agreement

In November 2021, Valneva Austria GmbH entered into an advance purchase agreement, or the EC APA, for Valneva’s SARS-CoV-2 vaccine candidate, or the Product, with the European Commission, or EC. Following the notice of intent to terminate the EC APA issued by the EC on May 13, 2022 because VLA2001 did not receive a marketing authorization from the European Medicines Agency (EMA) by April 30, 2022, Valneva and the EC entered into an amendment to the EC APA on July 29, 2022. Under the terms of the EC APA, Valneva had 30 days from May 13, 2022 to obtain marketing authorization or to propose a plan to remedy the situation in an acceptable manner. As a result of the remediation plan submitted by Valneva in early June, an amendment to the EC APA was entered into on July 29, 2022.

The EC APA originally included an order for approximately 24.3 million doses of Product to be delivered to participating Member States in 2022 and allowed participating Member States to purchase up to approximately 35.7 million doses of Product for delivery in 2023. Participating Member States made upfront payments equal to a certain percentage of the total purchase price for their respective quantities of Product. The EC APA, as amended, included an order for 1.25 million doses of the Product for delivery in 2022 and allowed the participating Member States (Austria, Denmark, Finland, Germany, and Bulgaria) that received these doses to order up to an additional equivalent amount for delivery in 2022. The amount of the advance payments received by Valneva under the initial agreement is €117 million (recorded as contract liabilities). We have no obligation to repay these sums, which had been committed and/or spent in accordance with the terms of the initial agreement.

The EC APA remained in effect until all quantities of the Product ordered under the EC APA, as amended, were delivered. As of December 31, 2023, we have no continuing material obligations under the EC APA.

Dynavax Supply Agreement

In September 2020, Valneva Scotland Limited and Valneva Austria GmbH entered into a supply agreement, or the Dynavax Agreement, with Dynavax Technologies Corporation, or Dynavax, pursuant to which Dynavax is obligated to manufacture and supply us with all of our requirements for certain component materials of our proprietary SARS-CoV-2 vaccine, or the Antigen, for use in the manufacture, commercialization, and supply of a product containing or comprising the Antigen and Dynavax’s proprietary adjuvant, which together with the Antigen is referred to as the Product, to prevent, treat, or ameliorate COVID-19 in humans, including for such use in connection with the UK Supply Agreement. We shall jointly own with Dynavax all patents that relate to the combination of the Antigen and Dynavax’s adjuvant. We obtained an exclusive (even as to Dynavax), worldwide, fully-paid-up, sublicensable (including through multiple tiers), transferable, royalty free license under these joint patents to make, use, develop, sell, and otherwise commercialize the Product or biosimilar versions thereof. The Dynavax Agreement included an initial purchase order commitment amount of up to \$136.8 million. On October 28, 2021, we entered into an amendment to the Dynavax Agreement. This amendment cancelled two previously placed purchase orders and included one further purchase order.

As amended, the Dynavax Agreement continued until Dynavax delivered all of the product ordered by Valneva.

IDT Product Schedule for VLA2001

In November 2021, Valneva Austria GmbH entered into a non-exclusive commercial manufacturing services agreement, or the IDT Agreement, as described above in “–Agreements Relating to Our Product Candidates–IDT Commercial Manufacturing Services Agreement and VLA1553 Product Schedule”.

A product schedule pertaining to Valneva’s proprietary vaccine candidate VLA2001, or the VLA2001 Product Schedule, provided that IDT would manufacture a certain number of batches of VLA2001 during the year ending December 31, 2022, with an option for IDT to manufacture additional batches during 2023. The maximum value of the VLA2001 Product Schedule, including the exercise of the maximum amount under the option, was approximately €280.6 million. In September 2022, following our decision to suspend manufacturing of VLA2001, Valneva and IDT announced the termination of the VLA2001 Product Schedule. Valneva agreed to pay IDT €36.2 million in cash and the equivalent of €4.5 million in kind, in the form of specified equipment purchased by Valneva.

UK Supply Agreement

In September 2020, Valneva Austria GmbH entered into a supply agreement, or the UK Supply Agreement, with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom, or the UK Authority, pursuant to which we were obligated to develop, manufacture, and supply SARS-CoV-2 vaccines to the UK Authority in the United

Kingdom of Great Britain and Northern Ireland, or the UK, including an obligation for us to upgrade our manufacturing facilities in Scotland using funds provided in large part by the UK Authority. Our new Almeida facility is the result of this upgrade. Valneva received notice in September 2021 of the UK Authority’s decision to terminate the UK Supply Agreement. Valneva had not received any indication from the UK Authority prior to that date of its intention to terminate the agreement. The termination, based on the UK Authority’s discretionary right to terminate for convenience, became effective on October 10, 2021. On June 15, 2022, Valneva and the UK Authority entered into a settlement agreement, or the Settlement Agreement, that resolves certain matters relating to the obligations of Valneva and the UK Authority following the termination of the UK Supply Agreement and also clarifies other matters contained in the parallel clinical trials agreement, which remains in force. Certain of Valneva’s obligations remain in effect despite the termination of the UK Supply Agreement, as explained below.

Under the UK Supply Agreement, we were obligated to use commercially reasonable efforts to develop the vaccine candidate, to secure marketing authorization (and to prosecute the application for minimum viable marketing authorization) in the UK, to conduct assigned activities in accordance with the facility and manufacturing plans and to perform other activities, including working with third parties to maintain sufficient manufacturing capacity. Under the terms of the UK Supply Agreement, the UK Authority had placed an initial order for 60 million doses to be delivered in 2021. In January 2021, the UK Authority exercised its option to order 40 million doses for delivery in 2022. Under the terms of the UK Supply Agreement, the UK Authority was required to make advance payments to Valneva to fund certain manufacturing-related expenses during the term of the project, subject to Valneva continuing to supply product in accordance with the terms of the UK Supply Agreement. As of December 31, 2021, the Group had received advances totaling £359.2 million (€408.3 million). The total amount of payments, including funds received in 2022, amounts to €420.6 million and breaks down as follows: (i) €47.5 million under the Settlement Agreement, (ii) €78 million related to capital expenditures and (iii) the remainder corresponding to prepayments under the UK Supply Agreement for vaccine doses.

Under the Settlement Agreement, we are required to pay the UK Authority a low single-digit royalty on net sales to non-UK customers of products manufactured in facilities used under the UK Supply Agreement, with a cap of €100 million. This obligation remains in effect after the termination of the UK Supply Agreement and after the Settlement Agreement, above a certain sales threshold. We have not recorded any repayment obligations under the royalties, as we consider the probability of repayment to be low. For further information, please refer to Note 5.5.2 of our financial statements for the year ended December 31, 2023, included elsewhere in this Annual Report. Through December 31, 2022, we had an obligation to repay the advances received from the UK Supply Agreement in connection with the new Almeida facility in the event of a sale, transfer or reallocation of those assets. This obligation amounted to €81.9 million and was recognized in our accounts as other revenue as of December 31, 2022 following the expiration of this condition on the same date.

D. Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

E. Taxation

Material U.S. federal income tax considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person’s decision to acquire securities. This discussion applies only to a U.S. Holder that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder’s particular circumstances, including state, local, and non-U.S. tax consequences, estate tax consequences, alternative minimum tax consequences, the impact of Special tax accounting rules under Section 451(b) of the Code, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, “straddle,” wash sale, conversion transaction or integrated transaction, or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose “functional currency” for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers, or traders in securities, commodities, or currencies;
- tax-exempt entities or government organizations;

- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding shares or ADSs in connection with a trade or business outside the United States;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between France and the United States, or the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect.

A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

- (1) an individual who is a citizen or resident of the United States;
- (2) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- (3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- (4) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local, and non-U.S. tax consequences of owning and disposing of ordinary shares or ADSs in their particular circumstances.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

Passive Foreign Investment Company rules

Under the Code, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the value of our assets (generally determined on the basis of a weighted quarterly average) consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property, and certain rents and royalties. Cash and cash-equivalents are passive assets for these purposes. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation or partnership is treated as holding and receiving directly its proportionate share of assets and income of such corporation or partnership. If we are a PFIC for any taxable year during which a U.S. Holder holds our shares, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

We do not believe that we were characterized as a PFIC for the year ended December 31, 2023. However, the determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year. In addition, the total value of our assets for PFIC testing purposes (including goodwill) may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Accordingly, if our market capitalization declines while we hold a substantial amount of cash and cash-equivalents for any taxable year we may be a PFIC for that taxable year. Under the income test, our status as a PFIC depends on the composition of our income for the relevant taxable year which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current, or future taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. Holder has made a “deemed sale” election under the PFIC rules. If such a deemed sale election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder’s ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any “excess distribution” the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we are a PFIC and cease to be a PFIC and such election becomes available.

For each taxable year that we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any “excess distribution” such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including a pledge) of ordinary shares or ADSs, unless our ordinary shares or ADSs constitute “marketable stock” and such U.S. Holder makes a mark-to-market election (as discussed below). Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder’s holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder’s holding period for the ordinary shares or ADSs;
- the amount allocated to the taxable year of the disposition or distribution (as applicable), and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries or any other entities in which we hold equity interests that also are PFICs, or lower-tier PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to lower-tier PFICs.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making an effective QEF Election. However, a U.S. Holder can only make a QEF election with respect to ordinary shares or ADSs in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. We do not presently intend to provide the information required to allow a U.S. Holder to make a QEF election if we are a PFIC.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are “marketable stock.” Ordinary shares or ADSs will be marketable stock if they are “regularly traded” on certain U.S. stock exchanges or on a non-U.S. stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be listed on the Nasdaq Global Select Market, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq Global Select Market and are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to U.S. Holders if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder’s adjusted tax basis in the ordinary shares or ADSs. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder’s adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs in any year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ordinary shares or ADSs cease to be marketable stock.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves “marketable stock.” As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the

PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an Annual Report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the Annual Report may result in substantial penalties and extend the statute of limitations with respect to the U.S. Holder's federal income tax return. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Taxation of distributions

Subject to the discussion above under "Passive Foreign Investment Company rules," distributions paid on ordinary shares or ADSs, other than certain *pro rata* distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder for our taxable year of the distribution or the preceding taxable year. The amount of a dividend will include any amounts withheld by us in respect of French income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain *pro rata* distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit purposes, our dividends will generally be treated as passive category income. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, any French income taxes withheld from dividends on ordinary shares or ADSs at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. Recently issued U.S. Treasury regulations, which apply to foreign taxes paid or accrued in taxable years beginning on or after December 28, 2021, may in some circumstances prohibit a U.S. Holder from claiming a foreign tax credit with respect to certain foreign taxes that are not creditable under applicable tax treaties. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any French income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or other taxable disposition of ordinary shares and ADSs

Subject to the discussion above under "Passive Foreign Investment Company rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals and certain closely-held entities may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by financial institutions, in which case the accounts themselves may have to be reported if maintained by non-U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

Material French Tax Considerations

The following describes the material French income tax consequences to U.S. holders of purchasing, owning, and disposing of our ADSs.

This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership, or disposition of our ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

The following discussion does not address the French tax consequences applicable to securities (including ADSs) held in trusts. If ADSs are held in trust, the grantor, trustee, and beneficiary are advised to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of such securities.

The description of the French income tax and real estate wealth tax consequences set forth below is based on the double tax treaty entered into between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, or the Treaty, which came into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax guidelines issued by the French tax authorities in force as of the date of this Annual Report, or the Treaty.

If a partnership holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership is urged to consult its own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of ADSs.

This discussion applies only to investors that hold ADSs as capital assets that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the ADSs is not effectively connected to a permanent establishment or a fixed base in France. Certain U.S. holders may be subject to special rules not discussed below, and are advised to consult their usual tax advisor regarding the specific tax consequences which may apply to their particular situation.

U.S. holders are advised to consult their own tax advisor regarding the tax consequences of the purchase, ownership, and disposition of ADSs in light of their particular circumstances, especially with regard to the "Limitations on Benefits" provision contained in the Treaty.

Tax on Sale or Other Disposals

As a matter of principle, under French tax law, a U.S. holder should not be subject to any French tax on any capital gain from the sale, exchange, repurchase, or redemption by us of ADSs, provided such U.S. holder is not a French resident for French tax purposes and has not held more than 25% of our dividend rights, known as "*droits aux bénéfices sociaux*," at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives (as an exception, a U.S. holder resident, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the French tax code ("*Code général des impôts*," or the FTC), other than those mentioned in Article 238-0 A, 2 bis, 2° of the FTC, may be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds).

Under application of the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty and is entitled to Treaty benefits will not be subject to French tax on such capital gain unless the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. U.S. holders who own ADSs through U.S. partnerships that are not resident for Treaty purposes are advised to consult their own tax advisor regarding their French tax treatment and their eligibility for Treaty benefits in light of their own particular circumstances. A U.S. holder that is not a U.S. resident for Treaty purposes or is not entitled to Treaty benefits (and in both cases is not resident, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC) and has held more than 25% of our dividend rights, known as "*droits aux bénéfices sociaux*" at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives may be subject to a levy in France (i) at the rate of 12.8% for individuals, and (ii) a rate of 25% for legal persons. Pursuant to Article 244 bis B of the FTC, such legal persons, whatever their form, may obtain a refund of the portion of such withholding tax which exceeds the corporate

income tax which they would have been liable to pay if their registered seat had been located in France, provided that (i) they do not effectively either participate in our management or our control and (ii) their registered office is located in a State or territory that has concluded a tax treaty with France that contains an administrative assistance clause on the exchange of information and the fight against tax fraud and tax evasion and that is not a non-cooperative State or territory within the meaning of Article 238-0 A of the FTC.

Financial Transactions Tax and Registration Duties

Pursuant to Article 235 *ter* ZD of the FTC, purchases of ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the AMF are subject to a 0.3% French tax on financial transactions provided that the issuer's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year, within the meaning of Article 235 *ter* ZD of the FTC, is published annually by the French tax authorities in their official guidelines.

As at December 1, 2023, our market capitalization did not exceed 1 billion euros, pursuant to BOI-ANNN-000467-20/12/2023.

As a result, the acquisition of ADSs is currently out of the scope of the tax on financial transactions, but this may change in the future. Purchases of our ADSs may, however, become subject to the tax on financial transactions as from January 1, 2025, provided that our market capitalization exceeds 1 billion euros as at December 1, 2024 and that the Nasdaq Global Market is acknowledged by the French AMF.

In the case where Article 235 *ter* ZD of the FTC is not applicable, the French tax code provides that transfers of shares—issued by a French company which are listed on a regulated or organized market within the meaning of Articles L421-1 and L424-1 of French monetary code (*Code monétaire et financier*) or, pursuant to French tax administrative doctrine (BOI-ENR-DMTOM-40-10-10-12/09/2012 # 50), listed on another similar regulated or organized market operating under similar conditions—are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written deed (*acte*) executed either in France or outside France.

However neither the French tax code, nor case law or official guidelines published by the French tax authorities indicate if the transfer of ADSs should be in the scope of the above-mentioned registration duties. As a result, transfer of ADSs should remain outside of the scope of such registration duties. U.S. Holders are urged to consult their own tax advisor about the possible application of the registration duty upon the transfer of ADSs.

Taxation of Dividends

Dividends paid by a French corporation to non-residents of France are generally subject to French withholding tax at a rate of currently (i) 25% for payment benefiting legal persons which are not French tax residents, and (ii) 12.8% for payment benefiting individuals who are not French tax residents. Dividends paid by a French corporation in non-cooperative States or territories, as defined in Article 238-0 A of the FTC other than those mentioned in Article 238-0 A, 2 bis, 2° of the FTC, will generally be subject to French withholding tax at a rate of 75% unless the company which pays the dividend proves that the distribution of such proceeds in that State or territory has neither the object nor the effect of permitting their location in such State or territory for the purpose of tax evasion).

However, eligible U.S. holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to this 12.8% or 25%, or 75% withholding tax rate, but may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is generally reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuer; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any.

For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complex, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisor regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that:

- such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000) in accordance with French guidelines (BOI-INT-DG-20-20-20-12/09/2012 dated September 12, 2012); or
- the depositary or other financial institution managing the securities account in the U.S. of such holder provides the French paying agent with a document listing certain information about the U.S. holder and its ADSs and a certificate whereby the financial institution managing the U.S. holder's securities account in the United States takes full responsibility for the accuracy of the information provided in the document.

Otherwise, dividends paid to a U.S. holder, if such U.S. holder is a legal person, will be subject to French withholding tax at the rate of 25%, or 75% if paid in certain non-cooperative States or territories (as defined in Article 238-0 A of the FTC other than those mentioned in Article 238-0 A, 2 bis, 2° of the FTC), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Certain qualifying pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary. The depositary will arrange for the filing with the French tax authorities of all such forms properly completed and executed by U.S. holders of ADSs and returned to the depositary in sufficient time so that they may be filed with the French tax authorities before the distribution in order to immediately obtain a reduced withholding tax rate. Otherwise, the depositary must withhold tax at the full rate of 25% or 75% as applicable. In that case, the U.S. holders may claim a refund from the French tax authorities of the excess withholding tax.

Estate and Gift Taxes

In general, a transfer of securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the double tax treaty entered into between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978 (as amended), unless (i) the donor or the transferor has the French citizenship or is domiciled in France at the time of making the gift or at the time of his or her death, or (ii) the ADSs were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Wealth Tax

Since January 1, 2018, the French wealth tax (*impôt de solidarité sur la fortune*) has been repealed and replaced by the French real estate wealth tax (*impôt sur la fortune immobilière*). The scope of such new tax is narrowed to real estate assets (and certain assets deemed to be real estate assets) or rights, held directly or indirectly through one or more legal entities and whose net taxable assets amount at least to €1,300,000.

Broadly, subject to provisions of double tax treaties and to certain exceptions, individuals who are not residents of France for tax purposes within the meaning of Article 4 B of the FTC, are subject to real estate wealth tax (*impôt sur la fortune immobilière*) in France in respect of the portion of the value of their shares of our company representing real estate assets (Article 965, 2° of the FTC). Some exceptions are provided by the FTC. For instance, any participations representing less than 10% of the share capital of an operational company and shares representing real estate for the professional use of the company considered shall not fall within the scope of the French real estate wealth tax (*impôt sur la fortune immobilière*).

Under the Treaty (the provisions of which should be applicable to this new real estate wealth tax (*impôt sur la fortune immobilière*) in France), the French real estate wealth tax (*impôt sur la fortune immobilière*) will however generally not apply to securities held by an eligible U.S. holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that such U.S. holder (i) does not own directly or indirectly more than 25% of the issuer's financial rights and (ii) that the ADSs do not form part of the business property of a permanent establishment or fixed base in France.

U.S. holders are advised to consult their own tax advisor regarding the specific tax consequences which may apply to their particular situation with respect to such French real estate wealth tax (*impôt sur la fortune immobilière*).

THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL FRENCH AND U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are

registered under the Exchange Act. Nevertheless, we file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with an opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.valneva.com. We intend to post our Annual Report on Form 20-F on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders.

Not applicable.

Item 11. Quantitative and Qualitative Disclosures about Market Risk

We operate internationally and are exposed to foreign exchange risks arising from various currencies, primarily with respect to the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK) and the U.S. Dollar (USD). The foreign exchange risks from the exposure to other currencies, including the Danish Krone, the Swiss Franc and the Norwegian Krone, are relatively limited. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations. Our objective is to limit the potential negative impact of the foreign exchange rate changes, for example by currency conversion of cash and cash equivalents denominated in foreign currency and by using foreign currency options. We have certain investments in foreign operations, the net assets of which are exposed to foreign currency translation risk.

With all other variables held constant, the impact from changes in exchange rates on the pre-tax result would be as follows:

in € thousand	Year ended December 31	
	2023	2022
\$/EUR +10%	(24,079)	(21,245)
\$/EUR -10%	29,430	25,966
GBP/EUR +10%	4,760	3,941
GBP/EUR -10%	(5,817)	(4,817)
SEK/EUR +10%	(8,846)	(9,318)
SEK/EUR -10%	10,812	11,388
CAD/EUR +10%	2,368	2,011
CAD/EUR -10%	(2,894)	(2,457)

The effect in the \$/EUR relationship is mostly due to borrowings denominated in US-Dollar while the cash and working capital is predominantly on a Euro basis. Due to higher borrowings in the year ended December 31, 2023, the Group's sensitivity has slightly increased. The Group has not used any hedging instruments to reduce the impact of foreign exchange rate changes.

A. Interest Rate Risk

We are exposed to market risks in connection with hedging both of our liquid assets and of our medium and long-term indebtedness and borrowings subject to variable interest rates. Borrowings issued at variable rates expose us to cash flow interest rate risks, which are offset by cash and financial assets held at variable rates. During 2023, as well as 2022 and 2021, the Group's investments at variable rates, as well as the borrowings at variable rates, were denominated in EUR, SEK, USD, CAD, and GBP. We analyze our interest rate exposure on a dynamic basis. Based on this analysis, we calculate the impact on profit and loss of a defined interest rate change. The same interest rate change is used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As at December 31, 2023 and December 31, 2022, no material interest risk was identified. In case of increasing interest rates, the positive effect from cash in banks will be higher than the negative effect from variable interest-bearing liabilities. In case of decreasing interest rates, there will be no material negative impact.

B. Credit Risk

We are exposed to credit risk. We hold bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of our counterparts, we rely on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. We have policies that limit the amount of credit exposure to any single financial institution. We are also exposed to credit risks from our trade debtors, as our income from product sales, collaborations, licensing, and services arises from a small number of transactions. We have policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits as set by the Management Board.

C. Interim Periods

Not applicable.

D. Safe Harbor

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Special Note Regarding Forward-Looking Statements.”

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Citibank, as depositary, registers and delivers our ADSs. Each ADS represents two ordinary shares deposited with Citibank Europe plc, located at 1 North Wall Quay, Dublin 1 Ireland or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The depositary’s corporate trust offices at which the ADSs will be administered are located at 388 Greenwich Street, New York, New York 10013.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-ordinary share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. 5¢ per ADS issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to ordinary share ratio, or for any other reason)	Up to U.S. 5¢ per ADS cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. 5¢ per ADS held
ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary
Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason)	Up to U.S. 5¢ per ADS (or fraction thereof) transferred
Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and vice versa).	Up to U.S. 5¢ per ADS (or fraction thereof) converted

ADS holders are also responsible for paying certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary, or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex, and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes, and other charges of the depositary and/or service providers (which may be a division, branch or affiliate of the depositary) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs, and expenses incurred by the depositary, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom the ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of

such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

Taxes

ADS holders are responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary, and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You are liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split, and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary, and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Use of Proceeds

May 2021 Global Offering

In May 2021, we announced the closing of a global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares, after full exercise of the overallotment option granted to the underwriters. The public offering consisted of 2,850,088 ADSs, each representing two ordinary shares, in the United States at an offering price of \$26.41 per ADS and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option were €89.6 million, whereas related expenses of €6.8 million were incurred. Net proceeds of this global offering were €82.8 million.

Goldman Sachs Bank Europe SE, Jefferies International Limited, Jefferies GmbH, and Jefferies LLC were the representatives of the underwriters in this offering.

The net proceeds from this offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering filed with the U.S. Securities and Exchange Commission on May 7, 2021. None of the net proceeds of the global offering were paid directly or indirectly to any director, officer, or general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

November 2021 Global Offering

In November 2021, we announced the closing of a global offering to specified categories of investors of an aggregate of 5,175,000 new ordinary shares, after full exercise of the overallotment option granted to the underwriters. The public offering consisted of 354,060 ADSs, each representing two ordinary shares, in the United States at an offering price of \$39.4160 per ADS and a concurrent private placement of 4,466,880 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €17.00 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option, were approximately €88.0 million, whereas related expenses of €6.7 million were incurred. Net proceeds of this global offering were €81.3 million.

Goldman Sachs Bank Europe SE, Jefferies International Limited, Jefferies GmbH, and Jefferies LLC were the representatives of the underwriters in this offering.

The net proceeds from this offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering filed with the U.S. Securities and Exchange Commission on November 1, 2021. None of the net proceeds of the global offering were paid directly or indirectly to any director, officer, or general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

October 2022 Global Offering

In October 2022, we announced the closing of a global offering to specified categories of investors of an aggregate of 21,000,000 new ordinary shares, after full exercise of the over-allotment option granted to the underwriters. The public offering consisted of 375,000 ADSs, each representing two ordinary shares, in the United States at an offering price of \$9.51 per ADS and a concurrent private placement of 20,250,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €4.90 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option, were approximately €102.9 million, whereas related expenses of €7.4 million were incurred. Net proceeds of this global offering were €96.0 million.

Goldman Sachs Bank Europe SE, Jefferies GmbH, and Jefferies LLC were the representatives of the underwriters in this offering.

The net proceeds from this offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering filed with the U.S. Securities and Exchange Commission on September 30, 2022. None of the net proceeds of the global offering were paid directly or indirectly to any director, officer, or general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and our chief financial officer (principal financial officer), has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13(a)-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended, “the Exchange Act”), as of December 31, 2023. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2023.

B. Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with International Financial Reporting Standards.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, including the possibility of human error, the circumvention or overriding of controls, or fraud. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements.

Under the supervision and with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), management conducted an assessment of the effectiveness of our internal control over financial reporting based upon the framework in “Internal Control — Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2023. The effectiveness of our internal control over financial reporting as of December 31, 2023, has been audited by PricewaterhouseCoopers Audit and Deloitte & Associés, independent registered public accounting firms, as stated in their report which appears under Item 15 C.

Remediation of Previously Reported Material Weaknesses

As previously disclosed in “Item 15 — Controls and Procedures” of our Annual Report on Form 20-F for the year ended December 31, 2022, our management identified deficiencies in our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company’s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Description of Previous Deficiencies

For the year ended December 31, 2022, the Company identified deficiencies in the control environment, risk assessment, control activities, information, and communication and monitoring components of the COSO framework that constitute material weaknesses, either individually or in the aggregate. The deficiencies in these components of the COSO framework from the year ended December 31, 2022 are discussed further below and resulted from the lack of resources in Valneva, commensurate with the nature, growth, and complexity of its business.

Control Environment

The Company identified a deficiency in one of the principles associated with the Control Environment component of the COSO framework, specifically relating to a lack of resources to: (i) design and implement certain risk-mitigating internal controls; and (ii) consistently operate certain of our internal controls. This deficiency contributed to other material weaknesses within our system of internal control over financial reporting in the remaining COSO framework components.

Risk Assessment

Management identified a deficiency in one of the principles associated with the Risk Assessment component of the COSO framework as the Company did not design and implement an effective risk assessment to identify and assess all changes in the business that could impact its system of internal controls.

Control Activities

The Company also identified deficiencies in the principles associated with the Control Activities component of the COSO framework, specifically relating to the design and deployment of control activities through policies that establish what is expected and procedures that put policies into action.

Information and Communication

The Company identified a deficiency in one of the principles associated with the Information and Communication component of the COSO framework as the Company did not establish a process to identify, maintain, and develop all control activities over the financial consolidation and reporting system.

Monitoring Activities

Further, the Company did not maintain effective monitoring activities in all instances, based on the criteria established in the COSO framework, relating to evaluating and communicating internal control deficiencies in a timely manner to those parties responsible for taking corrective actions.

Remediation Activities

Beginning in the second half of 2022 and throughout 2023, management implemented an extensive remediation plan to address the material weaknesses as noted below.

Control Environment

The Company recruited key control owners with appropriate knowledge and experience, engaged third party advisors, and enhanced organization-wide training to adequately support the goal of enhancing the Company’s internal control framework.

Risk Assessment

The Company performed iterative risk assessment activities and established a process to continually evaluate the business throughout the reporting period to allow for timely identification of risks with potential to impact internal controls over financial reporting. This process included performing periodic scoping assessments. The Company executed the remediation plans for the identified control deficiencies and tested the effectiveness of the remediated controls.

Control Activities

The Company established policies and procedures, including the improvements to process flows and control review documentation requirements. The Company provided ongoing training to finance and operations personnel concerning the application of these new policies and procedures. The Company subsequently tested the effectiveness of key controls to ensure control activities were properly executed.

Information and Communication

The Company designed and implemented controls over the financial consolidation and reporting system and associated processes to mitigate risks around key applications and data utilized in the production of the consolidated financial statements.

The Company established a robust process to identify, maintain, and develop key control activities over the consolidation and financial reporting system and processes. This included a comprehensive risk assessment of the Company’s processes and controls and data produced by relevant service organizations. The Company reviewed system and organization controls (SOC) reports for those service organizations to validate that key risks are sufficiently addressed through our updated controls framework, and where applicable, performed compensating activities.

Monitoring Activities

The Company established a SOX Steering Committee to maintain effective monitoring, communication, and implementation of controls. The committee meets regularly and comprises the members of the Audit, Compliance, and Risk Committee of the Board of Directors and the Company’s CEO, CFO, Head of Internal Controls and SOX Compliance, and its external advisors.

The Company further strengthened its SOX governance by establishing a defined structure of monitoring and communicating control related matters via dedicated meetings with Senior Management, control owners, and its control advisors.

Conclusion

Management concluded that, due to the design, implementation and operating effectiveness of the controls described above over a sufficient period of time, and confirmed through testing of the controls, the previously identified material weaknesses have been remediated as of December 31, 2023.

C. Attestation Report of the Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS
To the Shareholders and Board of Directors of Valneva SE

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Valneva SE and its subsidiaries (together the “Company”) as of December 31, 2023, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control — Integrated Framework (2013) issued by the COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated statement of financial position of the Company as of December 31, 2023 and the related consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year ended December 31, 2023 (collectively the “consolidated financial statements”). Our report dated March 22, 2024 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying “Management’s Annual Report on Internal Control over Financial Reporting”. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers Audit /s/ Deloitte & Associés

Neuilly-sur-Seine and Bordeaux, France
March 22, 2024

PricewaterhouseCoopers Audit and Deloitte & Associés have served as the Company’s auditors since 2012 and 2007, respectively.

D. Changes in Internal Control Over Financial Reporting

Except for the changes in connection with our implementation of the remediation plan discussed above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

A. Audit Committee Financial Expert

Our Board of Directors has determined that Mr. Sulat, Mr. Connolly, and Ms. Ferrère are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Board of Directors has further determined that Mr. Sulat is an “audit committee financial expert” as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

B. Code of Ethics

We have adopted a Code of Conduct & Ethics applicable to all of our employees and members of our Board of Directors and Executive Committee. Our Code of Conduct & Ethics is available on our website. We expect that any amendments to the Code of Conduct & Ethics, or any waivers of its requirements, will be disclosed on our website. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Conduct & Ethics applies to our principal executive officer, principal financial officer, principal accounting officer, or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not incorporated by reference into this Annual Report and does not constitute a part of this Annual Report.

C. Principal Accountant Fees and Services

PricewaterhouseCoopers Audit and Deloitte & Associés served as our independent auditors for the year ended December 31, 2023 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Valneva and consolidated subsidiaries in the years ended December 31, 2023 and 2022.

Principal Accountant Fees and Services:												
in € thousand	Year ended December 31,											
	PricewaterhouseCoopers						Deloitte & Associés					
	2023	%	2022	%	2021	%	2023	%	2022	%	2021	%
Audit fees	2,076	98 %	1,891	99 %	1,122	91 %	1,902	99 %	1,678	99 %	1,113	93 %
provided by the statutory auditor	1,539	73 %	1,386	72 %	937	76 %	1,622	84 %	1,376	81 %	939	78 %
provided by the statutory auditor's network	537	25 %	505	26 %	185	15 %	280	15 %	302	18 %	174	15 %
Audit-related Fees	0	– %	0	– %	90	7 %	0	– %	13	1 %	85	7 %
provided by the statutory auditor	0	– %	0	– %	85	7 %	0	– %	13	1 %	85	7 %
provided by the statutory auditor's network	0	– %	0	– %	5	– %	0	– %	0	– %	0	– %
Tax Fees	40	2 %	25	1 %	25	2 %	0	– %	0	– %	0	– %
provided by the statutory auditor's network	40	2 %	25	1 %	25	2 %	0	– %	0	– %	0	– %
All Other Fees	0	– %	0	– %	0	– %	19	1 %	0	– %	0	– %
Total	2,116	100 %	1,916	100 %	1,238	100 %	1,921	100 %	1,691	100 %	1,199	100 %

“Audit fees” are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that PricewaterhouseCoopers and Deloitte & Associés provides, such as consents and assistance with and review of documents filed with the SEC.

“Audit-related Fees” are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

“Tax fees” are the aggregate tax fees billed for services related to the production of certification in the context of the declaration of expenses for the obtention of grants and the preparation of special reports relating to certain operations on the Company’s capital.

Auditor Name	Auditor Location	Auditor Firm ID
PricewaterhouseCoopers Audit	Neuilly-sur-Seine, France	1347
Deloitte & Associés	Paris, France	1756

Audit and Non-Audit Services Pre-Approval Policy

French law requires that audit committees pre-approve any non-audit services to be performed by a company’s statutory auditors. Additionally, French law requires audit committees to ensure that such non-audit services will not affect the independence of the statutory auditors in performing their audit services, and the fees received for non-audit services cannot exceed 70% of the total fees for audit services.

Accordingly, our Audit and Governance Committee, or the Committee, has authority to propose the retention and compensation of the Company’s registered public accounting firms and oversees the independence and performance of such firms with respect to both audit-related and non-audit-related services. The Committee may approve the provision of services other than the certification of financial statements by the auditors following an analysis of the potential impact of providing such services on the auditors’ independence and the approval of any safeguards that may be required to mitigate such impact.

Prior to engagement of any prospective auditors, the Committee reviews a written disclosure by the prospective auditors of all relationships between the prospective auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and discusses with the prospective auditors the potential effects of such relationships on the independence of the prospective auditors, consistent with Ethics and Independence Rule 3526, Communication with Audit Committees Concerning Independence (“Rule 3526”), of the Public Company Accounting Oversight Board (United States). Consistent with Rule 3526, at least annually, the Committee receives and reviews written disclosures from the auditors delineating all relationships between the auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and a letter from the auditors affirming their independence, and considers and discusses with the auditors any potential effects of any such relationships on the independence of the auditors as well as any compensation or services that could affect the auditors’ objectivity and independence.

The Committee has considered the non-audit services provided by PricewaterhouseCoopers and Deloitte & Associés as described above and believes that they are compatible with maintaining PricewaterhouseCoopers and Deloitte & Associés’s independence as our independent registered public accounting firms.

D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

F. Changes to Certifying Accountant

Not applicable.

G. Corporate Governance

As a French *société européenne*, we are subject to various corporate governance requirements under French law. We are a “foreign private issuer” under the U.S. federal securities laws and the Nasdaq listing rules. The foreign private issuer exemption will permit us to follow home country corporate governance practices instead of certain Nasdaq listing requirements. A foreign private issuer that elects to follow a home country practice instead of Nasdaq listing requirements must submit to Nasdaq a written statement from an independent counsel in such issuer’s home country certifying that the issuer’s practices are not prohibited by the home country’s laws.

We apply the Middlednext code, which recommends that a majority of the members of the Board of Directors be independent (as such term is defined under the code). Neither the corporate laws of France nor our bylaws requires that (i) our compensation committee include only independent members of the Board of Directors, (ii) each committee of the Board of Directors have a formal written charter, or (iii) our independent members of the Board of Directors hold regularly scheduled meetings at which only independent members of the Board of Directors are present. We intend to continue to follow French corporate governance practices in lieu of Nasdaq listing requirements for each of the foregoing.

These exemptions do not modify the independence requirements for the audit and governance committee, and we intend to comply with the requirements of the Sarbanes-Oxley Act and the Nasdaq listing rules, which require that our audit and governance committee be composed of at least three independent members. Rule 10A-3 under the Exchange Act provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as

well as control over the performance of their duties, management of complaints made, and selection of consultants. Under Rule 10A-3, if the laws of a foreign private issuer’s home country require that any such matter be approved by the board of directors or our shareholders, the audit committee’s responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by our shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least 33¹/₃% of the outstanding shares of the company’s ordinary voting shares. We intend to continue to follow our French home country practice rather than complying with this Nasdaq rule. Consistent with French law, when first convened, general meetings of shareholders may validly convene only if the shareholders present or represented hold at least (i) 20% of the voting shares in the case of an ordinary general meeting or of an extraordinary general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits, or share premium (the ordinary general meeting shall make its decision on a majority of half of the votes cast by the shareholders present or represented), or (ii) 25% of the voting shares in the case of any other extraordinary general meeting (the general meeting shall make its decision on a majority of two thirds of the votes cast by the shareholders present or represented). If such quorum required by French law is not met, the meeting is adjourned. There is no quorum requirement under French law when an ordinary general meeting or an extraordinary general meeting is reconvened where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, but the reconvened meeting may consider only questions that were on the agenda of the adjourned meeting. When any other extraordinary general meeting is reconvened, the required quorum under French law is 20% of the shares entitled to vote. If a quorum is not met at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Furthermore, Nasdaq’s corporate governance rules require listed U.S. companies to seek shareholder approval for the implementation of certain equity compensation plans and issuances of securities, which we are not required to, and do not intend to, follow as a foreign private issuer.

H. Mine Safety Disclosure.

Not applicable.

I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

J. Insider Trading Policy

Not applicable.

K. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical systems and information (collectively, our “Information Systems and Data”).

Our Information Technology department, with support from members of our Legal and Compliance teams and our Head of Risk Management, helps identify and assess cybersecurity risks and prepare the Company to respond to these risks. We use various methods for monitoring and evaluating threats to our environment including, for example: using manual and automated tools to detect anomalies and attempted attacks, subscribing to reports and services that identify cybersecurity threats, evaluating our and our industry’s risk profile, analyzing reports of threats and actors, conducting scans of our environment, evaluating threats reported to us, conducting internal and external audits, conducting threat assessments for internal and external threats, and conducting vulnerability assessments, including penetration tests.

Depending on the environment and system, we implement and maintain various technical, organizational, and physical measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. These include, in addition to others discussed in this Item 16K, system monitoring, an incident detection and response plan, a disaster recovery plan, encryption and segregation of certain data, network security controls, and measures for the physical security of our technology infrastructure. We provide an annual information security awareness training to our employees and ask them to review certain information security policies on an annual basis.

Our identification, assessment and management of material risks from cybersecurity threats are integrated into the Company’s overall risk management processes. For example, we include information on cybersecurity risk evaluations conducted by management in reports provided to our internal Risk Management Committee, elements of which are shared with the Audit, Risk, and Compliance Committee (“the Audit Committee”) of our Board of Directors. Additionally, our Executive Committee may discuss cybersecurity risks and mitigation activities as part of its general risk management oversight. Our Chief Financial Officer (CFO) is the member of our Executive Committee with functional responsibility for cybersecurity and may elevate cybersecurity topics for the attention of the Executive Committee, Audit Committee, and Board of Directors.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants, threat intelligence service providers, cybersecurity software and service providers, penetration testing firms, dark web monitoring services, forensic investigators, and professional services firms, including legal counsels.

Support elements for a variety of functions across our business are performed by third parties, such as distributors, contract manufacturing organizations, contract research organizations, application providers, and supply chain resources. We consider cyber risks in evaluating third parties and services, and our vendor management processes are tailored to our assessment of a particular vendor's risk profile and criticality to our operations. Those processes may include, for example, some combination of the following: performing a risk assessment or issuing a security questionnaire, reviewing written security programs, performing certain vulnerability scans, conducting security assessment calls with the vendor's security personnel, performing audits on the vendor's compliance with our security requirements, or imposing contractual obligations relating to information security. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify and manage cybersecurity risks associated with a provider.

We have not identified risks from any known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may be reasonably likely to materially affect the Company and how they may do so, see our risk factors under Item 3D. Risk Factors in this Annual Report, including those described in "Risks Related to our Business Operations, Employee Matters and Managing Growth".

Governance

Our Board of Directors considers the Company's cybersecurity risk as part of its general oversight function. The Audit Committee is responsible for overseeing the Executive Committee's implementation and enforcement of our cybersecurity risk management processes.

Our cybersecurity risk assessment and management processes are implemented and maintained by a management team comprised of our Vice President of Information Technology and Analytics ("VP of IT/Analytics") and our CFO, to whom our VP of IT/Analytics reports. This management team is responsible for hiring appropriate personnel, managing spending relating to cybersecurity, providing information on cybersecurity risks, preparing for cybersecurity incidents, reviewing security assessments, approving cybersecurity processes and resources, and managing our response to significant cybersecurity incidents. The management team stays informed about and monitors efforts to prevent, detection, mitigate and remediate cybersecurity incidents through various means, which may include briefings with operational cybersecurity team members, outside threat intelligence sources, and from tooling described above that is deployed in our IT environment.

Individuals responsible for cybersecurity at an operational level within the Company have a minimum of five years experience in the field of information technology. For example, our Head of Information Security and Audit is certified within the TÜV Austria as a Manager and Auditor according to ISO 27001 & ISO 27002. We also have a Cyber Incident Response Team that includes the Head of Information Security, Data Protection Officer, and Director of Information Technology Infrastructure. This group may be expanded as needed to include representatives from our Legal and Corporate Communications teams as well as our Executive Committee, which is responsible for communicating with the Audit Committee or full Board of Directors as needed.

The Audit Committee receives regular reports from the VP of IT/Analytics concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them, as well as cybersecurity incidents deemed significant by the management team. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 17. Financial Statements

See the financial statements beginning on page F-1 of this Annual Report.

Item 18. Financial Statements

Not applicable.

Item 19. Exhibits

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	Filing Date
1.1*	Bylaws (statuts) of the Registrant (English translation)				
2.1	Form of Deposit Agreement	F-1/A	333-255155	4.1	April 29, 2021
2.2	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-255155	4.2	April 29, 2021
2.3*	Description of Securities				
4.1†	Research Collaboration and License Agreement, dated April 29, 2020, by and between Pfizer Inc. and Valneva Austria GmbH.	F-1	333-255155	10.1	April 9, 2021
4.2†	Amendment No. 1 to Research Collaboration and License Agreement dated July 14, 2021, by and between Valneva Austria GmbH and Pfizer Inc.	6-K	001-40377	10.5	August 15, 2022
4.3†	Amendment No. 2 to Research Collaboration and License Agreement dated November 10, 2021, by and between Valneva Austria GmbH and Pfizer Inc.	6-K	001-40377	10.6	August 15, 2022
4.4†	Amendment No. 3 to Research Collaboration and License Agreement dated June 19, 2022, by and between Valneva Austria GmbH and Pfizer Inc.	6-K	001-40377	10.7	August 15, 2022
4.5†	Amendment No. 4 to Research Collaboration and License Agreement dated November 22, 2022, by and between Valneva Austria GmbH and Pfizer Inc.	20-F	001-40377	4.3	March 30, 2023
4.6†	Master Supply and Commercial Manufacturing Services Agreement, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH.	20-F	001-40377	10.3	March 24, 2022
4.7†	Product Schedule, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH.	20-F	001-40377	10.7	March 24, 2022
4.8†	Product Schedule, dated December 16, 2022, by and between IDT Biologika GmbH and Valneva Austria GmbH.	20-F	001-40377	4.9	March 30, 2023
4.9†	Funding Agreement, dated April 1, 2019, by and between Coalition for Epidemic Preparedness Innovations and Valneva SE.	F-1	333-255155	10.4	April 9, 2021
4.10†	Contract dated September 9, 2020, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.	F-1	333-255155	10.8	April 9, 2021
4.11†	Amendment, dated August 23, 2021, to Contract dated September 9, 2020 by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.	F-1	333-260507	10.9	October 26, 2021
4.12**†	Contract dated September 21, 2023, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.				
4.13†	Distribution Agreement (IXIARO), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Austria GmbH.	F-1	333-255155	10.1	April 9, 2021

4.14†	Distribution Agreement (DUKORAL), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Sweden AB, as amended to date.	F-1	333-255155	10.1	April 9, 2021
4.15*†	Amendment to Distribution Agreements, dated May 15, 2023, by and between, <i>inter alios</i>, Bavarian Nordic A/S, Valneva Austria GmbH and Valneva Sweden AB.				
4.16†	Distribution Agreement, dated December 15, 2022, by and between Valneva SE and VBI Vaccines Inc.	20-F	001-40377	4.3	March 30, 2023
4.17*†	Amendment, dated January 1, 2024, to the Distribution Agreement dated December 15, 2022, by and between Valneva SE and VBI Vaccines Inc.				
4.18†	Sublicense Agreement, dated April 14, 2003, by and between VacciGen International LLC and Intercell AG, as assigned to the Registrant and as amended.	F-1	333-255155	10.6	April 9, 2021
4.19†	Supply Agreement, dated March 1, 2008, by and among Intercell AG, Vetter Pharma-Fertigung GmbH & Co. KG and Intercell Biomedical Ltd., as assigned to the Registrant.	F-1	333-255155	10.7	April 9, 2021
4.20*†	Commercial Supply Agreement, dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH.				
4.21*†	First Amendment, dated November 16, 2023, to the Commercial Supply Agreement dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH.				
4.22*†	Second Amendment, dated January 1, 2024, to the Commercial Supply Agreement dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH.				
4.23*†#	Credit Agreement, dated February 3, 2020, by and among Valneva Austria GmbH, Valneva SE, Wilmington Trust, National Association and the Lenders, as amended to date on June 24, 2020, July 31, 2020, January 15, 2021, November 30, 2021, January 3, 2022, April 25, 2022, September 22, 2022, August 16, 2023, October 30, 2023 and March 18, 2024.				
4.24	Sales Agreement, dated as of August 12, 2022, by and between Valneva SE and Jefferies LLC.	6-K	001-40377	1.1	August 15, 2022
4.25*†	Asset Purchase Agreement, dated February 2, 2024, by and between Valneva Austria GmbH and Novartis Pharma AG.				
4.26	Terms and Conditions Applicable to BSA 27 Equity Warrants and Form of Exercise Notice	F-1	333-255155	10.2	April 9, 2021
4.27+	Employee Stock Option Plan 2013	F-1	333-255155	10.1	April 9, 2021
4.28+	Employee Stock Option Plan 2015	F-1	333-255155	10.1	April 9, 2021
4.29+	Employee Stock Option Plan 2016	F-1	333-255155	10.1	April 9, 2021
4.30+	Employee Stock Option Plan 2017	F-1	333-255155	10.2	April 9, 2021
4.31+	Employee Stock Option Plan 2019	F-1	333-255155	10.2	April 9, 2021
4.32+	Employee Stock Option Plan 2022	20-F	001-40377		March 30, 2023
4.33+*	Employee Stock Option Plan 2023				
4.34+	Senior Leadership Group Stock Option Plan 2022	20-F	001-40377		March 30, 2023
4.35+*	Senior Leadership Group Stock Option Plan 2023				

4.36+	Free Convertible Preferred Share Plan 2017-2021	F-1	333-255155	10.2	April 9, 2021
4.37+	Free Share Plan 2019-2023	F-1	333-255155	10.2	April 9, 2021
4.38+*	Free Share Plan 2023-2026				
4.39+*	Special Free Ordinary Share Plan 2022-2025 N°2				
4.40+	Phantom Stock Option Plan 2017 and Form of Exercise Notice	F-1	333-255155	10.2	April 9, 2021
4.41+	Phantom Stock Option Plan 2019	F-1	333-255155	10.2	April 9, 2021
4.42+	Phantom Stock Plan 2020	F-1	333-255155	10.2	April 9, 2021
8.1*	Subsidiaries of the Registrant				
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
13.2**	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
15.1*	Consent of Deloitte et Associés, independent registered public accounting firm				
15.2*	Consent of PricewaterhouseCoopers Audit, independent registered public accounting firm				
97.1*	Clawback Policy				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing this Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

VALNEVA SE

By: /s/ Thomas Lingelbach
Thomas Lingelbach
Chief Executive Officer

Date: March 22, 2024

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Shareholders and Board of Directors of Valneva SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statement of financial position of Valneva SE and its subsidiaries (together the "Company") as of December 31, 2023 and 2022, and the related consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows for each of the three years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 22, 2024 expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Other Revenues and Refund Liabilities – Research Collaboration and License Agreement with Pfizer — Refer to Notes 5.3.1 Critical Judgments in Applying the Group's Accounting Policies, 5.5.2 Other Revenues, and 5.29 Refund Liabilities to the Consolidated Financial Statements

Critical Audit Matter Description

In April 2020, the Company signed the Research Collaboration and Licensing Agreement (the "Agreement") with Pfizer to co-develop and commercialize a Lyme disease vaccine. The Agreement is within the scope of IFRS 15 "Revenue from Contracts with Customers" and includes the exclusive license as well as research and development and support services which constitute performance obligations.

At the end of each reporting period, Valneva updates the estimated transaction price and its assessment of whether an estimate of variable considerations is constrained, or not. Variable considerations derive from upfront and milestone

payments received and to be received from Pfizer, contribution from Valneva to Pfizer in shared development costs, as well as specific facts and circumstances which could potentially increase future payments to Pfizer. Revenue is recognized when the variable consideration constraint is removed and if it is highly probable that a significant reversal in the amount of the cumulative revenue recognized will not occur.

Upfront, milestones and other payments received from Pfizer, net of contributions paid by Valneva to Pfizer are presented as refund liabilities and amount to €33.1 million as of December 31, 2023. Amendments to this Agreement signed in 2021 and 2022, reflecting an increase in expected payments to Pfizer related to Valneva’s contribution to the future shared development costs, resulted in Valneva concluding it is not highly probable that the Company will be entitled to the variable considerations. Therefore, no revenue relating to the Agreement was recognized during 2023.

We identified the estimates related to the valuation of these variable considerations associated with the Agreement as a critical audit matter because of the judgments necessary for management to determine the transaction price and the amount of constrained and not recognized revenue. This required extensive audit effort due to the high degree of auditor judgment when performing audit procedures to audit management’s judgments.

How the Critical Audit Matter Was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included:

- Obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management’s estimate of the transaction price.
- Confirming with Pfizer the current terms of the Agreement and relevant balance sheet positions.
- Verifying the mathematical accuracy of the refund liability by reperforming the amount of the considerations received and paid.
- Evaluating whether those considerations were fixed or variable based on the entity’s historical business practices.
- Evaluating the reasonableness of management’s judgments in determining whether the revenue is constrained, including the judgements about the likelihood that a reversal of the cumulative revenue recognized will occur, by, among other (i) making inquiries with management; (ii) inspecting minutes of the Steering Committee which oversees the execution of R&D activities to identify any evidence that may contradict management’s assertion; (iii) assessing the estimate of the variable considerations by considering historical expected cash payments compared to subsequent actual payments.
- Verifying that the notes to consolidated financial statements 5.3.1 “Critical Judgments in Applying the Group’s Accounting Policies”, 5.5.2 “Other Revenues”, and 5.29 “Refund Liabilities” provide appropriate information.

/s/ PricewaterhouseCoopers Audit /s/ Deloitte & Associés

Neuilly-sur-Seine and Bordeaux, France
March 22, 2024

PricewaterhouseCoopers Audit and Deloitte & Associés have served as the Company’s auditors since 2012 and 2007, respectively.



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1 Consolidated Statement of Profit or Loss and other Comprehensive Income

1.1 Consolidated Statement of Profit or Loss

in € thousand	Note	Year ended December 31,		
		2023	2022	2021
Product sales	5.5	144,624	114,797	62,984
Other revenues	5.5	9,088	246,506	285,101
REVENUES		153,713	361,303	348,086
Cost of goods and services	5.6	(100,875)	(324,441)	(187,920)
Research and development expenses	5.6	(59,894)	(104,922)	(173,283)
Marketing and distribution expenses	5.6	(48,752)	(23,509)	(23,643)
General and administrative expenses	5.6	(47,799)	(34,073)	(47,606)
Other income and expenses, net	5.8	21,520	12,199	22,976
OPERATING PROFIT/(LOSS)		(82,087)	(113,443)	(61,390)
Finance income	5.9	1,210	260	249
Finance expenses	5.9	(23,325)	(19,054)	(16,964)
Foreign exchange gain/(loss), net	5.9	5,574	(12,587)	8,130
Result from investments in associates		—	9	(5)
PROFIT/(LOSS) BEFORE INCOME TAX		(98,629)	(144,815)	(69,979)
Income tax benefit/(expense)	5.10	(2,800)	1,536	(3,446)
PROFIT/(LOSS) FOR THE PERIOD		(101,429)	(143,279)	(73,425)
EARNINGS/(LOSSES) PER SHARE				
for profit/(loss) for the period attributable to the equity holders of the Company (expressed in € per share)				
Basic	5.11	(0.73)	(1.24)	(0.75)
Diluted	5.11	(0.73)	(1.24)	(0.75)

The accompanying Notes form an integral part of these financial statements.

1.2 Consolidated Statement of Comprehensive Income

in € thousand	Note	Year ended December 31,		
		2023	2022	2021
PROFIT/(LOSS) FOR THE PERIOD		(101,429)	(143,279)	(73,425)
OTHER COMPREHENSIVE INCOME/(LOSS)				
Items that may be reclassified to profit or loss				
Currency translation differences	5.22.2	3,300	(73)	(2,877)
Items that will not be reclassified to profit or loss				
Defined benefit plan actuarial gains/(losses)	5.30.1	(130)	178	205
Other comprehensive income/(loss) for the year, net of tax		3,170	105	(2,672)
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD		(98,258)	(143,174)	(76,097)

The accompanying Notes form an integral part of these financial statements.



2 Consolidated Statement of Financial Position

		Year ended December 31	
<i>in € thousand</i>	Note	2023	2022
ASSETS			
Non-current assets		197,238	196,685
Intangible assets	5.12	25,567	28,711
Right of use assets	5.13	20,392	41,603
Property, plant and equipment	5.14	136,198	112,435
Deferred tax assets	5.10.2	6,592	5,637
Other non-current assets	5.19	8,490	8,299
Current assets		262,824	424,660
Inventories	5.17	44,466	35,104
Trade receivables	5.18	41,645	23,912
Other current assets	5.19	50,633	74,079
Cash and cash equivalents	5.20	126,080	289,430
Assets classified as held for sale	5.21	—	2,134
TOTAL ASSETS		460,062	621,344
EQUITY			
Share capital	5.22	20,837	20,755
Share premium	5.22	594,003	594,043
Other reserves	5.22.2	65,088	55,252
Retained earnings/(Accumulated deficit)	5.22	(450,253)	(306,974)
Loss for the period		(101,429)	(143,279)
TOTAL EQUITY		128,247	219,797
LIABILITIES			
Non-current liabilities		172,952	124,156
Borrowings	5.24	132,768	87,227
Lease liabilities	5.27	29,090	28,163
Refund liabilities	5.29	6,303	6,635
Provisions	5.30	1,074	1,320
Deferred tax liabilities	5.10.2	3,638	694
Other liabilities	5.31	79	116
Current liabilities		158,863	277,392
Borrowings	5.24	44,079	11,580
Trade payables and accruals	5.25	44,303	41,491
Income tax liability		632	532
Tax and Employee-related liabilities	5.26	16,209	15,738
Lease liabilities	5.27	2,879	25,411
Contract liabilities	5.28	5,697	9,411
Refund liabilities	5.29	33,637	136,450
Provisions	5.30	10,835	31,257
Other liabilities	5.31	592	5,523
TOTAL LIABILITIES		331,815	401,547
TOTAL EQUITY AND LIABILITIES		460,062	621,344

The accompanying Notes form an integral part of these financial statements.



3 Consolidated Statement of Cash Flows

		Year ended December 31,		
in € thousand	Note	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss for the year		(101,429)	(143,279)	(73,425)
Adjustments for non-cash transactions	5.32.1	44,984	44,070	56,476
Changes in non-current operating assets and liabilities	5.32.1	514	(147,713)	59,353
Changes in working capital	5.32.1	(145,578)	1,732	36,127
Cash used in operations	5.32.1	(201,509)	(245,189)	78,532
Income tax paid		(1,236)	(154)	(1,631)
NET CASH GENERATED FROM/(USED IN) OPERATING ACTIVITIES		(202,744)	(245,343)	76,901
CASH FLOWS FROM INVESTING ACTIVITIES				
Acquisition of subsidiaries, net of cash acquired	5.1.2	(10,951)	—	—
Purchases of property, plant and equipment		(14,231)	(29,246)	(92,229)
Proceeds from sale of property, plant and equipment		111	8	—
Purchases of intangible assets		(81)	(76)	(942)
Proceeds from assets classified as held for sale		3,358	—	—
Interest received		1,210	260	54
NET CASH GENERATED FROM/(USED IN) INVESTING ACTIVITIES		(20,585)	(29,054)	(93,117)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds/(payments) from issuance of common stock, net of costs of equity transactions	5.22	(240)	189,837	166,614
Disposal of treasury shares	5.22	—	—	209
Proceeds from borrowings, net of transaction costs	5.24	81,111	39,331	859
Repayment of borrowings	5.24	(2,097)	(1,793)	(1,956)
Payment of lease liabilities	5.27	(3,127)	(3,048)	(2,805)
Interest paid		(12,567)	(9,211)	(8,417)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES		63,081	215,116	154,504
NET CHANGE IN CASH AND CASH EQUIVALENTS				
		(160,248)	(59,282)	138,288
Cash and cash equivalents at beginning of the year ⁽¹⁾	5.20	286,532	346,642	204,394
Exchange gains/(losses) on cash		(204)	(828)	3,960
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD ⁽¹⁾		126,080	286,532	346,642

⁽¹⁾ Cash and cash equivalents as at December 31, 2022 amounted to €289.4 million as it included restricted cash of €2.9 million. As at December 2021 restricted cash amounted to €0.04 million.

The accompanying Notes form an integral part of these financial statements.

4 Consolidated Statement of Changes in Equity

<i>in € thousand</i>	Note	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/(loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2023		20,755	594,043	55,252	(306,974)	(143,279)	219,797
Total comprehensive income/(loss)		—	—	3,170	—	(101,429)	(98,258)
Income appropriation		—	—	—	(143,279)	143,279	—
Share-based compensation expense:							
Value of services	5.23	—	—	6,666	—	—	6,666
Exercises	5.23	82	(39)	—	—	—	42
BALANCE AS AT DECEMBER 31, 2023		20,837	594,003	65,088	(450,253)	(101,429)	128,247

<i>in € thousand</i>	Note	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/(loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2022		15,786	409,258	52,512	(233,549)	(73,425)	170,581
Total comprehensive income/(loss)		—	—	105	—	(143,279)	(143,174)
Income appropriation		—	—	—	(73,425)	73,425	—
Share-based compensation expense:							
Value of services	5.23	—	—	2,636	—	—	2,636
Exercises	5.23	387	3,371	—	—	—	3,758
Capital Increase	5.22	4,582	181,413	—	—	—	185,996
BALANCE AS AT DECEMBER 31, 2022		20,755	594,043	55,252	(306,974)	(143,279)	219,797

Capital Increase includes the cost of transactions, net of tax.

<i>in € thousand</i>	Note	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/(loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2021		13,646	244,984	52,342	(169,156)	(64,393)	77,422
Total comprehensive income/(loss)		—	—	(2,672)	—	(73,425)	(76,097)
Income appropriation		—	—	—	(64,393)	64,393	—
Share-based compensation expense:							
Value of services	5.23	—	—	2,632	—	—	2,632
Exercises	5.23	143	2,114	—	—	—	2,257
Capital Increase	5.22	1,998	162,160	—	—	—	164,158
Treasury shares	5.22	(1)	—	209	—	—	209
BALANCE AS AT DECEMBER 31, 2021		15,786	409,258	52,512	(233,549)	(73,425)	170,581

Capital Increase includes the cost of transactions, net of tax.

The accompanying Notes form an integral part of these financial statements.



5 Notes to the Consolidated Financial Statements

5.1 General information

5.1.1 Corporate Information

Valneva SE (the Company) together with its subsidiaries (the Group or Valneva) is a company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical needs. The Company takes a highly specialized and targeted approach, applying deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions. The Group has a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently markets three proprietary travel vaccines as well as certain third-party vaccines leveraging the Group's established commercial infrastructure. Revenues from the growing commercial business help fuel the continued advancement of the vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's first vaccine against the chikungunya virus, as well as vaccine candidates against the Zika virus and other global public health threats.

VLA2001, the only inactivated whole-virus COVID-19 vaccine approved in Europe, was first commercialized in late 2021. Valneva suspended manufacturing of the vaccine in August 2022 and inventories were fully written down as of December 31, 2022. In order to save additional costs linked to the vaccine including license fees, Valneva requested the withdrawal of VLA2001's marketing authorization in Europe. The withdrawal was accepted by EMA and became effective on December 1, 2023.

As at December 31, 2023, the Group's portfolio includes three commercial vaccines:

- IXIARO (also marketed as JESPECT), indicated for the prevention of Japanese encephalitis;
- DUKORAL, indicated for the prevention of cholera, and, in some countries, prevention of diarrhea caused by enterotoxigenic Escherichia coli; and
- IXCHIQ, Valneva's single-shot chikungunya vaccine.

The Company is registered at 6 rue Alain Bombard, 44800 Saint-Herblain, France. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the United States and over 700 employees in total.

Valneva SE is a public company listed on the Euronext Paris (symbol: VLA) and on the The Nasdaq Global Select Market (symbol: VALN) since May 2021.

Significant events of the period and significant agreements

Divestment of CTM Unit in Solna, Sweden

Valneva decided to divest its Clinical Trial Manufacturing (CTM) unit in Solna. The Company completed a business transfer agreement with NorthX Biologics, an established contract development and manufacturing organization (CDMO), with over 30 years of Good Manufacturing Practices (GMP) production experience. Their ownership of the unit took effect on July 1, 2023. Valneva maintains the manufacturing site in Sweden where the DUKORAL vaccine is manufactured and filled. The deal comprised Valneva's CTM production equipment and approximately 30 staff members in Sweden, including the existing Valneva Sweden Site Head. The CTM business continues to utilize the existing premises in Solna. Valneva Sweden is sub-leasing the premises to NorthX Biologics and provides services in Facility Management, Engineering and Warehousing. Valneva is considering this sub-lease as an operational lease. A loss of €1.4 million from the divestment of the CTM Unit in Solna is included in the "Miscellaneous income/(expenses), net" (see Note 5.8).

Extension of existing loan agreement by \$100 million (€90 million)

On August 16, 2023, Valneva entered into an agreement to increase the principal amount of its existing \$100 million (€90 million) senior secured loan agreement with funds managed by leading U.S. healthcare investment firms Deerfield Management Company and Orbimed ("the D&O Loan Agreement"). The add-on loan facility has a three-year interest-only period and will mature in the third quarter of 2028. The loan interest rate remains unchanged. The increased funding will be used to further invest in research and development (R&D), as well as continued market access preparation and commercialization of Valneva's chikungunya vaccine (see Note 5.24).

Sale of BliiNK equity interest

On September 8, 2023, the Company sold its 48.9% equity interest in BliiNK Biomedical SAS, Marseille, which had been classified as an asset held for sale since June 30, 2022 (see Note 5.21).

Purchase of the office building in Vienna (VBC3)

On October 31, 2023, the Company acquired VBC 3 Errichtungs GmbH, Vienna, the legal entity that owns the Vienna building occupied by Valneva, which was previously leased. The acquisition price net of the entity's cash is €11.0 million. For more information please refer to Note 5.1.2.

U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ

On November 10, 2023, Valneva's single-shot chikungunya vaccine candidate VLA1553 received approval from the U.S. Food and Drug Administration (FDA) under the brand name IXCHIQ. In the U.S., the vaccine is indicated for the



prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV.

EMA accepts Chikungunya vaccine Marketing Authorization Application for accelerated assessment

The European Medicines Agency (EMA) performed a technical validation of the Marketing Authorization Application (MAA) for Valneva's single-shot chikungunya vaccine candidate VLA1553 and determined that all essential regulatory elements required for scientific assessment were included in the application. The MAA was granted accelerated assessment in November 2023 by EMA's Committee for Medicinal Products for Human Use (CHMP) based on the vaccine candidate's "major interest for public health and therapeutic innovation".

Change in the Company's governance structure

On December 20, 2023, the Company's shareholders approved a transition from the Company's two-tier governance model with a Supervisory Board and Management Board to a one-tier governance model led by a Board of Directors. This transition was effective on December 20, 2023. For convenience, references in these Notes to the "Board" should be interpreted to refer to the Supervisory Board or Board of Directors, as applicable.

The Executive Committee comprises the Company's former Management Board and in addition, since January 1, 2024, the Company's Chief Operating Officer and Chief People Officer. The Company's Board of Directors also changed the name of the Board's Audit and Risk Committee to the Audit, Compliance and Risk Committee in connection with the governance change, and for convenience these Notes refer to this committee as the Audit Committee.

5.1.2 Group information

The following list shows all subsidiaries held by the Company directly or indirectly:

Name	Country of incorporation	Consolidation Method	Interest held as at	
			December 31, 2023	December 31, 2022
Vaccines Holdings Sweden AB	SE	Full Consolidation	100 %	100 %
Valneva Austria GmbH	AT	Full Consolidation	100 %	100 %
Valneva Canada Inc.	CA	Full Consolidation	100 %	100 %
Valneva France SAS	FR	Full Consolidation	100 %	100 %
Valneva Scotland Ltd.	UK	Full Consolidation	100 %	100 %
Valneva Sweden AB	SE	Full Consolidation	100 %	100 %
Valneva UK Ltd.	UK	Full Consolidation	100 %	100 %
Valneva USA, Inc.	US	Full Consolidation	100 %	100 %
VBC 3 Errichtungs GmbH	AT	Full Consolidation	100 %	— %

The closing date for the consolidated financial statements is December 31 of each year.

The Company's site in Saint-Herblain includes general and administrative functions as well as research and development facilities. Valneva SE has a site in Lyon which operates commercial activities.

Vaccines Holdings Sweden AB, located in Solna, Sweden, is the holding company of Valneva Sweden AB, also located in Solna, which manufactures DUKORAL and commercializes DUKORAL, IXIARO and third-party products such as Moskito Guard and other vaccines in the Nordic countries.

Valneva Austria GmbH, located in Vienna, Austria, focuses on pre-clinical and clinical development activities of vaccines. The facilities accommodate departments for pre-clinical R&D, technical/clinical product development, quality and regulatory affairs, general and administrative as well as commercial functions. Valneva Austria GmbH commercializes IXIARO, DUKORAL, VLA2001 and third-party products such as FLUCELVAX TETRA, FLUAD, Moskito Guard, Rabipur/RabAvert and Encepur.

Valneva Canada Inc., located in Kirkland, Canada, commercializes IXIARO, DUKORAL and third-party products such as KAMRAB and Rabipur.

Valneva France SAS, located in Lyon, France, commercializes IXIARO, DUKORAL and third-party products such as PreHevbri, Rabipur and Encepur.

Valneva Scotland Ltd., located in Livingston, Scotland (United Kingdom) is primarily involved in the production of IXIARO and Valneva's new chikungunya vaccine IXCHIQ. Valneva Scotland Ltd. was also executing the production of VLA2001 prior to suspension of its manufacturing.

Valneva UK Ltd., located in Fleet, England (United Kingdom), commercializes DUKORAL, IXIARO and third-party products such as PreHevbri, Rabipur in the United Kingdom.

Valneva USA, Inc., located in Bethesda, Maryland (USA), focuses on the commercialization of IXIARO to the U.S. military and the U.S. private market.

Acquisition of VBC 3 Errichtungs GmbH (VBC3)

On October 31, 2023, the Group acquired 100% of the equity of VBC 3 Errichtungs GmbH, located in Vienna, Austria, whereby Valneva SE purchased 6% and Valneva Austria GmbH 94% of the equity. VBC3 owns the building in which Valneva Austria GmbH carries out central administrative and R&D activities. Formerly the building was under a finance



lease. The purchase was treated as an acquisition of a group of assets, and the cost of the group was allocated to the individual identifiable assets and liabilities on the basis of their relative fair values at the date of purchase.

The following table summarizes the recognised amounts of identifiable net assets based on their relative fair values at the acquisition date which was determined as October 1, 2023 as per contract details:

<i>in € thousand</i>	October 1, 2023
Cash	1,003
Property, Plant & Equipment	22,373
Loans and borrowings	(11,296)
Other liabilities	(126)
TOTAL IDENTIFIABLE NET ASSETS	11,955

The fair value of the consideration transferred, excluding the entity's cash of €1.0 million, was €11.0 million and was settled in cash. Acquisition-related costs were of minor relevance and are not included as part of consideration transferred. They have been recognised as an expense in the consolidated statement of profit or loss, as part of other expenses.

5.2 Summary of significant accounting policies

The principal accounting policies applied in preparing these consolidated financial statements are outlined below. These policies have been consistently applied to all years presented.

5.2.1 Basis of preparation

These 2023 Consolidated Financial Statements have been prepared in accordance with the International financial reporting standards, which comprise IFRS (International Financial Reporting Standards), IAS (International Accounting Standard) and their interpretations, SIC (Standards Interpretations Committee) and IFRIC (International Financial Reporting Interpretations Committee), as issued by the International Accounting Standards Board (IASB).

The preparation of financial statements in conformity with IFRS as issued by the IASB requires the use of certain critical accounting estimates. It also requires the Group's management to exercise its judgement in applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 5.3.

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

These consolidated financial statements were approved and authorized for issuance by the Board of Directors on March 18, 2024.

5.2.2 Impact of new, revised or amended Standards and Interpretations

Standards, amendments to existing standards and interpretations issued by IASB whose application has been mandatory since January 1, 2023

New standards and interpretations adopted by the Group		Effective date in accordance with IASB	Effects
IFRS 17	Insurance Contracts including Amendments to IFRS 17	January 1, 2023	none
AMENDMENTS ADOPTED BY THE GROUP			
IAS 1	Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies	January 1, 2023	none
IAS 8	Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates	January 1, 2023	none
IAS 12	Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023	none
IAS 12	Amendments to IAS 12 Income taxes: International Tax Reform – Pillar Two Model Rules	January 1, 2023	none
IFRS 9 & IFRS 17	Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information	January 1, 2023	none

The interpretations listed above did not have any material impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods. The amendments to IAS 1 Presentation of Financial Statements have had an impact on the Group's disclosures of accounting policies, but not on the measurement, recognition or presentation of any items in the Group's financial statements.



Standards, amendments to existing standards and interpretations whose application is not yet mandatory.

The Group did not elect for early application of the following new standards, amendments and interpretations which were issued but not mandatory as at January 1, 2023.

New standards, Interpretations and Amendments		Effective date in accordance with IASB	Effects
IAS 1	Amendments to IAS 1 Presentation of Financial Statements	January 1, 2024	none
IFRS 16	Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback	January 1, 2024	none
IAS 7 & IFRS 7	Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements	January 1, 2024	none
IAS 21	Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability	January 1, 2025	none

These standards and amendments are not expected to have a material impact on the entity in the current reporting periods and on foreseeable future transactions.

5.2.3 Consolidation

Subsidiaries

Subsidiaries are entities over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date that control ceases.

The Group uses the acquisition method of accounting to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair value of assets transferred, the liabilities incurred, and the equity interests issued by the Company. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Acquisition-related costs, other than those associated with the issue of debt or equity securities, are expensed as incurred. Identifiable assets acquired, liabilities, and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the consideration transferred over the fair value of the Company's share of the identifiable net assets acquired is recorded as goodwill. If the fair value of the net assets of the acquired subsidiary exceeds the consideration, the difference is recognized directly in the income statement as a bargain purchase gain. Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated.

5.2.4 Foreign currency translation

Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Euros which is Valneva SE's functional and presentation currency.

Transactions and balances

Foreign currency transactions are converted into the functional currency using exchange rates applicable on the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in the income statement.

Subsidiaries

The results and financial position of all subsidiaries (none of which have the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are converted into the presentation currency as follows:

- assets and liabilities presented for each balance sheet are converted according to the exchange rate valid on the balance sheet date;
- income and expenses for each income statement are converted at monthly average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are converted on the dates of the transactions); and
- all resulting exchange differences are recognized as other comprehensive income and are shown as other reserves.

When a foreign operation is partially disposed of or sold, exchange differences that had been recorded in equity are recognized in the income statement as part of the gain or loss on sale.



5.2.5 Financial risk management

The Group's activities expose it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk, and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

Financial risk management is carried out under the CFO's responsibility. The Group's risk management systems identify, evaluate and manage financial risks. The Audit Committee of the Group's Board of Directors receives regular reports on the Group's risk management systems, including the management of financial risks.

Market risk

Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risks arising from various currencies, primarily with respect to the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK) and the US Dollar (USD). The foreign exchange risks from the exposure to other currencies are relatively limited. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations.

The objective of the Group is to limit the potential negative impact of the foreign exchange rate changes, for example by currency conversion of cash and cash equivalents denominated in foreign currency and by using foreign currency options. The Group has certain investments in foreign operations, the net assets of which are exposed to foreign currency translation risk.

Interest rate risk

The Group is exposed to market risks in connection with hedging both its liquid assets and its medium and long-term indebtedness and borrowings subject to variable interest rates.

Borrowings issued at variable rates expose the Group to cash flow interest rate risks, which are offset by cash and financial assets held at variable rates. During 2023, as well as 2022, both the Group's investments as well as the borrowings at variable rates were denominated in EUR, SEK, USD, CAD and GBP.

The Group analyzes its interest rate exposure on a dynamic basis. Based on this analysis, the Group calculates the impact on profit and loss of a defined interest rate change. The same interest rate change is used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As at December 31, 2023 and December 31, 2022, no material interest risk was identified. In case of increasing interest rates the positive effect from cash in banks will be higher than the negative effect from variable interest-bearing liabilities; in case of decreasing interest rates there will be no material negative impact.

Credit risk

The Group is exposed to credit risk which is the risk of financial loss if customers or counterparties to a financial instrument fail to meet their contractual obligations.

Valneva holds bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of its counterparts, the Group relies on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. The Group has policies that limit the amount of credit exposure to any single financial institution. The Group is also exposed to credit risks from its trade debtors, as its income from product sales, collaborations, licensing and services arises from a small number of transactions. The Group has policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits. The credit quality of financial assets is described in Note 5.16.4.

Liquidity risk

The Group is exposed to liquidity risk due to the maturity of its financial liabilities and the fluctuations of its operating cash flow, and the potential implementation of early repayment clauses in loan or grant agreements. Furthermore, fluctuations in the Group's operating cash flow during accounting periods also generate liquidity risks. Prudent liquidity risk management therefore implies maintaining sufficient cash resources, cash equivalents and short-term deposits in order to satisfy ongoing operating requirements and the ability to close out market positions. Extraordinary conditions on the financial markets may, however, temporarily restrict the possibility to liquidate certain financial assets.

Although it is difficult to predict future liquidity requirements, the Group considers that the existing cash and cash equivalents as at December 31, 2023 will be sufficient to fund its operations for at least 12 months from the date of authorization for issuance of these consolidated financial statements. This is further supported by the gross proceeds of \$103 million for the sale of the Priority Review Voucher (PRV) which Valneva received in February 2024. For the existing D&O Loan Agreement with covenants, amendments were agreed to reduce the minimum liquidity covenant and the minimum revenue covenant to prevent a breach of the covenants (see Note 5.24.1).

The table below analyzes the Group's financial liabilities into relevant maturity groupings based on the remaining period from the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

Balance as at December 31, 2023

<i>in € thousand</i>	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Over 5 years	Total
Borrowings	44,079	62,378	70,390	—	176,847
Lease liabilities	2,879	5,313	5,414	18,362	31,969
Refund liabilities	33,637	6,303	—	—	39,941
Trade payables and accruals	44,303	—	—	—	44,303
Tax and employee-related liabilities ⁽¹⁾	10,815	—	—	—	10,815
Other liabilities	34	—	—	—	34
TOTAL	135,747	73,995	75,804	18,362	303,908

⁽¹⁾ Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required for financial instruments only.

Balance as at December 31, 2022

<i>in € thousand</i>	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Over 5 years	Total
Borrowings	11,629	74,815	44,859	939	132,242
Lease liabilities	26,674	5,915	5,706	21,268	59,563
Refund liabilities	140,098	—	7,000	—	147,098
Trade payables and accruals	41,491	—	—	—	41,491
Tax and employee-related liabilities ⁽¹⁾	10,778	—	—	—	10,778
Other liabilities	87	—	—	—	87
TOTAL	230,756	80,731	57,565	22,207	391,260

⁽¹⁾ Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required for financial instruments only.

The fair values as well as the book values of the Group's borrowings are disclosed in Note 5.24. To manage liquidity risk, the Group holds a combination of cash, cash equivalents and short-term deposit balances.

5.2.6 Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide benefits for shareholders and for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. The Group actively manages its funds to primarily ensure liquidity and principal preservation while seeking to maximize returns. The Group's cash and short-term deposits are located at several different banks. In order to maintain or adjust the capital structure, the Group may issue new shares or sell assets to reduce debt.

In order to pursue its business strategy to grow into a major, self-sustained vaccine company through organic growth and opportunistic mergers & acquisitions, the Group may rely on additional equity and debt financing. Capital consists of "Equity" as shown in the consolidated balance sheet.

5.2.7 Fair value estimation

The carrying value less impairment provision of trade receivables and payables are assumed to approximate their fair values due to the relatively short maturity of the respective instruments.

5.3 Critical accounting judgements and key sources of estimation uncertainty

In applying the Group's accounting policies, which are described in Note 5.2: Summary of significant accounting policies, management is required to make judgements (other than those involving estimations) that have a significant impact on the amounts recognised and to make estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

5.3.1 Critical judgements in applying the Group's accounting policies

The following are the critical judgements, apart from those involving estimations (which are presented separately below), that management has made in the process of applying the Group's accounting policies and that have the most significant effect on the amounts recognised in financial statements:

- Note 5.5.2 Other revenues and Note 5.29 Refund liabilities: Revenue recognition of other revenues/refund liabilities: management's judgement is required to determine the identification of performance obligations (especially when determining whether the license is distinct, which is the case when the customer can benefit from the license without further involvement), the determination of the transaction price (including the judgement of payables to customers), and allocation of the transaction price to the performance obligations on relative standalone selling price. The standalone selling price is sometimes not available or is based on hard-to-value intangible assets, so various valuation techniques are used. In addition, management's judgement is required regarding whether revenue from collaborations, licensing and service agreements is recognized over time or at a point in time. Revenue is only recognized when it is highly likely that it will not reverse in future, and this is a judgement required from management. In particular, Note 5.5.2 underlines the judgements made in applying accounting policies, whereby the Research Collaboration and License Agreement with Pfizer and several amendments thereto are most relevant.

5.3.2 Key sources of estimation uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty in the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below:

- Note 5.5 Revenues: Revenue recognition of product sales: estimate of expected returns and replacements, and supply of products free of charge;
- Note 5.5.2 Other revenues: Likelihoods for refund liabilities and for revenue recognition in accordance with the actual costs compared to the budget;
- Notes 5.8 Other income/(expenses), net and 5.31 Other liabilities: Estimates of income recognized and repayments from grants, measured according to cost incurred compared to the budget;
- Note 5.10 Income tax benefit/(expense): Recognition of deferred tax assets: availability of future taxable profit against which deductible temporary differences and tax losses carried forward can be utilized and whether sufficient evidence is provided for entities;
- Note 5.12 Intangible assets: Amortization period of development expenditures and acquired technologies. The most significant criteria considered for the determination of the useful life include the patent life as well as the estimated period when Valneva can benefit from this intangible asset. These assumptions are considered to be a key source of estimation uncertainty as relatively small changes in the assumptions used may have a significant effect on the Group's financial statements within the next year;
- Note 5.14 Property, plant and equipment: Depreciation period - assessment of useful life;
- Note 5.15 Impairment testing: Impairment test of intangible, tangible assets and right of use assets: key assumptions underlying recoverable amounts. Budgets comprise forecasts of revenue, staff costs and overheads based on current and anticipated market conditions that have been considered and approved by the Executive Committee. The revenue projections are inherently uncertain due to the short-term nature of the business and unstable market conditions. If the Group does not successfully develop vaccine candidates and receive regulatory approval, or if Valneva fails to successfully manufacture or commercialize vaccine candidates if approved, an impairment may be required. For the main estimates and sensitivities related to the impairment test regarding the CGU, see Note 5.15;
- Note 5.17 Inventories: Write-down analysis for inventories: For the assessment of write-down of raw material the current production plans have been taken into account. Raw material which will not be used before expiry date was written down. For this assessment the status of the expiry dates as of the balance sheet date was used. For the assessment of write-downs of work in progress, finished goods and purchased goods, the forecasted sales plans for 2024 and a minimum shelf life at the time of the most current sales expectation have been taken into account. In addition, those inventories have been assessed on the likelihood of the release of those products.
- Note 5.23 Share-based compensation: Share-based payments and related expected employer contribution costs: assumption for fair value determination as well as the determination of accelerated vesting in the event of a change of control (as considered remotely);
- Note 5.29 Refund liabilities: Recognition and classification of the refund obligation related to the Pfizer Collaboration and License Agreement;
- Notes 5.30 Provisions and 5.33 Commitments and contingencies: Recognition and measurement of provisions and contingencies: key assumptions about the likelihood and magnitude of an outflow of resources. In estimating the provision for onerous contracts, management made assumptions regarding the likelihood of termination costs for certain agreements.
- Note 5.18 Trade receivables and 5.16.5 Impairment of financial assets: A simplified approach based on historical loss rates is used to determine the loss allowances in order to recognize expected credit losses (ECL) for short-term financial assets such as trade receivables.

5.3.3 Measurements of fair values

A number of the Group's accounting policies and disclosures require the measurement of fair values, for both financial and non-financial assets and liabilities.

When measuring the fair value of an asset or a liability, the Group uses observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

Further information about the assumptions made in measuring fair values is included in the following Notes:

- Note 5.16: Financial instruments and
- Note 5.23: Share-based compensation.

5.4 Segment information

The Company's Management Board, and since December 20, 2023, its Executive Committee, as the Company's chief operating decision maker ("CDM"), considers Valneva's operating business in its entirety to allocate resources and assess performance. The committee evaluates all vaccine candidates and vaccine products together as a single operating segment, "development and commercialization of prophylactic vaccines". Therefore, the split used to allocate resources and assess performance is based on a functional view, thus correlating to the income statement format.

As a consequence, the Group has changed its internal reporting process as at January 1, 2023 to present a single operating segment instead of the previously disclosed product-based segments.

Segment reporting information for earlier periods has been restated to conform to these changes.

5.5 Revenues

Revenues include both revenues from contracts with customers and other revenues (mainly subleases) which are out of scope from IFRS 15:

in € thousand	Year ended December 31,		
	2023	2022	2021
Product sales	144,624	114,797	62,984
Other revenues from contracts with customers	8,075	245,709	284,202
Other non-IFRS 15 revenue	1,014	797	899
REVENUES	153,713	361,303	348,086

Product sales increased in the year ended December 31, 2023 by €29.8 million compared to the prior period. This is a result of higher demand for IXIARO following globally increased travel activities. Further, DUKORAL sales went up substantially in 2023 after supply shortages in 2022. COVID-19 VLA2001 product sales strongly decreased following the Company's decision to suspend the program.

Other revenues from contracts with customers decreased in the year ended December 31, 2023 by €237.6 million. In 2022, €169.2 million and in 2021 €253.3 million of revenues for COVID-19 VLA2001 were recognized as other revenues from the re-assessment of the likelihood of the royalty obligation and the de-recognition of the previously included capex obligation towards the UK Authority following the settlement agreement in connection to the UK Supply Agreement (discussed in Note 5.5.2). Furthermore, a release of non-refundable advance payments from EU member states related to the COVID-19 VLA2001 Advance Purchase Agreement (APA) with the European Commission amounting to €110.8 million was included as other revenues in 2022. This was offset by €45.9 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer. The other changes compared to 2022 are made up of individually insignificant transactions.

5.5.1 Product sales

The Group mostly generates product sales revenues from the sale of its commercialized travel vaccines and from the sale of third-party products.

The Group's product sales contracts generally include one nature of performance obligation. Revenue is recognized at the point in time when the identified performance obligation is transferred to the customer, either when the customer obtains control over the goods at the time of shipment or when the product is received by the customer, depending on the terms of the agreement, which generally happens within a few days. Sales contracts with retailers and with the U.S. Department of Defense (DOD) are shown as "direct product sales", whereas sales to distributors are reported as "indirect sales - sales through distributors".

Some of the Group's product sales agreements include retrospective rebates, charge-back clauses, discounts and under certain conditions return rights which give rise to variable consideration under IFRS 15. The constraint on variable consideration (expected rebates, discounts and considerations for product returns) are taken into account and recognized on an accrual basis and reported as refund liabilities or as contract liabilities (for replacement doses) in the consolidated balance sheet.

In most cases, Valneva sells the products through retailers. When more than one party is involved in providing or distributing goods or services, the standard requires an entity to determine whether itself and its retailers are principals or agents in these transactions by evaluating the nature of its promises to the customer. An entity is a principal if it controls a promised good or service before transferring that good or service to the customer. An entity is an agent if its role is to arrange for another entity to provide the goods or services. Indicators that control has been transferred are that a) the retailer is primarily responsible for fulfilling the promise to its customers, b) the retailer has inventory risk, and c) the retailer has discretion in establishing the price for the sale to its customers. One of Valneva's retailers has extensive rights to return and consequently no inventory risk and does not have the power to establish the price for the sales to its customers. Therefore, this retailer acts as agent rather than as principal. All of Valneva's other retailers act as principal. While revenues to principals are recognized when the control is transferred to the principals, revenue from product sales to agents are recognized when the control is transferred to the final customer, when the goods are delivered to the final customer. Distribution costs and other amounts payable to customers are deducted from revenue for principals, and costs paid to agents are recognized as "Marketing and distribution expenses".

Valneva also sells products acquired from third parties. Valneva considers that it is acting as principal given that it controls products before transferring them to the final customer. More specifically, Valneva has an inventory risk before the goods have been transferred to customers and has discretion in establishing the prices. Revenue is recognized when the product is delivered to the customers. Products purchased from third parties are recognized as "inventory" in the balance sheets and when sold as "cost of goods" in the statements of income.

5.5.2 Other revenues

The Group generates other revenues for its product candidates and proprietary technologies. The contracts in place often include several different promised goods or services such as research licenses, commercial licenses and further R&D services. The terms of such agreements include license fees received as initial fees, annual license maintenance fees and fees to be paid upon achievement of milestones, as well as license option fees and fees for the performance of research services. In addition, the Group's licensing arrangements generally provide for royalties payable on the licensee's future sales of products developed within the scope of the license agreement. Revenue recognized due to the termination of agreements is recognized in other revenues.

The Group's license contracts in place provide distinct right to use licenses, and therefore the revenue is recognized at the point in time at which the licensee is able to direct the use of and benefit from the license. The consideration for licensing contracts may consist of fixed and variable parts. In case of right-to-use licenses, the fixed part of the consideration is recognized at the point in time when the licensee is able to direct the use and benefit from the license. For any variable consideration, revenue is recognized at the point in time when the variable consideration constraint is removed.

Revenue for research and development services within the Group's contracts currently in place is recognized over time. The progress is measured on an input basis (costs incurred related to total costs expected). This input method is considered an appropriate measure of the progress towards complete satisfaction of these performance obligations under IFRS 15.

Variable considerations are included in revenues only to the extent that it is highly probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the end of each reporting period, the Group updates the estimated transaction price and its assessment of whether an estimate of variable consideration is constrained. Amounts allocated to a satisfied performance obligation are recognized as revenue, or as a reduction of revenue, in the period in which a change in estimate of variable consideration occurs. Revenues from license royalties are recognized when the underlying product sales occur.

Vaccine Supply Agreement with the UK Authority (UK Supply Agreement)

In September 2020, Valneva entered into the UK Supply Agreement with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom (the UK Authority), pursuant to which Valneva was obligated to develop, manufacture and supply SARS-CoV-2 vaccines to the UK Authority in the United Kingdom of Great Britain and Northern Ireland, including an obligation for Valneva to upgrade its manufacturing facilities in Scotland. In September 2021,

Valneva received notice of the UK Authority's decision to terminate the UK Supply Agreement, and the termination became effective in October 2021.

The impact of the termination of the UK Supply Agreement was assessed as at December 31, 2021. Payments received, where the likelihood of repayment is remote, totaled €253.3 million and were recognized as revenue in 2021. For amounts with uncertainties and a repayment likelihood which was more than remote, a refund liability of €166.9 million was recognized for the royalty on sales and certain other obligations which survive the termination of the UK Supply Agreement.

In June 2022, Valneva and the UK Authority signed a settlement agreement (the UK Settlement Agreement). The UK Settlement Agreement resolves certain matters relating to the obligations of the Company and UK Authority following the termination of the UK Supply Agreement and in relation to the separate agreement relating to clinical trials of VLA2001 in the UK, which remains in place. The Company continues to have certain other obligations pursuant to provisions of the UK Supply Agreement that survive its termination. Due to the termination of the agreements other revenue in the amount of €169.2 million (of which €80.0 million related to the capex obligation and €89.2 million related to the royalty obligation) were recognized in the year ended December 31, 2022.

There was no impact on the financial position of the Group for the year ended December 31, 2023.

Advance Purchase Agreement with the European Commission (EC APA)

In November 2021, Valneva entered into the EC APA in order to supply its VLA2001 COVID-19 vaccine to participating EC member states. The EC APA was amended in July 2022 to reduce the amount of doses of VLA2001 ordered. At the time of the amendment, Valneva had received advance payments for the original order volume. Per the terms of the EC APA, Valneva is not obligated to repay any amount of such advance payments that had already been spent or committed.

As of December 31, 2022, Valneva had fulfilled its remaining performance obligations under the contract and assessed that the risk of reimbursement of the advance payments was remote. Accordingly, the contract liability was released in full to revenue for the year ended December 31, 2022, including €6.0 million attributed to product sales (as partial advance payment for delivery of 1.25 million doses of VLA2001) and €110.8 million attributed to other revenue from contracts with customers. Therefore, product sales present the part directly related to vaccines sale with the original dose price according to the agreement.

There was no impact on the financial position of the Group for the year ended December 31, 2023.

Lyme - Pfizer Collaboration and License Agreement

In April 2020, Valneva signed the Collaboration and License Agreement with Pfizer to co-develop and commercialize the Group's Lyme disease vaccine candidate (VLA15). This is classified as an agreement with a customer as defined by IFRS 15 guidance on revenue contracts with customers, and accordingly, amounts received or payable by Valneva under the Collaboration and License Agreement are accounted for in the Group's revenues.

In 2021 and 2022 several amendments to the transaction price were made via amendments to the Collaboration and License Agreement and resulted in a reduction to the constrained (i.e. highly probable) transaction price, reflecting an increase in expected payments to customer related to Valneva's contribution to Pfizer's future development costs.

In addition, Valneva considered the constraint to determine if it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Valneva considered that it is no longer highly probable that it will be entitled to the consideration as payments to customers might further increase in the future. Therefore, for the year ended December 31, 2022, the cumulated revenue of €45.9 million was reversed as other revenues from contracts with customers. In the year ended December 31, 2023, no revenues were recognised.

While license and equipment purchase orders were fulfilled in prior periods, the R&D activities and additional services are ongoing through 2024 and will satisfy the performance obligation over time. During this period Valneva will fund 40% of the remaining shared development costs. Items not included in the transaction price as of December 31, 2023 are (i) \$143 million of early commercialization milestones, (ii) royalties, ranging from 14% to 22%, and (iii) \$100 million of sales milestones which will be recognized when they occur.

As at December 31, 2023, the discounted refund liability amounted to €33.1 million (December 31, 2022: €135.5 million). The decrease was due to payments made in the period in connection with the terms of this agreement. The amounts not recognized in revenue are disclosed as refund liabilities as well as trade receivables which amounted to €10.7 million for the year ended December 31, 2023 (December 31, 2022: €4.6 million).



5.5.3 Disaggregated revenue information

The Group's revenues are disaggregated as follows:

Type of goods or service

in € thousand	Year ended December 31,		
	2023	2022	2021
IXIARO	73,483	41,349	45,118
DUKORAL	29,775	17,334	2,440
Third party products	35,675	26,545	15,426
COVID VLA2001	5,691	29,568	—
PRODUCT SALES	144,624	114,797	62,984
IXCHIQ ⁽¹⁾	2,733	5,565	3,257
COVID VLA2001 ⁽¹⁾	1,973	280,010	253,314
Lyme VLA15	—	(45,869)	14,265
Services related to clinical trial material	275	3,205	10,001
Others	3,093	2,798	3,364
OTHER REVENUES FROM CONTRACTS WITH CUSTOMERS	8,075	245,709	284,202
Other non-IFRS 15 revenue	1,014	797	899
REVENUES	153,713	361,303	348,086

⁽¹⁾ Revenues from these products were derived from contractual arrangements and do not represent product sales.

In the year ended December 31, 2023 product sales revenues for all active products increased significantly by €29.8 million compared to the same period in 2022.

IXIARO/JESPECT sales showed a 78% increase in sales which was primarily the result of the continued travel market recovery, as well as price increases. The increase in IXIARO product sales included an adverse €1.5 million foreign currency impact. DUKORAL sales in 2023 were 72% higher compared to 2022. This increase is also a result of the significant recovery in the private travel markets and price increases. Foreign currency fluctuations reduced DUKORAL sales by €0.9 million. Third Party product sales recorded a 34% increase which was mainly driven by sales of Rabipur/RabAvert and Encepur under the distribution agreement with Bavarian Nordic. On the other hand, sales revenues for the COVID-19 VLA2001 product decreased by 81% as the program was suspended given the strongly decreased demand.

In the year ended December 31, 2022, other revenues from contracts with customers were strongly influenced by one-off effects. An income of €169.2 million was related to the termination of the UK Supply Agreement and further €110.8 million to the termination of the EC APA. For more detail see above within this Note. This was partially offset by €45.9 million of negative revenue resulting from an increase in the refund liability linked to the amendment to the Collaboration and License Agreement with Pfizer.

In the year ended December 31, 2021, other revenues from VLA2001 of €253.3 million were related to the termination of the UK Supply Agreement. For more detail see further above within this Note. In 2021 other revenues included €14.3 million from the collaboration with Pfizer related to the Lyme vaccine candidate.

Sales channels for product sales

Products are sold via the following sales channels:

in € thousand	Year ended December 31,		
	2023	2022	2021
Direct product sales	119,305	75,968	60,306
Indirect product sales (Sales through distributors)	25,320	38,828	2,678
TOTAL PRODUCT SALES	144,624	114,797	62,984

Geographical markets

In presenting information on the basis of geographical markets, revenue is based on the final location where Valneva's distribution partner sells the product or where the customer/partner is located.

in € thousand	Year ended December 31,		
	2023	2022	2021
United States	32,964	(23,803)	54,791
Canada	28,193	18,904	4,226
United Kingdom	20,266	181,129	256,075
Austria	14,583	21,793	18,529
Germany	13,503	68,529	966
Nordics	12,695	12,043	2,440
France	5,866	46,608	1,367
Other Europe	9,335	18,740	5,006
Rest of World	16,308	17,360	4,684
REVENUE TOTAL	153,713	361,303	348,086

Nordics includes Finland, Denmark, Norway and Sweden.

In the year ended December 31, 2023, revenues from product sales increased considerably, driven by the continued recovery of travel vaccine sales. Revenues from Canada and the United States especially contributed to this increase.

Revenues in the year ended December 31, 2022 were strongly influenced by one-off effects. Revenues from the United States included a €45.9 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer. Further 2022 revenues from the United Kingdom included non-product revenues of €169.2 million from the UK Authority following the UK Settlement Agreement. 2022 also contained a release of non-refundable advance payments from several EU member states, affecting specifically revenues from Germany, France, Austria, Nordics and Other Europe.

In the year ended December 31, 2021, revenues in the United Kingdom were related to VLA2001 including other revenues of €253.3 million following the termination of the UK Supply Agreement. For more detail see further above within this Note.

Information about major customers

The concentration risk on the customer portfolio of the Group is limited. In 2023, there was one single customer (share of 12%) with a contribution exceeding 10% of the annual revenue.

Product sales to the largest customer amounted to €17.7 million in 2023 (2022: €16.0 million, 2021: €41.8 million). Other revenues from the largest customer amounted to €5.0 million in 2023 (2022: €169.2 million, 2021: €253.3 million). In 2022 and 2021, the UK Authority was the largest customer due to the UK Supply Agreement explained above in Note 5.5.2.

5.5.4 Assets and liabilities related to contracts with customers

See Note 5.18 for details on trade receivables, Note 5.19 for details on costs to obtain a contract, Note 5.28 for details of contract liabilities and Note 5.29 for details of refund liabilities.

5.6 Expenses by nature

The consolidated income statement line items cost of goods and services, research and development expenses, marketing and distribution expenses and general and administrative expenses include the following items by nature of cost:

in € thousand	Note	Year ended December 31,		
		2023	2022	2021
Consulting and other purchased services		80,988	141,631	169,158
Cost of services and change in inventory		11,417	190,086	105,648
Employee benefit expense other than share-based compensation	5.7	72,997	56,393	85,334
Share-based compensation expense	5.7	6,276	(5,215)	14,678
Raw materials and consumables used		14,113	12,723	14,676
Depreciation and amortization and impairment	5.12/13/14	16,853	44,285	14,281
Building and energy costs		13,088	14,696	10,960
Supply, office and IT costs		11,663	11,739	7,409
License fees and royalties		5,492	6,830	4,865
Advertising costs		13,361	7,343	2,176
Warehousing and distribution costs		3,939	1,898	1,419
Travel and transportation costs		2,700	2,208	538
Other expenses		4,432	2,329	1,309
OPERATING EXPENSES		257,320	486,945	432,452

The €229.6 million decrease in operating expenses from €486.9 million in the year ended December 31, 2022 to €257.3 million in the year ended December 31, 2023 primarily resulted from one-off expenses recorded in 2022 which were related to the suspended COVID-19 program. These expenses included the write-down of COVID-19 vaccine inventory of €159.4 million (presented under "cost of services and change in inventory") as well as impairment charges of fixed assets.

Expenses for "consulting and other purchased services" reduced substantially in the year ended December 31, 2023, as the comparison period of 2022 included considerable expenses for VLA2001 related to research and development and external manufacturing costs.

Expenses for "cost of services and change in inventory" strongly decreased as in the year ended December 31, 2022 effects from the significant changes to the ordered volumes and the expected future demand for VLA2001, in particular a write-down of inventory of €159.4 million, were recorded.

The expense position "depreciation and amortization and impairment" contains a reversal of a fixed asset impairment in the amount of €1.9 million related to production equipment in the year ended December 31, 2023, whereas 2022 included one-off charges of €14.8 million for the impairment of VLA2001 related fixed assets including idle manufacturing equipment, leasehold improvements and Right of Use assets.

"Employee benefit expenses other than share-based compensation" increased in the year ended December 31, 2023 compared to December 31, 2022 because of a €23.2 million release of the employer contribution provision and therefore an income to the social security contributions in 2022. In the same year "Share-based compensation expense" showed an income due to share-based payment program valuations resulting from the reduction in the share price.

Principal Accountant Fees and Services

in € thousand	Year ended December 31,											
	PricewaterhouseCoopers						Deloitte & Associés					
	2023	%	2022	%	2021	%	2023	%	2022	%	2021	%
Audit fees	2,076	98 %	1,891	99 %	1,122	91 %	1,902	99 %	1,678	99 %	1,113	93 %
provided by the statutory auditor	1,539	73 %	1,386	72 %	937	76 %	1,622	84 %	1,376	81 %	939	78 %
provided by the statutory auditor's network	537	25 %	505	26 %	185	15 %	280	15 %	302	18 %	174	15 %
Audit-related Fees	—	— %	—	— %	90	7 %	—	— %	13	1 %	85	7 %
provided by the statutory auditor	—	— %	—	— %	85	7 %	—	— %	13	1 %	85	7 %
provided by the statutory auditor's network	—	— %	—	— %	5	— %	—	— %	—	— %	—	— %
Tax fees	40	2 %	25	1 %	25	2 %	—	— %	—	— %	—	— %
provided by the statutory auditor's network	40	2 %	25	1 %	25	2 %	—	— %	—	— %	—	— %
All Other Fees	—	— %	—	— %	—	— %	19	1 %	—	— %	—	— %
Total	2,116	100 %	1,916	100 %	1,238	100 %	1,921	100 %	1,691	100 %	1,199	100 %

Audit-related fees comprised mainly the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

5.7 Employee benefit expense

Employee benefit expenses include the following:

in € thousand	Year ended December 31,		
	2023	2022	2021
Salaries	55,793	57,272	47,717
Social security contributions	14,359	(3,035)	35,923
Share-based compensation expense	6,276	(5,215)	14,678
Training and education	1,292	840	603
Other employee benefits	1,553	1,317	1,091
TOTAL EMPLOYEE BENEFIT EXPENSE	79,273	51,178	100,012

In the year ended December 31, 2022, the social security contributions included an income of €23.2 million resulting from the release of the provision of employer contribution charges on share-based payment programs due to the reduction in the share price.

During 2023, the Group had an average of 684 employees (2022: 778 employees, 2021: 722 employees).

5.8 Other income/(expenses), net

Other income and expenses, net include the following:

in € thousand	Year ended December 31,		
	2023	2022	2021
Research and development tax credit	6,797	15,348	21,949
Grant income	11,350	191	1,684
Profit/(loss) on disposal of fixed assets and intangible assets, net	(21)	(38)	(42)
Profit/(loss) from revaluation of lease agreements	45	(32)	—
Taxes, duties, fees, charges, other than income tax	(475)	(217)	(212)
Miscellaneous income/(expenses), net	3,824	(3,054)	(403)
OTHER INCOME AND EXPENSES, NET	21,520	12,199	22,976

Other operating income and expenses increased by €9.3 million, **or 76%**, to €21.5 million for the year ended December 31, 2023 from €12.2 million for the year ended December 31, 2022 due to higher grant income and net miscellaneous income.

In the year ended December 31, 2023, "grant income" increased due to the recognition of an €11.1 million grant income received from Scottish Enterprise, Scotland's national economic development agency, for developing non-COVID-19 vaccines (the chikungunya vaccine and IXIARO).

On the other hand the "research and development tax credit" was positively affected in the year 2022 by an amount of €13.9 million related to the research and development programs executed in Austria, mainly for the COVID-19 and chikungunya vaccine candidates. For the year ended December 31, 2021, the research and development tax credit, included €20.2 million from the the research and development programs executed in Austria.

In the "miscellaneous income/(expenses), net", an income of €4.7 million from a settlement with a supplier in connection with COVID-19 activities was recognised in the year ended December 31, 2023. Further non-recurrent transaction results were recorded, namely a loss of €1.4 million from the divestment of the CTM Unit in Solna as well as a €0.3 million gain from the sale of BliNK. In the year ended December 31, 2022, this position was negatively impacted by a litigation provision in the amount of €3.1 million.

5.8.1 Grants

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and the Group will comply with all conditions.

Grants received as reimbursement of approved research and development expenses are recognized as other income when the respective expenses have been incurred and there is reasonable assurance that funds will be received. Advance payments received under such grants are deferred and recognized when these conditions have been met. Advanced payments received which need to be repaid are recognized as borrowings (see Note 5.24.1).

Government grants received to support the purchase of property, plant and equipment are included in non-current liabilities as deferred government grants and are credited to the income statement on a straight-line basis over the expected lives of the related assets.

In February 2022 the Group received two grants worth up to £20.0 million (approximately €23.9 million) from Scottish Enterprise, Scotland's national economic development agency, to support research and development relating to the manufacturing processes of the COVID-19 vaccine and other vaccine candidates. Following the termination of the COVID-19 vaccine program, in May 2023 the grant relating to this program was amended, reducing the available funding by £0.7 million and adjusting how the funds will be used. The funds under these grants will be received over three years, beginning in March 2022. If Valneva fails to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date. In the year ended December 31, 2023, €11.1 million (£9.6 million) of grant funds from Scottish Enterprise were recognized.

In 2019 the Group signed a funding agreement with CEPI. Valneva will receive up to \$24.6 million for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine against chikungunya (VLA1553). In line with CEPI's commitment to equitable access, the funding will underwrite a partnership effort to accelerate regulatory approval of Valneva's chikungunya vaccine for use in regions where outbreaks occur and support World Health Organization prequalification to facilitate broader access in lower- and middle-income countries. Valneva has to pay back part of the consideration upon achievement of certain milestones. The refundable consideration is accounted for as a loan and measured in accordance with IFRS 9 (see Note 5.24.1). The difference between the proceeds from CEPI and the carrying amount of the loan is treated under IAS 20 and presented as "Borrowings". The amount from the CEPI grant which benefits Instituto Butantan is recognized as revenue (see Note 5.5). In the year ended December 31, 2023, €0.2 million of grant income (2022: €0.2 million) and €5.0 million of other revenues (2022: €3.9 million) related to CEPI were recognized.

5.8.2 Research and development tax credits

Research and development tax credits granted by tax authorities are accounted for as grants under IAS 20. As a consequence, the portion of the research tax credit covering operating expenses is recognized in the income statement in "Other income and expenses, net" and the portion covering capitalized development expenditures under "Intangible assets" is recorded as deduction from the assets relating to fixed assets.

In both periods the position included tax credits primarily from Austria and to a lesser extent from France.

5.9 Finance income/(expenses), net

Interest income is recognized on a time-proportion basis using the effective interest method.

in € thousand	Year ended December 31,		
	2023	2022	2021
FINANCE INCOME			
Interest income from other parties	1,210	260	249
TOTAL FINANCE INCOME	1,210	260	249
FINANCE EXPENSES			
Interest expense on loans	(13,681)	(8,238)	(7,273)
Interest expense on refund liabilities	(8,419)	(9,597)	(8,478)
Interest expenses on lease liabilities	(1,183)	(955)	(903)
Other interest expense	(42)	(264)	(309)
TOTAL FINANCE EXPENSES	(23,325)	(19,054)	(16,964)
FOREIGN EXCHANGE GAIN/(LOSSES), NET	5,574	(12,587)	8,130
FINANCE INCOME/(EXPENSES), NET	(16,541)	(31,381)	(8,584)

The foreign exchange gain/(losses), net are primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions, especially caused by USD denominated liabilities (devaluation of the USD against the EUR of 4% in 2023).

The increase in interest expense on loans is due to the 45% increase in Valneva's average loan volume in 2023 and due to the increase of the average interest rate by 1.48 percentage points. In the year ended December 31, 2023 further tranches of the D&O Loan Agreement were drawn, for further details see Note 5.24.

The interest expense on refund liabilities for the year ended December 31, 2023 of €8.4 million was mainly caused by payment deferrals related to the Pfizer agreement. Please refer to Note 5.29 for more information on the refund liability balances.

5.10 Income tax benefit/(expense)

The tax expense for the period comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively. The current Income tax income/(expense) is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Group's subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions, where appropriate, based on amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred income tax is provided on temporary differences arising on investments in subsidiaries and associates, except where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not be reversed within the foreseeable future.

5.10.1 Current income tax

Income tax income/(expense) is comprised of current and deferred tax.

in € thousand	Year ended December 31,		
	2023	2022	2021
CURRENT TAX			
Current income tax charge	(931)	(1,029)	(32)
Adjustments in respect of current income tax of previous year	(175)	97	(19)
DEFERRED TAX			
Relating to origination and reversal of temporary differences	(1,695)	2,468	(3,395)
INCOME TAX BENEFIT/(EXPENSE)	(2,800)	1,536	(3,446)

The individual entities' reconciliations, which are prepared on the basis of the tax rates applicable in each country while taking consolidation procedures into account, have been summarized in the reconciliation below. The estimated tax charge is reconciled to the effective tax charge disclosed.

The tax on the Group's loss before tax differs from the theoretical amount that would arise using the weighted average tax rate applicable to profits of the consolidated companies as follows:

in € thousand	Year ended December 31,		
	2023	2022	2021
LOSS BEFORE TAX	(98,629)	(144,815)	(69,979)
Tax calculated at domestic tax rates applicable to profits in the respective countries	23,400	37,203	18,824
Income not subject to tax (mainly R&D tax credit)	190	7,435	10,739
Expenses not deductible for tax purposes	(1,902)	(26)	(2,509)
Deferred tax asset not recognized	(23,360)	(45,955)	(26,902)
Utilization of previously unrecognized tax losses	(1,593)	2,628	—
Income tax credit/withholding tax/other adjustments	553	101	(459)
Effect of change in applicable tax rate	(160)	586	(3,291)
Exchange differences	(25)	(526)	296
Income tax of prior years	98	90	(64)
Minimum income tax	(2)	(2)	(80)
INCOME TAX BENEFIT/(EXPENSE)	(2,800)	1,536	(3,446)
Effective income tax rate	—	—	—

Although the Group operates at a loss overall, there are profitable entities with revenues from the sale of commercialized travel vaccines and from the sale of third-party products.

5.10.2 Deferred tax

As at December 31, 2023, the deferred tax assets of €204.5 million (December 31, 2022: €199.5 million) were not recognized as there was not sufficient evidence that adequate taxable profit will be available against which the unused tax losses can be utilized in the foreseeable future. Deferred tax assets were only recognized for entities where sufficient evidence has been provided that adequate taxable profit will be available against which the unused tax losses can be utilized in the foreseeable future.

As at December 31, 2023, the Group had tax losses carried forward of €879.1 million (December 31, 2022: €821.6 million), of which €290.0 million related to Valneva SE (December 31, 2022: €272.1 million), €564.2 million related to Valneva Austria GmbH (December 31, 2022: €521.7 million), €10.4 million related to Valneva Scotland, Ltd. (December 31, 2022: €19.6 million), €13.7 million related to Valneva Sweden AB (December 31, 2022: €8.2 million) and €0.9 million related to Vaccines Holdings Sweden AB (December 31, 2022: €0.0 million).

Tax losses carried forward in France, Austria, United Kingdom and Sweden have no expiry date.

The gross movement on the deferred income tax account was as follows:

in € thousand	Year ended December 31,		
	2023	2022	2021
BEGINNING OF THE YEAR	4,943	2,292	5,158
Exchange differences	(294)	171	529
Income statement charge / (credit)	(1,695)	2,480	(3,395)
END OF THE YEAR	2,954	4,943	2,292



The deferred tax assets and liabilities are allocable to the various balance sheet items as follows:

in € thousand	Year ended December 31,	
	2023	2022
DEFERRED TAX ASSET FROM		
Tax losses carried forward	207,858	203,852
Fixed assets	1,765	3,541
Inventory	4,388	3,306
Borrowings and accrued interest	4,722	1,526
Provision	1,501	1,659
Other items	217	2,502
Non-recognition of deferred tax assets	(204,529)	(199,493)
TOTAL DEFERRED TAX ASSETS	15,921	16,893
DEFERRED TAX LIABILITY FROM		
Fixed assets	(6,364)	(4,789)
Intangible assets	(5,157)	(6,229)
Other items	(1,446)	(932)
TOTAL DEFERRED TAX LIABILITY	(12,967)	(11,950)
DEFERRED TAX, NET	2,954	4,943

The corporate income tax rate in Austria was 25% in 2022 and was reduced to 24% in 2023. The corporate income tax rate will be reduced to 23% from 2024 onward.

The corporate income tax rate in the United Kingdom was 19% until March 2023 and was increased to 25% from April 2023 onward.

The corporate income tax rate in France was reduced to 25% from 2022 onward.

The deferred tax assets and liabilities presented above as at December 31, 2023 and December 31, 2022 have been adjusted for these changes in tax rates.

5.11 Earnings (Losses) per share

Basic

Basic earnings (losses) per share are calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of outstanding shares during the year, excluding shares purchased by the Company and held as treasury shares (see Notes 5.22 and 5.23).

	Year ended December 31,		
	2023	2022	2021
Net profit (loss) from continuing operations attributable to equity holders of the Company <i>(in € thousand)</i>	(101,429)	(143,279)	(73,425)
Weighted average number of outstanding shares	138,624,381	115,473,914	97,619,320
BASIC EARNINGS (LOSSES) FROM CONTINUING OPERATIONS PER SHARE (€ PER SHARE)	(0.73)	(1.24)	(0.75)

Diluted

Diluted earnings per share are calculated by adjusting the weighted average number of ordinary outstanding shares to assume conversion of all dilutive potential ordinary shares. The Company has share options as dilutive potential ordinary shares. For the share options, a calculation is done to determine the number of shares that could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the monetary value



of the subscription rights attached to outstanding share options. The number of shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the share options.

	Year ended December 31,		
	2023	2022	2021
Profit used to determine diluted earnings per share (in € thousand)	(101,429)	(143,279)	(73,425)
Weighted average number of outstanding shares for diluted earnings (losses) per share ⁽¹⁾	138,624,381	115,473,914	97,619,320
DILUTED EARNINGS/(LOSSES) FROM CONTINUING OPERATIONS PER SHARE (€ PER SHARE)	(0.73)	(1.24)	(0.75)

⁽¹⁾ Potentially dilutive securities (2023: 2,861,904 share options; 2022: 1,504,892 share options, 2021: 5,846,267) have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact due to the losses reported.

5.12 Intangible assets

Computer software

Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and implement the specific software. These costs are amortized on a straight-line basis over their estimated useful lives, generally three to six years.

Costs associated with developing or maintaining computer software programs are recognized as expenses when they were incurred.

The costs of computer software subject to a software as a service agreement (SaaS) are recognized as expenses when they are incurred.

Acquired research and development technology and projects

Acquired research and development technology projects are capitalized. Amortization of the intangible asset over its useful life starts when the product has been fully developed and is ready for use. These costs are amortized on a straight-line basis over their useful lives. This useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods of 24 years, which is based on the patent life and technological replacement of a newer vaccine generation.

Development costs

Research expenses are recognized as expenses when incurred. Development expenses incurred on clinical projects (related to the design and testing of new or significantly improved products) are recognized as intangible assets when the following criteria have been fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and to utilize or sell it;
- there is an ability to utilize or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial, and/or other resources to complete the development and to utilize or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as expenses when they are incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its useful life, generally 10 - 15 years. In 2023 and 2022, no development costs were capitalized.

Amortization

Amortization of intangible assets is calculated using the straight-line method to allocate their cost amounts to their residual values over their estimated useful lives, as follows:

- Software 3 - 6 years
- Acquired R&D technology and projects 1 - 24 years
- Development costs 1 - 15 years

The useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods of 24 years (with a remaining useful life period of 9 years) which is based on estimated period where Valneva benefits from the patent.

<i>in € thousand</i>	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
YEAR ENDED DECEMBER 31, 2023					
Opening net book value	585	26,731	1,394	—	28,711
Additions	85	—	—	—	85
Amortization charge	(420)	(2,683)	(160)	—	(3,262)
Exchange rate differences	4	24	4	—	33
CLOSING NET BOOK VALUE	255	24,073	1,239	—	25,567
AS AT DECEMBER 31, 2023					
Cost	6,368	80,562	7,314	—	94,244
Accumulated amortization and impairment	(6,113)	(56,489)	(6,075)	—	(68,677)
CLOSING NET BOOK VALUE	255	24,073	1,239	—	25,567

<i>in € thousand</i>	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
YEAR ENDED DECEMBER 31, 2022					
Opening net book value	1,217	29,768	1,581	134	32,700
Additions	201	1	—	—	201
Amortization charge	(792)	(2,957)	(171)	—	(3,920)
Disposals	—	—	(2)	(125)	(127)
Exchange rate differences	(41)	(80)	(14)	(9)	(144)
CLOSING NET BOOK VALUE	585	26,731	1,394	—	28,711
AS AT DECEMBER 31, 2022					
Cost	6,240	80,514	7,304	—	94,058
Accumulated amortization and impairment	(5,655)	(53,783)	(5,910)	—	(65,347)
CLOSING NET BOOK VALUE	585	26,731	1,394	—	28,711

As at December 31, 2023 and December 31, 2022, there were no acquired research and development technology project assets with a definite useful life which are not yet amortized.

Significant intangible assets (included in acquired R&D technology and projects as well as in development costs) with definite useful life are comprised primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €78.8 million (December 31, 2022: €78.7 million) and a net book value amounting to €25.0 million (December 31, 2022: €27.7 million).

For impairment test, see Note 5.15.

5.13 Leases (right of use assets)

The Group leases various premises, equipment, and vehicles. Rental contracts are typically made for fixed periods ranging from a few months to five years. The rental contracts for the premises in Sweden (10 and 15 years) include a significantly longer fixed period. Generally, the rental contracts do not include an option for early termination or prolongation of the rental period. The rental contracts for the premises in Sweden include options to terminate the agreements earlier. The notice periods in these contracts are between one and six years. At the commencement date, it was not reasonably certain that these early termination options were to be exercised, so they were not included in the valuation of the lease liabilities and right of use assets. Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, which is generally the case for leases in the Group, the Group uses its incremental borrowing rate. The incremental borrowing rate depends on the term, currency and start date of the lease and is determined based on a series of inputs including: the risk-free rate based on government bond rates, a country-specific risk adjustment, a credit risk adjustment based on bond yields, and an entity-specific adjustment when the risk profile of the entity that enters into the lease is different than that of the Group and the lease does not benefit from a guarantee from the Group. Valneva uses incremental borrowing rates between 0.183% and 7.000%, depending on the currency and the remaining term until maturity. For the rental contracts

for the premises in Sweden interest rates of 2.493% and 3.401% were determined following significant increases in right of use assets in Sweden.

The Group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset. This includes also the major contracts for the premises in Sweden, which contain variable payments based on inflation rates or on published interest rates.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets (below €10,000) are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less and for which there is no option for the lessee to prolong the contract to more than 12 months or there is no reasonable certainty that such an option will be exercised. Low-value assets comprise mainly IT equipment and small items of office furniture.

The Group does not have residual value guarantees in the rental contracts.

5.13.1 Development of right-of-use assets

<i>in € thousand</i>	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total assets
YEAR ENDED DECEMBER 31, 2023				
Opening net book value	41,365	—	238	41,603
Additions	3,593	—	189	3,781
Amortization	(2,428)	—	(141)	(2,569)
Termination of contracts	(22,516)	—	(32)	(22,548)
Exchange rate differences	127	—	(2)	125
CLOSING NET BOOK VALUE	20,141	—	251	20,392

<i>in € thousand</i>	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total assets
YEAR ENDED DECEMBER 31, 2022				
Opening net book value	47,993	15	278	48,285
Additions	1,482	—	147	1,629
Amortization	(2,944)	(15)	(145)	(3,103)
Impairment charge	(4,178)	—	—	(4,178)
Revaluation due to variable payments	859	—	—	859
Termination of contracts	—	—	(32)	(32)
Exchange rate differences	(1,847)	—	(10)	(1,857)
CLOSING NET BOOK VALUE	41,365	—	238	41,603

In the year ended December 31, 2023, right of use assets decreased from €41.6 million to €20.4 million, mainly due to termination of contracts and amortizations. This was partly offset by modifications of lease contacts for buildings in Sweden and a new lease contract for office space in the United States.

The largest lease agreements for the premises in Austria was terminated in September 2023 with a termination value of €22.5 million. The largest remaining active lease contract was for the building in Solna, Sweden with a book value of €15.5 million as at December 31, 2023 (December 31, 2022: €14.7 million).

For details on lease liabilities, see Note 5.27. For details on the impairment charge, see Note 5.15.

5.13.2 Other amounts recognized in the consolidated income statement

Expense relating to short-term leases and leases of low-value assets as well as expenses relating to termination of lease contracts have not been material in 2023 and 2022. There have been no substantive revaluations in 2023 and 2022.

5.14 Property, plant and equipment

Property, plant and equipment mainly comprise a manufacturing facility and leasehold improvements in rented office and laboratory space. All Property, plant and equipment are stated at historical cost less depreciation and less impairment losses when necessary. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or are recognized as a separate asset, only when it is probable that future economic benefits associated with the item will flow to the Group and that the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they incur.

Property, plant and equipment include machinery, for which validation is required to bring the asset to its working condition. The costs of such validation activities are capitalized together with the cost of the asset. Validation costs beyond the normal validation costs, which are usually required to bring an asset to its working condition, are expensed immediately. The usual validation costs are capitalized on the asset and depreciated over the remaining life of the asset or the shorter period until the next validation is usually required.

Depreciation of assets is calculated using the straight-line method to allocate their cost amounts to their residual values over their estimated useful lives, as follows:

- Buildings, leasehold improvements 5 - 40 years
- Machinery, laboratory equipment 1 - 15 years
- Furniture, fittings and office equipment 4 - 10 years
- Hardware 3 - 5 years

Leasehold improvements are depreciated over the shorter of their useful life or the lease term, unless the entity expects to use the assets beyond the lease term.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date.

An asset's carrying amount is immediately written down to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains and losses are included in the income statement "other income and expenses, net" (see Note 5.8).

<i>in € thousand</i>	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Computer hardware	Furniture, fittings and other	Assets in the course of construction	Total
YEAR ENDED DECEMBER 31, 2023						
Opening net book value	74,493	34,544	1,140	675	1,583	112,435
Change in consolidation scope	22,373	—	—	—	—	22,373
Additions	9,088	2,884	414	33	1,985	14,404
Depreciation charge	(6,008)	(4,372)	(442)	(155)	—	(10,976)
Impairment charge/reversal	—	1,869	—	—	—	1,869
Disposals	(1,837)	(3,547)	(61)	(2)	—	(5,448)
Exchange rate differences	991	383	3	9	155	1,541
CLOSING NET BOOK VALUE	99,100	31,761	1,053	560	3,724	136,198
AS AT DECEMBER 31, 2023						
Cost	125,580	73,686	3,438	1,895	3,724	208,323
Accumulated depreciation and impairment	(26,479)	(41,926)	(2,384)	(1,335)	—	(72,125)
CLOSING NET BOOK VALUE	99,100	31,761	1,053	560	3,724	136,198

The change in consolidation scope came from the acquisition of VBC3, see Note 5.1.2. The additions were primarily from the finalization of the Almeida facility in Livingston. The reversal of impairment is due to a reversal of a fixed asset impairment in the amount of €1.9 million related to production equipment.

<i>in € thousand</i>	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Computer hardware	Furniture, fittings and other	Assets in the course of construction	Total
YEAR ENDED DECEMBER 31, 2022						
Opening net book value	10,284	21,066	1,335	202	92,659	125,545
Reclassification	45,082	16,576	—	—	(61,658)	—
Additions	30,902	24,484	281	552	(29,043)	27,176
Depreciation charge	(3,091)	(10,424)	(432)	(64)	—	(14,012)
Impairment charge	(4,453)	(14,618)	—	—	—	(19,071)
Disposals	—	(43)	(2)	—	—	(45)
Exchange rate differences	(4,230)	(2,497)	(42)	(14)	(375)	(7,158)
CLOSING NET BOOK VALUE	74,493	34,544	1,140	675	1,583	112,435
AS AT DECEMBER 31, 2022						
Cost	96,528	76,315	3,245	1,912	1,583	179,583
Accumulated depreciation and impairment	(22,035)	(41,770)	(2,105)	(1,238)	—	(67,148)
CLOSING NET BOOK VALUE	74,493	34,544	1,140	675	1,583	112,435

Additions in 2022 mainly referred to investments in Scotland and Sweden and related to the production of VLA2001. Reclassification in 2022 mainly related to assets in Scotland for which final construction took place in 2022. With regards to impairment charges recognized in 2022, see Note 5.15.

From the total of €16.9 million (2022: €44.3 million) of depreciation, amortization and impairment expenses, €12.5 million (2022: €39.5 million) were charged to cost of goods and services, €3.0 million (2022: €3.5 million) were charged to research and development expenses, €0.8 million (2022: €0.7 million) were charged to marketing and distribution expenses and €0.5 million (2022: €0.6 million) were charged to general and administrative expenses. The decrease in depreciation and amortization charged to costs of goods and services was caused by impairments in VLA2001 and DUKORAL in 2022.

Non-current operating assets by region

Non-current operating assets for this purpose consist of intangible assets, right of use assets and property, plant and equipment. The main non-current operating assets are allocated to sites where production and research and development activities take place. Sales activities by distribution sites do not require major non-current operating assets. Revenues by region (see Note 5.5) are structured according to the location of the final customer. In some countries there are customers, but no assets.

<i>in € thousand</i>	Year ended December 31,	
	2023	2022
United Kingdom	87,646	84,843
Austria	49,460	52,199
Nordics	39,111	40,250
Other Europe	4,839	5,211
United States	934	64
Canada	166	183
NON-CURRENT ASSETS	182,156	182,749

5.15 Impairment testing

At the end of each reporting period Valneva assesses whether there is any indication that an asset may be impaired. Indicators for the necessity of an impairment test are, among others, actual or expected declines in sales or margins and significant changes in the economic environment with an adverse effect on Valneva's business. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units or CGUs). The cash-generating units correspond with the specific vaccine products and vaccine candidates. Non-financial assets, other than goodwill, that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

De-recognition of VLA2001

As at December 31, 2022, impairment tests were adapted to the changes resulting in de-recognition of the COVID vaccine VLA2001 as a CGU as no material future cash flows are expected to be generated by this CGU following the Company's decision to wind down the COVID-19 program, and utilization of dedicated and shared assets was reviewed.

In addition, future cash flows generated by the IXCHIQ vaccine were taken into account as fixed assets originally expected to be utilized by COVID are now expected to be used across the IXIARO, DUKORAL and IXCHIQ CGUs. A triggering event was identified in December 2022 for the CGUs impacted by suspending manufacturing of VLA 2001 and impairment tests were performed as at December 31, 2022. As a consequence, impairment charges for VLA2001 of €14.8 million were recorded for the year ended December 31, 2022. This impairment was composed of €1.0 million for right of use assets, €1.9 million for leasehold improvements and €11.9 million for manufacturing equipment. In the year ended December 31, 2023, the impairment for manufacturing equipment could be reduced by €1.9 million, as certain assets were usable for other vaccine productions, especially IXCHIQ (see also Note 5.13 and 5.14).

IXIARO

The impairment test for the CGU of IXIARO did not result in any impairment for the years ended December 31, 2023 and 2022. Further, no triggering event was identified.

DUKORAL

As at December 31, 2022, impairment charges for DUKORAL CGU were recorded in the amount of €8.3 million, including €3.2 million of right of use assets, €2.5 million of leasehold improvements and €2.7 million of manufacturing equipment. As at December 31, 2023, no triggering event was identified and also the impairment testing did not result in further impairment needs. The results of the impairment testing on DUKORAL were not materially different from the position as at December 31, 2022. An increase in the WACC or reduction in revenue may result in further impairment charges (see table below).

IXCHIQ

The impairment test for the CGU of the new vaccine IXCHIQ as at December 31, 2023 did not result in any impairment requirement as the value in use for the CGU was considerably higher than the book value of its assets. Additionally, no triggering events were identified for IXCHIQ. Further details can be seen in the below sensitivity analysis.

Sensitivity to changes in assumptions

The net present value calculations are based upon assumptions regarding market size, expected sales volumes resulting in sales value expectations, expected royalty income or expected milestone payments. The net present value calculations are most sensitive to the following assumptions:

- discount rate
- reduction of expected revenues

The following table shows the these parameters and their sensitivity to the overall result in case of described changes:

<i>in € thousand except ratios</i>	IXIARO	DUKORAL	IXCHIQ	CTM*
WEIGHTED AVERAGE COST OF CAPITAL (WACC)				
2023	9.08 %	8.94 %	9.04 %	— %
2022	8.34 %	8.30 %	8.25 %	9.50 %
BREAK-EVEN WACC				
2023	81.06 %	8.04 %	113.62 %	— %
2022	56.27 %	7.59 %	113.60 %	15.00 %
Impairment if WACC increases by 1% (in € thousand)				
2023	NO	3,330	NO	—
2022	NO	5,095	NO	NO
Impairment if sales reduce by 10% (in € thousand)				
2023	NO	6,508	NO	—
2022	NO	4,023	NO	1

* CTM CGU was sold in July 2023, see Note 5.1.1.

5.16 Financial instruments

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value at each balance sheet date.

The valuation techniques utilized for measuring the fair values of assets and liabilities are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect management's market assumptions.

The fair value of instruments that are quoted in active markets are determined using the quoted prices where they represent those at which regularly and recently occurring transactions take place. Furthermore, the Group uses valuation techniques to establish the fair value of instruments where prices, quoted in active markets, are not available.

5.16.1 Financial instruments by category

The Group has materially only short-term assets and all of the financial instruments are categorized as assets at amortized costs. Financial instruments can be found in the following positions within the assets:

in € thousand	Year ended December 31	
	2023	2022
FINANCIAL INSTRUMENTS IN ASSETS		
Trade receivables	41,645	23,912
Other assets ⁽¹⁾	1,109	11,988
Cash and cash equivalents	126,080	289,430
TOTAL ASSETS	168,834	325,330

(1) Prepayments and tax receivables and other non-financial assets are excluded from the other assets balance, as this analysis is required only for financial instruments.

The Group has only financial instruments which are categorized as liabilities at amortized costs. Financial instruments can be found in the following positions within the liabilities:

in € thousand	Year ended December 31	
	2023	2022
FINANCIAL INSTRUMENTS IN LIABILITIES		
Borrowings	176,847	98,806
Trade payables and accruals	44,303	41,491
Tax and employee-related liabilities ⁽¹⁾	10,815	10,778
Lease liabilities	31,969	53,574
Refund liabilities	39,941	143,085
Other liabilities ⁽²⁾	34	32
TOTAL LIABILITIES	303,908	347,767

(1) Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required only for financial instruments.

(2) Deferred income is excluded from the other liabilities balance, as this analysis is required only for financial instruments.

5.16.2 Fair value measurements

As at December 31, 2023 and December 31, 2022, the Group did not have assets and liabilities measured through profit and loss. In both periods, the Group also did not have open foreign currency options nor foreign currency forwards. Due to the short-term nature of its financial instruments fair valuation has no effect on the financial position.

5.16.3 Foreign currency sensitivity analysis

The following table details the Group's sensitivity of financial instruments to a 10% increase and decrease in currency units against the relevant foreign currencies. 10% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management's assessment of the reasonably possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the year-end for a 10% change in foreign currency rates. The sensitivity analysis includes external loans as well as loans to foreign operations within the Group where the denomination of the loan is in a currency other than the currency of the lender or the borrower. A positive number below indicates an increase in pre-tax profit or a reduction in pre-tax loss.

With all other variables held constant, the impact from changes in exchange rates on the pre-tax result would be as follows:

in € thousand	Year ended December 31	
	2023	2022
\$/EUR +10%	(24,079)	(21,245)
\$/EUR -10%	29,430	25,966
GBP/EUR +10%	4,760	3,941
GBP/EUR -10%	(5,817)	(4,817)
SEK/EUR +10%	(8,846)	(9,318)
SEK/EUR -10%	10,812	11,388
CAD/EUR +10%	2,368	2,011
CAD/EUR -10%	(2,894)	(2,457)

The effect in the USD/EUR relationship is mostly due to borrowings denominated in USD while the cash and working capital is predominantly on a EUR basis. Due to higher borrowings in the year ended December 31, 2023, the Group's sensitivity has slightly increased. The Group has not used any hedging instruments to reduce the impact of foreign exchange rate changes.

5.16.4 Credit quality of financial assets

The credit quality of financial assets that are not impaired can be assessed by reference to external credit ratings (if available) or to historical information about counterparty default rates as follows:

in € thousand	Year ended December 31	
	2023	2022
TRADE RECEIVABLES		
Receivables from governmental institutions (AAA-country)	205	757
Receivables from governmental institutions (AA-country)	11,535	3,620
Receivables from governmental institutions (A-country)	—	—
AA	—	—
A	—	4,861
Counterparties without external credit rating or rating below A	29,905	14,674
TRADE RECEIVABLES	41,645	23,912
OTHER ASSETS		
A	—	11,296
Assets from governmental institutions (AA-country)	—	151
Counterparties without external credit rating or rating below A	1,109	541
OTHER ASSETS	1,109	11,988
CASH AND CASH EQUIVALENTS		
AA	17,581	11,557
A	108,253	272,719
Counterparties without external credit rating or rating below A	245	5,154
CASH AND CASH EQUIVALENTS	126,080	289,430

The rating information refers to long-term credit ratings as published by Standard & Poor's or another rating organization (equivalent to the Standard & Poor's rating).

The maximum exposure to credit risk at the reporting date is the fair value of the financial assets.

5.16.5 Impairment of financial assets

Trade receivables

According to IFRS 9.5.5.15, the simplified approach (measure the loss allowance at an amount equal to lifetime expected credit losses) has to be used for trade receivables, which do not contain a significant financing component. This is the case for the Group, as all trade receivables are short-term with a maturity lasting less than 12 months.

Loss allowances have to be established for each trade receivable based on the expected credit losses. Accordingly, at the end of each reporting period, trade receivables were adjusted through a loss allowance in accordance with the revised expected outcome.

According to IFRS 9.5.5.17, default probabilities are to be determined on the basis of historical data but must be adjusted on the balance sheet date on the basis of up-to-date information and forward looking information. The analysis of the historical data showed as at December 31, 2023 and December 31, 2022 that losses incurred were immaterial, taking further into account the limited number of customers as well as credit checks mentioned in Note 5.2.5. Therefore, loss allowance was considered immaterial as at December 31, 2023 and December 31, 2022.

Other assets and cash and cash equivalents

Historically, no losses have been incurred on other assets measured at amortized costs and on cash and cash equivalents. As at December 31, 2023 and December 31, 2022, the expected credit loss was calculated using the cumulative expected default rate based on the counterparties' ratings and was immaterial.

5.17 Inventories

Inventories are stated at the lower of cost and net realizable value. The cost of finished goods and work in progress comprises raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity) at standard costs. The variances between the actual costs and the standard costs are calculated monthly and allocated to the inventory, so there is no difference between actual and standard costs. Inventories exclude borrowing costs. Provisions for batches which fail to meet quality requirements and may not be sold (failed batches) are deducted from the value of inventories.

in € thousand	Year ended December 31	
	2023	2022
Raw materials	35,379	86,452
Work in progress	38,094	114,218
Finished goods	12,968	11,783
Purchased goods (third party products)	3,626	3,518
GROSS AMOUNT OF INVENTORIES BEFORE WRITE-DOWN	90,067	215,970
Less: write-down provision	(45,601)	(180,866)
INVENTORIES	44,466	35,104

The decrease in gross amounts of inventories before write-down is primarily related to decrease in the inventory of raw materials and work in progress as of December 31, 2023.

The total write-down provision on inventory amounts to €45.6 million as of December 31, 2023 (December 31, 2022: €180.9 million). The decrease in the write-down provision compared to prior year is mainly attributable to the suspension of manufacturing of VLA2001 in 2022. As a result, raw material acquired to produce VLA2001 which could not be repurposed and used for other products was written down. Work in progress related to VLA2001 was written down due to reduced sales expectations following the termination of supply agreements. In total an amount of €176.9 million related to VLA2001 inventory was included in 2022.

Write-down provisions related to the inventory categories as follows:

in € thousand	Year ended December 31	
	2023	2022
Raw materials	28,158	79,939
Work in progress	15,177	99,089
Finished goods	1,524	1,417
Purchased goods (third party products)	743	421
TOTAL WRITE-DOWN PROVISION	45,601	180,866

As at December 31, 2023, €31.2 million of the inventory reserve related to VLA2001 (December 31, 2022: €176.9 million), of which €26.6 million was attributable to the raw materials (December 31, 2022: €78.8 million) and €4.6 million to work in progress (December 31, 2022: €98.1 million). As at December 31, 2023, the remaining write-down provision of €12.2 million in raw materials and work in progress relate to Valneva's commercialized vaccines IXIARO, DUKORAL and IXCHIQ (December 31, 2022: €2.2 million).

As at December 31, 2023, the write down provision for finished goods for Valneva's commercialized vaccines IXIARO and DUKORAL based on sales expectations and limited shelf life of the products amount to €1.5 million (December 31, 2022: €1.4 million). Also a slight increase in the provision for third party products was necessary as at December 31, 2023 (December 31, 2022: €0.4 million).

5.18 Trade receivables

Trade receivables are initially recognized at fair value. The carrying amount of trade receivables is reduced through an allowance for doubtful account. When a trade receivable is considered uncollectible, it is written off against this

allowance account. Subsequent recoveries of amounts previously written off are credited against the allowance account. Changes in the carrying amount of the allowance account are recognized in the profit or loss.

Trade receivables include the following:

in € thousand	Year ended December 31	
	2023	2022
Trade receivables	41,714	23,997
Less: loss allowance of receivables	(69)	(84)
TRADE RECEIVABLES, NET	41,645	23,912

In 2023 and 2022, no material impairment losses were recognized. As at December 31, 2023, the amount of trade receivables past due (which is defined as being more than 30 days late) reached €4.5 million (December 31, 2022: €4.4 million) of which €3.4 million come from a governmental authority with a credit rating of B+/B2.

Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

As at December 31, 2023, trade receivables included €41.6 million (December 31, 2022: €23.9 million) of receivables from contracts with customers.

5.19 Other assets

Other assets include the following:

in € thousand	Year ended December 31	
	2023	2022
R&D tax credit receivables	43,762	49,174
Advance payments	759	1,672
Tax receivables	3,921	9,066
Prepaid expenses	4,468	4,939
Contract costs	3,710	3,710
Consumables and supplies on stock	872	1,380
Miscellaneous current assets	522	451
OTHER NON-FINANCIAL ASSETS	58,014	70,391
Deposits	194	11,822
Miscellaneous financial assets	916	165
OTHER FINANCIAL ASSETS	1,109	11,988
OTHER ASSETS	59,123	82,378
Less non-current portion	8,490	8,299
CURRENT PORTION	50,633	74,079

Due to the short term nature of the financial instruments included in other assets, their carrying amount is considered to be the same as their fair value.

The "R&D tax credit receivables" is mainly related to the received research and development tax credit primarily in connection with the COVID-19, chikungunya and Lyme vaccine candidates.

The reduction in "tax receivables" goes back to receipt of VAT claims. The reduction in "deposits" is related to the termination of the lease agreement and the subsequent purchase of VBC3. In 2022, VBC3 was still under a lease agreement for which a deposit was given. For more information about the VBC3 acquisition, see Note 5.13.

5.20 Cash and cash equivalents

Cash includes cash at bank, cash in hand, and deposits held at call with banks. Cash equivalents include short-term bank deposits and medium-term notes with a maximum maturity of three months that can be assigned or sold on very short notice and are subject to insignificant risk of changes in value in response to fluctuations in interest rates.

<i>in € thousand</i>	Year ended December 31	
	2023	2022
Cash in hand	9	3
Cash at bank	126,071	286,530
Clearing accounts	(1)	(1)
Restricted cash	—	2,898
CASH AND CASH EQUIVALENTS	126,080	289,430

As at December 31, 2023, there was no restricted cash. As at December 31, 2022 the restricted cash mainly consisted of a locked bank account for a bank guarantee provided to a supplier as security for a payment relating to a settlement agreement announced in September 2022. As a result of a payment made in February 2023, this restriction has been removed.

In 2023, the minimum liquidity requirement for the Group according to the D&O Loan Agreement. (see Note 5.24.1) was €35 million.

5.21 Assets classified as held for sale

BiINK Biomedical SAS

Valneva previously held a 48.9% equity interest in BiINK Biomedical SAS, Marseille (BiINK), a private company not listed on a stock exchange. As a result of the management's intent to sell the equity interest, it was classified as an asset held for sale as of June 30, 2022.

On September 8, 2023, the Company sold its equity interest in BiINK. The proceeds of the sale amounted to €2.4 million. For the year ended December 31, 2023, the final sale resulted in a profit of €0.2 million. The transaction stipulates an earn-out component which entitles the Company to receive 0.006491% for each equity interest share of BiINK's net revenue over a period of seven years. The Company has assessed the fair value of the earn-out component as at December 31, 2023 to be immaterial.

Divestment of CTM Unit in Solna, Sweden

Valneva decided to divest its CTM unit in Solna as explained in Note 5.1.1 and 5.8. The transfer of ownership of the unit took effect on July 1, 2023. With the payment of the proceeds no remaining assets or liabilities held for sale were shown for the CTM unit as of December 31, 2023.

5.22 Equity

5.22.1 Share capital and share premium

The ordinary shares and convertible preferred shares are classified as equity.

<i>number of shares</i>	Year ended December 31	
	2023	2022
Ordinary shares issued (€0.15 par value per share)	138,912,142	138,346,968
Convertible preferred shares registered	—	20,514
TOTAL SHARES ISSUED	138,912,142	138,367,482
Less Treasury shares	(124,322)	(124,322)
OUTSTANDING SHARES	138,787,820	138,243,160

Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, if any, from the proceeds.

When the Company purchases its own equity share capital (treasury shares), the consideration paid, including any directly attributable incremental costs (net of income taxes, if any) is deducted from equity attributable to the Company's equity holders until the shares are cancelled, reissued or otherwise disposed of. In cases where such shares are subsequently sold or reissued, any consideration received, net of any directly attributable incremental transaction costs and related income tax effects is included in equity attributable to the Company's equity holders.

The profit or loss for the year is fully included in net result, while other comprehensive income solely affects retained earnings and other reserves.

The following table shows the development of the number of outstanding shares:

number of shares	Year ended December 31	
	2023	2022
OUTSTANDING AS AT JANUARY 1	138,243,160	105,114,763
Share-based compensation exercises	544,660	2,578,636
Capital Increase	—	30,549,761
OUTSTANDING AT YEAR END	138,787,820	138,243,160

The Company has issued stock options to employees under various employee stock option plans (ESOPs) established in the last 10 years. For details, please refer to Note 5.23.

In June 2022, Pfizer invested €90.6 million (\$95.0 million) million net representing 9,549,761 shares at a price of €9.49 per share through a reserved capital increase. In October 2022, the Company closed the Global Offering for a total of 21,000,000 new ordinary shares. Aggregate gross proceeds of the Global Offering, before deducting underwriting commissions and expenses payable by the Company, were €102.9 million (\$99.9 million). The costs of both equity transactions which were directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

Conditional and authorized capital

As at December 31, 2023, the Company had 9,919,432 (December 31, 2022: 7,267,281) shares of conditional capital in connection with (see Note 5.23):

- the possible exercise of existing stock options; and
- the possible final grant of existing Free Ordinary Shares.

Pursuant to resolution No. 21 of the Combined General Meeting held on December 20, 2023, the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future, under resolutions 13 to 20 of said Meeting, may not exceed €5.2 million, it being specified that to this maximum aggregate amount will be added the additional nominal amount of shares or securities to be issued in accordance with applicable legal or regulatory provisions and, if applicable, with contractual provisions providing for other forms of adjustment, in order to preserve the rights of the holders of securities or other rights giving immediate and/or future access to the capital of the Company.

5.22.2 Other reserves

<i>in € thousand</i>	Other regulated reserves	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
BALANCE AS AT JANUARY 1, 2023	52,820	(5,041)	(645)	17,636	(9,517)	55,252
Currency translation differences	—	3,300	—	—	—	3,300
Defined benefit plan actuarial losses	—	(130)	—	—	—	(130)
Share-based compensation expense	—	—	—	6,666	—	6,666
Purchase/sale of treasury shares	—	—	—	—	—	—
BALANCE AS AT DECEMBER 31, 2023	52,820	(1,871)	(645)	24,301	(9,517)	65,088

<i>in € thousand</i>	Other regulated reserves	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
BALANCE AS AT JANUARY 1, 2022	52,820	(5,146)	(645)	15,000	(9,517)	52,512
Currency translation differences	—	(73)	—	—	—	(73)
Defined benefit plan actuarial gains	—	178	—	—	—	178
Share-based compensation expense	—	—	—	2,636	—	2,636
Purchase/sale of treasury shares	—	—	—	—	—	—
BALANCE AS AT DECEMBER 31, 2022	52,820	(5,041)	(645)	17,636	(9,517)	55,252

Other regulated reserves contain a non-distributable mandatory legal reserve from the merger with InterCell AG.

The Company did not obtain a dividend from its subsidiaries or pay a dividend to its shareholders in 2023 and 2022.

5.23 Share-based compensation

The Company operates various share-based compensation plans, both equity-settled and cash-settled plans. The consolidated statement of profit or loss includes the following expenses arising from share-based payments:

in € thousand	Year ended December 31		
	2023	2022	2021
Stock option plans	5,152	1,916	646
Free convertible preferred share plans	—	—	652
Free ordinary shares program	1,514	719	1,334
Phantom shares	(390)	(11,291)	11,877
SHARE-BASED COMPENSATION EXPENSE /(INCOME)	6,276	(8,656)	14,509

5.23.1 Stock option plans

The fair value of such share-based compensation is recognized as an expense for employee services received in exchange for the grant of the options. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted, excluding the impact of any non-market vesting conditions. Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Annually, the Group revises its estimates of the number of options that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement and makes a corresponding adjustment to equity.

The proceeds received net of any directly attributable transaction costs are credited to nominal capital (nominal value) and share premium (amount exceeding nominal value) when the options are exercised.

Beginning in 2013, the Company granted stock options to employees and management pursuant to seven successive plans.

Stock options granted from 2013 to 2017 are exercisable in two equal portions after being held for two and for four years (the vesting periods), while stock options granted from 2019 onwards are exercisable in three equal portions after being held for one year, two years and three years. Stock options granted in 2019 are subject to performance conditions.

All options expire no later than ten years after being granted. Stock options are not transferable or negotiable and unvested options lapse without compensation upon termination of employment with the Group (forfeiture). Stock options granted from 2013 onwards vest with the effectiveness of the takeover of more than 50% of the outstanding voting rights of the Group. As this change of control event was considered remote, it has not been considered in the determination of the vesting period.

Changes in the number of stock options outstanding and their related weighted average exercise prices are as follows:

	2023			2022		
	Number of options	Number of shares available	Average exercise price (in € per share)	Number of options	Number of shares available	Average exercise price (in € per share)
OUTSTANDING AS AT JANUARY 1	5,774,339	5,776,114	4.90	3,933,385	3,996,588	3.11
Granted	3,441,269	3,441,269	5.25	3,152,751	3,152,751	6.47
Expired	(3,648)	(4,015)	2.92	—	—	—
Forfeited	(647,024)	(647,024)	5.25	(196,834)	(196,834)	3.05
Exercised	(14,134)	(15,542)	2.92	(1,114,963)	(1,176,391)	3.32
OUTSTANDING AT YEAR END	8,550,802	8,550,802	5.02	5,774,339	5,776,114	4.90
Exercisable at year end	3,296,856	3,296,856	3.98	2,621,588	2,623,363	3.02

14,134 employee stock options (of which 14,134 were granted from ESOP 2013, 0 from ESOP 2015 and 0 from ESOP 2016) were exercised in 2023, whereas 1,114,963 employee stock options (of which 615,918 were granted from ESOP 2013, 478,845 from ESOP 2015 and 20,200 from ESOP 2016) were exercised in 2022.

Stock options outstanding at the end of the period have the following expiry dates and exercise prices:

expiry date	Exercise price (in € per share)	Number of options as at December 31, (presentation as number of convertible shares)	
		2023	2022
2023	2.92	—	19,557
2025	3.92	43,655	43,655
2026	2.71	14,500	14,500
2027	2.85	551,475	551,475
2029	3.05	1,770,676	1,994,176
2032	6.47	2,750,477	3,152,751
2033	5.25	3,420,019	—
OUTSTANDING AT YEAR END		8,550,802	5,776,114

In 2023, 3,441,269 stock options were granted (2022: 3,152,751). The weighted average grant date fair value of options granted during 2023 was €3.22 (2022: €3.77). The fair value of the granted options was determined using the Black Scholes valuation model.

The significant inputs into the models were:

	As at Dec 15, 2023
Expected volatility (%), based on historical volatility	72.95
Expected vesting period (term in years)	5.50 – 6.50
Risk-free interest rate (%)	2.12 – 3.15

5.23.2 Free ordinary shares

In 2023, the Company's Management Board granted 445,320 free ordinary shares for the benefit of Management Board and members of the Company's senior management (2022: 401,911). The purpose of this free share plan 2023-2026 is to provide a long-term incentive program for the Company's senior management.

The number of free ordinary shares granted was as follows:

number of free ordinary shares granted	Year ended December 31	
	2023	2022
Executive Committee (formerly Management Board)	263,842	196,855
Senior Leadership Group	181,478	205,056
FREE ORDINARY SHARES GRANTED	445,320	401,911

In accordance with the foregoing, changes in the outstanding free ordinary shares are as follows:

number of free shares	Year ended December 31	
	2023	2022
OUTSTANDING AS AT JANUARY 1	1,487,667	1,842,404
Granted	445,320	401,911
Forfeited	(14,725)	(120,000)
Exercised	(549,632)	(636,648)
OUTSTANDING AT YEAR END	1,368,630	1,487,667

Subject to vesting conditions (service conditions), the free share granted to a participant will vest in and be delivered to that participant ("seront définitivement attribuées") in three tranches. Each tranche will amount to one third of the total individual allocation. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche.

The first and the second tranche for the free shares granted in 2023 will vest on December 15, 2025, and the third tranche will vest on December 15, 2026.

Following the vesting of the free shares, no compulsory holding period will apply to the vested shares.

The expenses arising from the free ordinary share plan is the number of shares granted expected to vest multiplied with the share price at the grant date.

The 2023 and 2022 plans further provide for accelerated vesting of the free shares in the event of a Change of Control (as defined in the applicable terms & conditions) occurring no earlier than two years after the grant date. For the 2022 plan that is October 10, 2024, and for the 2023 plan it is December 15, 2025. As management considered the chance of a Change of Control remote at the grant date, this was not included in the determination of the vesting period. In addition,

the plan provides for the possibility to remain entitled to a prorated number of shares, for any unvested tranche, in case of retirement of a beneficiary before complete vesting. Finally, the terms and conditions applicable to the free share plans state that if a Change of Control takes place before the specified date and section III of Article L. 225-197-1 of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the participants for the loss of unvested free shares, and, for the Management Board members, to getting all required shareholder approvals. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable terms and conditions of the plan will apply to this calculation, mutatis mutandis.

In accordance with section II (4th paragraph) of Article L. 225-197-1 of the French Commercial Code, the Supervisory Board decided during its meetings held on June 22, 2022 and March 9, 2023 that the Management Board members should keep no less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.

5.23.3 Phantom shares

In 2017, 2019 and 2020, phantom share plans were issued for employees who are US citizens, with the same conditions as the stock option programs (see above) but which will not be settled in equity, but in cash. Therefore, it is considered as a cash settled plan. The liability for the phantom shares is measured (initially and at the end of each reporting period until settled) at the fair value of the share options rights, by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

No new phantom shares were granted in 2023. In 2022, no new phantom shares were granted, but a change from one phantom share program to another for one employee was agreed.

In accordance with the foregoing, changes in the outstanding phantom shares are as follows:

number of phantom shares	Year ended December 31	
	2023	2022
OUTSTANDING AS AT JANUARY 1	670,500	841,450
Granted	—	117,000
Forfeited	(50,000)	(67,001)
Exercised	(210,000)	(220,949)
OUTSTANDING AT YEAR END	410,500	670,500

The carrying amount of the liability relating to the phantom shares as at December 31, 2023 was €1.4 million (December 31, 2022: €3.0 million). The fair values of the granted options were determined on the balance sheet dates using the Black Scholes valuation model.

Phantom shares outstanding at the end of the period have the following expiry dates and exercise prices:

expiry date	Exercise price (in € per share)	Number of phantom shares as at December 31,	
		2023	2022
2027	2.85	6,250	6,250
2029	3.05	194,250	244,250
2030	—	210,000	420,000
OUTSTANDING AT YEAR END		410,500	670,500

The significant inputs into the models were:

	Year ended December 31	
	2023	2022
Expected volatility (in %)	51.26	51.07-86.95
Expected vesting period (term in years)	—	0.25-0.93
Risk-free interest rate (in %)	2.10	1.32-2.37

5.24 Borrowings

Borrowings are initially recognized at fair value if determinable, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date.



Borrowings of the Group at period-end include the following:

in € thousand	Year ended December 31	
	2023	2022
NON-CURRENT		
Debentures and other loans	132,768	87,227
CURRENT		
Debentures and other loans	44,079	11,580
TOTAL BORROWINGS	176,847	98,806

The maturity of the borrowings is as follows:

in € thousand	Year ended December 31	
	2023	2022
Between 1 and 3 years	62,378	57,838
Between 3 and 5 years	70,390	28,765
Over 5 years	—	624
NON-CURRENT BORROWINGS	132,768	87,227
Current borrowings	44,079	11,580
TOTAL BORROWINGS	176,847	98,806

The carrying amounts of the Group's borrowings are denominated in the following currencies:

in € thousand	Year ended December 31	
	2023	2022
Borrowings denominated in EUR	3,581	4,433
Borrowings denominated in USD	173,266	94,373
TOTAL BORROWINGS	176,847	98,806

5.24.1 Other loans

In August 2023, Valneva signed the 7th amendment of the D&O Loan Agreement originally signed in February 2020. The amendment provided the Company with immediate access to \$100.0 million (€90.0 million), out of which \$50.0 million (€45.0 million) was drawn at the execution date of the amendment on August 16, 2023 and the remaining \$50.0 million (€45.0 million) was drawn on December 28, 2023. The interest rate on the new debt remains unchanged at 9.95%, translating into an effective interest rate for the first draw of 14.17% and for the second draw of 13.47% as of December 31, 2023. The new tranches have a three-year interest-only period and will mature on August 16, 2028. Transaction costs amounting to €11.2 million have been deducted from the loan proceeds received. As at December 31, 2023, a total of \$200.0 million have been drawn under the loan agreement. The book value of the loan amounts to \$186.2 million (€167.5 million).

In April 2022, Valneva signed an amendment to increase the principal amount of the \$60.0 million (€54.0 million) D&O Loan Agreement. The April 2022 amendment provided Valneva immediate access to \$20.0 million (€18.0 million), with an additional \$20.0 million (€18.0 million) available upon potential approval of VLA2001 by the European Medicines Agency. This additional \$20.0 million (€18.0 million) was drawn in September 2022. The loan interest rate on this additional debt remains unchanged at 9.95% (equivalent to 10.09% on an annual basis). The interest-only period was extended from the second quarter of 2023 to the third quarter of 2024, and the loan will now mature in the first quarter of 2027 instead of the first quarter of 2026. As at December 31, 2022, \$100.0 million (€90.0 million) was drawn down and the carrying amount was \$95.0 million (€89.2 million). As at December 31, 2021, \$60.0 million (€54.0 million) was drawn down and the carrying amount was \$56.3 million (€49.7 million). The loan is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. Please refer to Note 5.35 for information about changes to the D&O Loan Agreement after December 31, 2023.

Noting the COVID-19 pandemic's impact on the travel industry and following a temporary waiver of the revenue covenant for the second half of 2020, Valneva, Deerfield and OrbitMed agreed to modify this covenant for 2021 and 2022, replacing the twelve-month rolling €115.0 million minimum revenue requirement with quarterly minimum revenue requirements representing an annual total of €64.0 million in 2021 and €103.8 million in 2022. In 2023, the twelve-month rolling €115.0 million minimum revenue requirement is effective again. The parties also agreed to modify the minimum cash requirement to €50.0 million for 2021 and 2022. Following an amendment to the D&O Loan Agreement in April 2022, the minimum liquidity requirement is €35.0 million for 2023.

The Group does not expect these limitations to affect its ability to meet its cash obligations. As at December 31, 2023, the Group's consolidated liquidity or net revenues did not fall below the covenant minimum values.

If the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, Valneva would not be able to comply with the financial covenants in the D&O Loan Agreement, which could result in additional costs (up to

additional 10 percentage points of interest over the duration of the default) and an early repayment obligation. The Group does not expect these limitations to affect its ability to meet its cash obligations.

The D&O Loan Agreement is included in the balance sheet item "Borrowings" and developed as follows:

<i>in € thousand</i>	2023	2022
BALANCE AS AT JANUARY 1	89,182	49,671
Proceeds of issue	91,111	38,502
Transaction costs	(11,198)	(255)
Accrued interest	12,942	7,521
Payment of interest	(11,022)	(7,685)
Exchange rate difference	(3,494)	1,429
BALANCE AS AT DECEMBER 31	167,520	89,182
Less: non-current portion	(127,119)	(79,709)
CURRENT PORTION	40,401	9,473

As at December 31, 2023, other loans also included borrowings related to financing of research and development expenses and CIR (R&D tax credit in France) of €3.6 million (December 31, 2022: €4.4 million) as well as an amount related to CEPI of €5.7 million (December 31, 2022: €5.2 million), representing payments received which are expected to be paid back in the future. For detailed information see Note 5.8.1.

5.24.2 Borrowings and other loans secured

As at December 31, 2023, €171.1 million (December 31, 2022: €93.6 million) of the outstanding borrowings and other loans were guaranteed, secured or pledged. These borrowings and other loans related to financing of research and development expenses, fixed assets and CIR (R&D tax credit in France) and have various conditions (interest rates) and terms (maturities).

5.24.3 Fair value of borrowings and other loans

The fair value of the borrowings and other loans are calculated by discounting the contractual cash flows with interest rates derived from relevant bond yields and swap rates and adjusted for any further potential risk and liquidity risks related to the nature of each loan. The relevant bond yields were determined by an internal analysis based on Moody's RiskCalc corporate rating methodology. In the year ended December 31, 2023, the resulting calculations revealed no material difference between the carrying amount and the fair value.

As at December 31, 2022, differences were identified only for guaranteed other loans, with a fair value of €3.9 million (carrying amount was €4.4 million).

5.25 Trade payables and accruals

Trade payables and accruals include the following:

	Year ended December 31	
<i>in € thousand</i>	2023	2022
Trade payables	17,564	14,505
Accrued expenses	26,739	26,986
TOTAL	44,303	41,491
Less non-current portion	—	—
CURRENT PORTION	44,303	41,491

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature. All trade payables and accruals are current.

5.26 Tax and employee-related liabilities

Liabilities for tax and employee-related liabilities are generally measured at amortized costs. Liabilities related to employees comprise mainly accruals for bonuses and unconsumed vacations. The line social security and other taxes consists of amounts owed to tax authorities and social security institutions.

in € thousand	Year ended December 31	
	2023	2022
Employee-related liabilities	10,815	10,778
Social security and other taxes	5,394	4,960
BALANCE AS AT DECEMBER 31	16,209	15,738
Less non-current portion	—	—
CURRENT PORTION	16,209	15,738

5.27 Lease liabilities

Lease liabilities are effectively secured as the rights to the leased assets revert to the lessor in the event of default.

in € thousand	Year ended December 31	
	2023	2022
OPENING NET BOOK VALUE	53,574	56,822
Additions	3,759	1,629
Revaluation due to variable payments	(2)	859
Termination of contracts	(22,539)	—
Lease payments	(4,286)	(3,900)
Interest expenses	1,183	833
Exchange rate differences	280	(2,669)
CLOSING NET BOOK VALUE	31,969	53,574

In the year ended December 31, 2023, lease liabilities decreased by €21.6 million, mainly due to the termination of the lease agreement for the premises in Austria in September 2023 with a termination value of €22.5 million.

The maturity of non-current lease liabilities is as follows:

in € thousand	Year ended December 31	
	2023	2022
Between 1-3 years	5,313	4,573
Between 3-5 years	5,414	4,608
Over 5 years	18,362	18,982
NON-CURRENT LEASE LIABILITIES	29,090	28,163
Current lease liabilities	2,879	25,411
TOTAL LEASE LIABILITIES	31,969	53,574

The carrying amounts of the Group's lease liabilities are denominated in the following currencies:

in € thousand	Year ended December 31	
	2023	2022
EUR	1,479	24,694
SEK	28,308	27,314
Other	2,182	1,566
TOTAL LEASE LIABILITIES	31,969	53,574

5.28 Contract liabilities

A contract liability has to be recognized when the customer already provided the consideration or part of the consideration before an entity has fulfilled its performance obligation (agreed goods or services which should be delivered or provided) resulting from the "contract".

Development of contract liabilities is presented in the table below:

<i>in € thousand</i>	Year ended December 31	
	2023	2022
BALANCE AS AT JANUARY 1	9,411	128,758
Revenue recognition	(4,394)	(130,678)
Addition	1,870	10,833
Other releases	(1,032)	—
Exchange rate differences	(159)	498
BALANCE AS AT CLOSING DATE	5,697	9,411
Less non-current portion	—	—
CURRENT PORTION	5,697	9,411

In the year ended December 31, 2023, revenue recognition in the amount of €3.8 million came from the Advanced Purchase Agreement (APA) for VLA2001 with the Kingdom of Bahrain. The other releases of €1.0 million are from the divestment of Valneva's CTM Unit in Solna as of July 1, 2023.

In 2022, revenue recognized in the amount of €116.8 million related to the APA with the European Commission, €2.3 million related to the APA with the Kingdom of Bahrain, €2.0 million related to the agreement with Instituto Butantan and €5.9 million related to the Collaboration and License Agreement with Pfizer. Additions (amounts received for future performance obligations) in 2022 amounting to €4.2 million related to the Collaboration and License Agreement with Pfizer, €2.0 million related to Instituto Butantan, and €3.8 million related to the APA with the Kingdom of Bahrain.

5.29 Refund liabilities

A refund liability has to be recognized when the customer already provided a consideration which is expected to be refunded partially or totally. It is measured at the amount the Company has an obligation to repay or amounts which did not meet the criteria for revenue recognition in the past, but there are no remaining goods and services to be provided in future. Development of refund liabilities during the period is presented below:

<i>in € thousand</i>	Year ended December 31	
	2023	2022
BALANCE AS AT JANUARY 1	143,085	254,582
Additions	465	52,012
Payments	(352)	(2,626)
Other releases	(108,542)	(879)
Revenue recognition	(40)	(169,242)
Interest expense capitalized	8,419	9,597
Exchange rate difference	(3,095)	(357)
BALANCE AS AT CLOSING DATE	39,941	143,085
Less non-current portion	(6,303)	(6,635)
CURRENT PORTION	33,637	136,450

As at December 31, 2023, from the total of €39.9 million, an amount of €33.1 million is connected to the Collaboration and License Agreement with Pfizer. Beside the future payment obligations to Pfizer these refund liabilities also contain considerations which should be recognized in future as revenue and amount to €10.7 million for the year ended December 31, 2023 (December 31, 2022: €4.6 million). Refund liabilities of €6.5 million relate to the expected payment to GlaxoSmithKline (GSK) due to the termination of the strategic alliance agreements (SAA) in 2019. The other releases in the year ended December 31, 2023 relate largely to payments made in the period in connection with the terms of the Pfizer Collaboration and License Agreement.

As at December 31, 2022, €135.5 million stems from the collaboration with Pfizer and €6.6 million (of which €6.6 million was non-current) related to the expected payment to GSK from the termination of the SAA in 2019. Revenue recognized in 2022 related primarily to the de-recognition of the previously included royalty obligation towards the UK Authority in the amount of €89.2 million and the de-recognition of the previously included capex obligation towards the UK Authority in the amount of €80.0 million. Additions included the milestone of \$25 million (€24.5 million) received related to the Collaboration and License Agreement with Pfizer as well as other payments received where Valneva has a repayment obligation.

5.30 Provisions

5.30.1 Provisions for employee commitments

in € thousand	Year ended December 31	
	2023	2022
Employer contribution costs on share-based compensation plans	1,684	3,330
Phantom shares	1,421	2,976
Retirement termination benefits	459	330
Leaving indemnities	670	267
BALANCE AS AT CLOSING DATE	4,234	6,903
Less non-current portion	490	1,320
CURRENT PORTION	3,744	5,583

Share-based provisions

Employer contribution costs on share-based compensation plans and phantom shares are calculated at the balance sheet date using the share price of Valneva as at December 31, 2023: €4.72 (December 31, 2022: €6.22).

Retirement termination benefits

Some Group companies provide retirement termination benefits to their retirees.

For defined benefit plans, retirement costs are determined once a year:

- Up to December 31, 2020, using the projected unit credit method where each period of service gave rise to an additional unit of benefit entitlement and where each unit was measured separately to determine the final obligation.
- From December 31, 2021 onward, under the new calculation method proposed by the IFRS IC and according to the updated recommendation of the ANC n 2013-02 as at December 31, 2021: under this method, when the plan provides for the payment of an indemnity to the employee, if he or she is present at the date of retirement, the amount of which depends on seniority and is capped at a certain years of service, the commitment must be calculated solely on the basis of the years of service prior to the retirement date.

The final obligation is then discounted. These calculations mainly use the following assumptions:

- a discount rate;
- a salary increase rate;
- an employee turnover rate.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise.

For basic schemes and defined contribution plans, the Group recognizes the contributions as expenses when payable, as it has no obligations over and above the amount of contributions paid.

Assumptions used

	Year ended December 31	
	2023	2022
Discount rate	3.20 %	3.60 %
Salary increase rate	2.50 %	2.50 %
Turnover rate	0%-21.35%	0%-21.35%
Social security rate	43.00%-47.00%	43.00%-47.00%
Average remaining lifespan of employees (in years)	22	20

Changes in defined benefit obligation

Present value of obligation development:

in € thousand	Year ended December 31	
	2023	2022
BALANCE AS AT JANUARY 1	330	422
Current service cost	(1)	86
Actuarial losses/(gains)	130	(178)
BALANCE AS AT CLOSING DATE	459	330

5.30.2 Other provisions

<i>in € thousand</i>	Year ended December 31	
	2023	2022
Non-current	584	960
Current	7,091	24,714
PROVISIONS	7,675	25,674

The position mostly comprises €5.2 million from a provision for expected legal and settlement costs under a court proceeding related to the Interoell AG/Vivalis SA merger (December 31, 2022: €5.2 million). As at December 31, 2022 an amount of €18.8 million related to onerous purchase agreements in connection with the wind-down of COVID-19 activities which mostly were used during the year ended December 31, 2023.

5.31 Other liabilities

<i>in € thousand</i>	Year ended December 31	
	2023	2022
Deferred income	513	5,519
Other financial liabilities	34	32
Miscellaneous liabilities	125	88
OTHER LIABILITIES	671	5,639
Less non-current portion	(79)	(116)
CURRENT PORTION	592	5,523

As at December 31, 2022 deferred income mainly included conditional advances from government enterprise grants in Scotland.

5.32 Cash flow information

5.32.1 Cash generated from operations

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

in € thousand	Year ended December 31,		
	2023	2022	2021
LOSS FOR THE YEAR	(101,429)	(143,279)	(73,425)
ADJUSTMENTS FOR			
Depreciation and amortization	17,584	21,036	14,281
Write-off / impairment fixed assets/intangibles	(731)	23,249	—
Share-based compensation expense	5,111	(8,656)	14,509
Income tax expense/(income)	2,800	(1,536)	3,446
Dividends received from associated companies	—	—	—
(Profit)/loss from disposal of property, plant, equipment and intangible assets	(12)	38	46
Share of (profit)/loss from associates	—	(9)	5
(Profit)/loss from disposal held for sale	580	—	—
Provision for employer contribution costs on share-based compensation plans ⁽¹⁾	(1,659)	(22,933)	19,079
Other non-cash (income)/expense	(804)	14,088	(11,604)
Interest income	(1,210)	(260)	(249)
Interest expense	23,325	19,054	16,964
	44,984	44,070	56,476
CHANGES IN NON-CURRENT OPERATING ASSETS AND LIABILITIES (EXCLUDING THE EFFECTS OF ACQUISITION AND CONSOLIDATION)			
Other non-current assets	(192)	10,981	194
Long term contract liabilities	—	(5,241)	4,662
Long term refund liabilities ⁽²⁾	1,136	(154,833)	54,501
Other non-current liabilities and provisions	(430)	1,379	(3)
	514	(147,713)	59,353
CHANGES IN WORKING CAPITAL (EXCLUDING THE EFFECTS OF ACQUISITION AND EXCHANGE RATE DIFFERENCES ON CONSOLIDATION)			
Inventory	(9,165)	84,224	(92,373)
Trade and other receivables	(2,855)	12,401	(21,349)
Contract liabilities	(3,471)	(114,603)	34,453
Refund liabilities	(112,689)	33,784	80,160
Trade and other payables and provisions	(17,398)	(14,053)	35,236
	(145,578)	1,732	36,127
CASH USED IN OPERATIONS	(201,509)	(245,189)	78,532

(1) In the year ended December 31, 2022, the position "employee benefit other than share-based compensation" includes an income of €23.2 million, which resulted from release of the employer contribution provision, which was accounted for as of December 31, 2021 for the payable at the exercise of the IFRS 2 programs.

(2) As at December 31, 2022, the terms of the royalty and the CAPEX obligation towards the UK Authority were redefined under the 2022 settlement agreement. Management assessed the likelihood for this future obligation as remote. This resulted in a reduction of refund liabilities and recognition of other revenues recognized of €169.2 million.

5.32.2 Reconciliation of liabilities arising from financing activities

Liabilities arising from financing activities are those for which cash flows were (or future cash flows will be) classified in the Group's consolidated statement of cash flows as cash flows from financing activities. For development of borrowings and lease liabilities see Note 5.24 and 5.27.

in € thousand	Year ended December 31	
	2023	2022
BALANCE AS AT JANUARY 1	98,806	57,834
Proceeds of issue	92,309	39,587
Transaction costs	(11,198)	(255)
Repayments	(2,097)	(1,793)
Revaluations	393	1,115
Accrued interest	13,365	7,932
Payment of interest	(11,025)	(7,685)
Exchange rate difference	(3,706)	2,073
BALANCE AS AT DECEMBER 31	176,847	98,806

5.33 Commitments and contingencies

As at December 31, 2023, there were €3.7 million of capital expenditure contracted, mainly related to manufacturing sites (December 31, 2022: €9.9 million). The respective contracts are all related to the finalization of the Almeida building in Scotland, the new manufacturing facility and production site for IXIARO and IXCHIQ.

5.33.1 Other commitments, pledges and guarantees

The other commitments relate to minimum payments and consist of:

in € thousand	Year ended December 31	
	2023	2022
Loans and grants	6	49
Royalties	6,798	8,262
OTHER COMMITMENTS	6,804	8,311

The pledges consist of:

in € thousand	Year ended December 31	
	2023	2022
Pledges on bank accounts	121,085	284,889
GUARANTEES AND PLEDGES	121,085	284,889

The stated pledges on cash at banks originate from the requirements of the D&O Loan Agreement which in addition is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by the Company and certain of its subsidiaries. For more information about this loan agreement, please refer to Note 5.24.

5.33.2 Contingencies and litigations

Following the merger between the companies Vivalis SA and Intercell AG in 2013, certain former Intercell shareholders initiated legal proceedings before the Commercial Court of Vienna to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used in the merger. In October 2021, a court-appointed expert recommended an increase in the cash compensation as well as further valuation work on the exchange ratio. In April 2022, this expert presented the result of its work on the exchange ratio, and in April 2023 the court's expert committee provided their view. However, the final outcome will depend on the court's position on specific legal points. The Company therefore assessed the probability of several scenarios and decided to hold a provision of €5.2 million to cover the reassessed risk and potential legal costs (December 31, 2022: €5.2 million).

In July 2016, a claim for additional payment was raised and litigation was filed in December 2016, in connection with the 2009 acquisition of Humalys SAS, from which the Company had acquired a technology, which was later combined with other antibody discovery technologies and spun off to BiINK Biomedical SAS in early 2015. Former shareholders of Humalys claimed additional consideration as a result of the spin-off transaction. A first instance decision in the Humalys case was rendered on September 6, 2023. The court has rejected the plaintiff's claims. No appeal was filed within the statutory timeline; therefore the judgment has become final.



5.34 Related-party transactions

In the year ended December 31, 2023, there have been no changes to related parties. Due to their significant influence through material transactions and provision of essential technical information Groupe Grimaud La Corbière SAS, Sevreinoise (France) and its affiliate Vital Meat SAS are considered as related parties. Bpifrance, Maisons-Alfort (France) is considered as related party with significant influence through a membership in the Company's Board of Directors.

5.34.1 Rendering of services

Transactions with related parties are carried out similar to market:

in € thousand	Year ended December 31		
	2023	2022	2021
PROVISION OF SERVICES			
Operating activities	260	1,200	231
Financing activities	76	8	—
PROVISION OF SERVICES	335	1,208	231

Services provided by Valneva to Groupe Grimaud La Corbière SAS, a significant shareholder of Valneva, are considered related party transactions and consist of services within a collaboration and research license agreement and of the provision of premises and equipment and sale of patents and cells.

Operating activities include Valneva's agreement with Vital Meat SAS, an affiliate of Group Grimaud La Corbière SAS, to which Valneva transferred certain assets (patent and cell lines) for a consideration of €1.0 million in the year ended December 31, 2022.

From June 2022 onward, Bpifrance qualified as a related party, as a shareholder of Valneva with significant influence through membership on the Company's Board. Valneva has borrowed amounts amounting to 80% of French Tax Authorities receivables relating to Research Tax Credits for 2020, 2021 and 2022 from Bpifrance. The total amount borrowed from Bpifrance is €3.5 million. A commitment fee of 0.5% as well as interest at the EURIBOR one-month average rate of the previous month (the rate mentioned is a variable rate deducted at nil percent if it were to be negative) plus 1.7% p.a. is applicable to these borrowed amounts (see table above).

The borrowings related to the Research Tax Credits outstanding:

in € thousand	Amount	Grant date
BPI payable relating to Research tax credit 2020	859	November 2021
BPI payable relating to Research tax credit 2021	1,419	November 2022
BPI payable relating to Research tax credit 2022	1,198	December 2023

5.34.2 Key management compensation

The aggregate compensation of the key management (including Executive Committee and Board of Directors) was as follows:

in € thousand	Year ended December 31		
	2023	2022	2021
Salaries and other short-term employee benefits	3,439	3,172	2,213
Other long-term benefits	52	45	24
Share-based payments (expense of the year)	2,145	722	856
KEY MANAGEMENT COMPENSATION	5,636	3,939	3,093

In the year ended December 31, 2023, the aggregate compensation of the members of the Company's Executive Committee (former Management Board) amounted to €5.2 million (2022: €3.6 million, 2021: €2.8 million) and represents primarily salaries and share-based payments.

The presented key management compensation includes that of the former Supervisory Board in the amount of €0.5 million for the year ended December 31, 2023 (2022: €0.4 million; 2021: €0.3 million).

5.35 Events after the reporting period

Sale of Priority Review Voucher for \$103 million

The Company sold the Priority Review Voucher (PRV) it received from the U.S. Food and Drug Administration (FDA) for \$103 million (€95 million) on February 2, 2024. The Company was awarded a tropical disease PRV in November 2023 following U.S. FDA approval of IXCHIQ, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of



disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. With this approval, IXCHIQ became the world's first licensed chikungunya vaccine available to address this unmet medical need. Valneva will invest proceeds from the sale of the PRV into its R&D projects, including the co-development of its Phase 3 vaccine candidate against Lyme disease, additional clinical trials for its chikungunya vaccine IXCHIQ and the expansion of the Company's clinical pipeline.

Amendment of the D&O Loan Agreement

On March 18, 2024 Valneva signed an amendment to the with US Healthcare funds Deerfield and OrbilMed, deferring the commencement of the re-payment of the initial \$100 million loan from July 1, 2024 to January 1, 2026. The maturity date of the loan will remain unchanged and the interest-only period has been extended by 18 months.

**DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO
SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

The following description of the ordinary shares, the American Depositary Shares and the articles of association, or bylaws, of Valneva SE (“Valneva,” the “Company,” “us” or “we”) is a summary and does not purport to be complete. This summary is subject to, and qualified in its entirety by reference to, the complete text of the Company’s bylaws, which are incorporated by reference as Exhibit 3.1 of the Company’s Annual Report on Form 20-F to which this description is also an exhibit. The Company encourages you to read the Company’s bylaws carefully.

As of December 31, 2023, Valneva had the following series of securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, nominal value €0.15 per share*	*	The Nasdaq Global Select Market*
American Depositary Shares, each representing two ordinary shares, nominal value €0.15 per share	VALN	The Nasdaq Global Select Market

** Not for trading, but only in connection with the registration of the American Depositary Shares.*

ORDINARY SHARES

As of December 31, 2023, our issued share capital consisted of a total of 138,912,142 ordinary shares with a nominal value of €0.15 per share. Of these 138,912,142 issued ordinary shares, 124,322 are treasury shares.

The description below reflects the terms of our bylaws and summarizes the material rights of holders of our ordinary shares under French law. Please note that this is only a summary and is not intended to be exhaustive. For further information, please refer to the full text of our bylaws, which are incorporated by reference as Exhibit 3.1 of the Company’s Annual Report on Form 20-F to which this description is also an exhibit.

Business Purpose

Our business purpose, within France and in every country is the following:

- research and development within the field of biomedicine and pharmacy;
- commercial exploitation of patents and know-how;
- trading in products of all kinds, and the provision of services in the field of data processing and information technology;
- production, monitoring and marketing of all products, services and research programs with applications to human and animal health, using the technologies of molecular and cellular biology and all of the associated techniques;
- participation of the Company by all means, direct or indirect, in all operations which may be associated with its company object, though the creation of new companies, contributions, subscription or purchase of securities or company rights, mergers or otherwise, the creation, acquisition, leasing, lease management of all operating assets or facilities;
- the acquisition, exploitation or sale of all procedures and patents regarding these activities, within France and abroad;

and more generally, all industrial, commercial or financial, securities or property operations, which may be directly or indirectly associated with its business object or likely to favor its exploitation, realization or development.

Governance Structure

On December 20, 2023, our shareholders approved the change from a two-tier governance system under which we were governed by a Supervisory Board and Management Board to a one-tier governance system led by a Board of Directors, with Executive Officers in charge of the general management. Our former Chair of the Management Board was appointed by our Board as the Company's Chief Executive Officer (*directeur général*), and five former Management Board members were appointed as Deputy Chief Executive Officers (*directeurs généraux délégués*): our Chief Financial Officer, Chief Medical Officer, Chief Business Officer, Chief Commercial Officer, and General Counsel. These Deputy Chief Executive Officers, together with the other members of our Executive Committee (which includes our Chief Operating Officer and Chief People Officer and will in the future include a Chief Scientific Officer), assist our Chief Executive Officer with the operational management of the Company. We present the details of both the Supervisory Board and the Board of Directors below.

Board of Directors (formerly the Supervisory Board)

Unless otherwise indicated, the details presented below apply with respect to the former Supervisory Board and the present Board of Directors, both of which are referred to as the "Board" for convenience.

Members

The Board is made up of a minimum of three members and a maximum of eighteen. The members of the Board are appointed for a renewable term of three years at the General Meeting of shareholders, which may revoke their appointments at any time. The directors may be individuals or companies.

The maximum age for membership on the Board is 80 years old, and no more than 20% of the members of the Board of Directors may be over 75 years old.

Chair of the Board

The Board appoints a Chair from its members who are individuals and may appoint a Vice Chair. The Chair, or in his or her absence the Vice Chair, is in charge of convening the Board and directing its discussions.

In a report to the General Meeting of shareholders attached to the Management Report, the Chair of the Board reports on the conditions for preparing and organizing the work of the Board as well as the internal control procedures set up by us.

Meetings and Powers of the Board

The Board meets as often as is in our interests but least once per quarter. Meetings are called under the circumstances and according to the conditions set forth in the bylaws, by the Chair or, if any, the Vice Chair or Lead Independent Director.

Board meetings may also be held (i) by videoconference or any other electronic means of telecommunication or remote transmission, or (ii) by written decision on the conditions and within the limits provided for by law.

At least half of the members of the Board must be present to constitute a quorum and decisions are made by a majority of the members of the Board present or represented. In the case of a tie vote, the Chair of the session shall have the deciding vote.

Executive Officers are required to obtain the Board's approval prior to the conclusion of certain agreements or transactions. Prior to the change from a two-tier to a one-tier governance system, the Supervisory Board exercised permanent control over the Management Board, pursuant to the powers explicitly conferred on it by the French laws.

Under French law, any agreement entered into, directly or through an intermediary, between us and one of the members of the Board of Directors, our Chief Executive Officer, our Deputy Chief Executive Officers, or a shareholder that holds over 10% of the voting rights, or, if such shareholder is a company, the controlling company thereof, must be subject to prior authorization from the Board of Directors. The interested member cannot vote on such decision. The same applies to agreements in which a person referred to above has an indirect interest. Such prior authorization also applies to agreements between us and another company if one of our Executive Officers or Board members is the owner, a partner with unlimited liability, manager, director, managing director, member of the supervisory board or of the board of directors, or, in a general manner is in a position of responsibility within the other company. These provisions are not applicable to agreements concerning ordinary operations entered into under normal conditions.

Compensation of the Board

The General Meeting of shareholders may allocate an annual fixed sum and our Board allocates this sum among its members as it sees fit. In addition, the Board may allocate exceptional compensation (*rémunération exceptionnelle*) for missions or mandates entrusted to its members; in this case, this remuneration is subject to the provisions regarding related-parties agreements.

Committees

The Board may decide to establish committees responsible for reviewing matters which the Board or its Chair wish to submit to them for examination and advice.

Board Observers

The Board may appoint one or more observers. The observer or observers are called to attend the meetings of the Board of Directors in their observational capacity, without voting rights. They hold the same information and communication rights as the Board’s members and they are bound to the same confidentiality obligations.

Rights and Obligations Attached to Ordinary Shares

Each of our ordinary shares gives the right to a share of the profits and assets in proportion to the amount of capital it represents. It also gives the right to vote and be represented in the General Meeting of shareholders under the conditions set forth by French law and the bylaws.

If we are liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of our ordinary shares. Any surplus will be distributed pro rata among shareholders in proportion to the number of ordinary shares respectively held by them, taking into account, where applicable, of the rights attached to ordinary shares of different classes.

Shareholders are liable for corporate liabilities only up to the par value of the ordinary shares they hold; they are not liable to further capital calls.

We have not issued any ordinary shares giving holders privileged rights compared to those attached to other ordinary shares.

Shareholders’ rights may be modified as allowed by French law. Only the extraordinary shareholders’ meeting is authorized to amend any and all provisions of our bylaws. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

Voting Rights

The voting rights attached to the ordinary shares are in proportion to the amount of capital they represent and each share gives the right to one vote. However, ordinary shares fully paid up and evidenced as having been held in registered form in the name of the same shareholder for at least two years, carry a double voting right in respect to that granted to other ordinary shares, according to the portion of share capital they represent. The ownership of a share implies, ipso facto, the acceptance of our bylaws and any decision of our shareholders. However, ADSs are not eligible for double voting rights.

Under French law, treasury shares or ordinary shares held by entities controlled by us are not entitled to voting rights and do not count for quorum purposes.

There is no limitation on voting rights in our bylaws nor limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities.

Under French law, the holders of warrants of the same class (i.e., warrants that were issued at the same time and with the same rights), including founders’ warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

Dividends

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law. The conditions for payment of dividends in cash shall be set at the shareholders’ meeting.

“Distributable Profits” consist of our statutory net profit in each fiscal year, calculated in accordance with accounting standards applicable in France, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts. Pursuant to French law, we must allocate at least 5% of our statutory net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Such allocation is compulsory until the amount in the legal reserve is equal to 10% of the aggregate par value of our issued and outstanding share capital.

Dividends are distributed to shareholders pro rata according to their respective holdings of ordinary shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders’ meeting or by our Board in the absence of such a decision by the shareholders. Shareholders that own ordinary shares on the actual payment date are entitled to the dividend.

Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

Shareholders may be granted an option to receive dividends in cash or in ordinary shares, in accordance with legal conditions.

Change in Share Capital

Any change to the capital or the rights attached to the ordinary shares is subject to legal provisions, as our bylaws do not set forth any particular requirements.

Increase in Share Capital

Pursuant to French law, our share capital may be increased only with shareholders’ approval at an extraordinary general shareholders’ meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the nominal value of existing shares;
- creating a new class of equity securities (preference shares); and
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following issuances:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer or merger;
- by conversion of previously issued debt instruments;
- by exercise of the rights attached to securities giving access to the share capital;
- by capitalization of profits, reserves or share premium; and
- subject to certain conditions, by way of offset against debt incurred by us.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders’ approval at an extraordinary general shareholders’ meeting, acting under the quorum and majority requirements applicable to ordinary shareholders’ meetings. Increases effected by an increase in the nominal value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders’ approval at an extraordinary general shareholders’ meeting acting under the regular quorum and majority requirements for such meetings.

Reduction in Share Capital

Pursuant to French law, any reduction in our share capital requires shareholders' approval at an extraordinary general shareholders' meeting. The share capital may be reduced either by decreasing the nominal value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise, depending on the contemplated operations.

Preferential Subscription Rights

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights to these securities on a pro rata basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe pro rata based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, our share capital by means of a cash payment or a set-off of cash debts. Pursuant to French law, the preferential subscription rights are transferable during a period equivalent to the subscription period relating to a particular offering but starting two days prior to the opening of the subscription period and ending two days prior to the closing of the subscription period.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of our shareholders or individually by each shareholder.

Our Board of Directors and our independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

Form, Holding and Transfer of Shares

Form of Shares

The ordinary shares are held under registered or bearer form, if the legislation so permits, according to the shareholder's choice.

Further, in accordance with applicable laws, we may request at any time from the central depository responsible for holding our shares, the information referred to in Article L. 228-2 of the French Commercial Code. Thus, we are, in particular and at any time, entitled to request the name and year of birth or, in the case of a legal entity, the name and the year of incorporation, nationality and address of holders of securities conferring immediate or long-term voting rights at its shareholders' meeting and the amount of securities owned by each of them and, where applicable, the restrictions that the securities could be affected by.

Holding of Shares

In accordance with French law concerning the "dematerialization" of securities, the ownership rights of shareholders are represented by book entries instead of share certificates. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions.

Ownership of ADSs by Non-French Residents

Neither the French Commercial Code nor our bylaws currently impose any restrictions on the right of non-French residents or non-French shareholders to own and vote shares. However, non-French residents must file a declaration for statistical purposes with the Bank of France (*Banque de France*) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold. Violation of this filing requirement may be sanctioned by five years of imprisonment and a fine of up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity.

Certain foreign investments in French companies are subject to prior authorization from the Minister of the Economy when all or a portion of the target's business activity is related to a strategic sector, such as energy, transport, public health, telecommunications, etc. We operates certain activities covered by the regulation on foreign investments in France, particularly for public health. Due to the operation of activities, we fall within the scope of the laws and regulations governing foreign investments in France set forth by Articles L. 151-3 and R. 151-2 et. seq. of the French Monetary and Financial Code.

Under these provisions, the acquisition by a non-French citizen, a French citizen who does not reside in France, a non-French entity or a French entity controlled by such persons or entities, of control, within the meaning of Article L. 233-3 of the French Commercial Code, or of all or a portion of a branch of activity of the Company or one of its French subsidiaries conducted activities enumerated by the aforementioned provisions, is subject to the prior authorization of the French Minister of the Economy. Moreover, the acquisition by an investor that is not a citizen of a member State of the European Union, or of a State that is a party to the agreement on the European Economic Area (EEA), that results, directly or indirectly, in exceeding, alone or in concert, the threshold of 25% of the voting rights of the Company or of one of its French subsidiaries conducting these activities, is subject to this same procedure. Within the context of the COVID-19 pandemic, a decree temporarily lowered this threshold to 10% of the voting rights for French companies whose shares are listed for trading on a regulated market. This provision has been made permanent by Decree 2023-1293 of December 28, 2023.

In the context of the prior authorization procedure, the Minister of the Economy is charged with verifying that the conditions of the planned transaction preserves the national interests; in this respect the Minister may attach one or more conditions to the authorization of such a transaction in order to ensure the continuity of the concerned activities, industrial capacities, research and development capacities or related expertise, or even, on the basis of a motivated decision, refuse such an authorization, particularly if national interests cannot be protected.

Any transaction executed in violation of these provisions is null and void; it is also subject to financial sanction, the maximum amount of which is twice the amount of the illegal investment, and to a criminal sanctions set forth in Article 459 of the French Customs Code.

Foreign Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

Availability of Preferential Subscription Rights

Under French law, shareholders have preferential rights to subscribe for cash issues of new ordinary shares or other securities giving rights to acquire additional ordinary shares on a pro rata basis. Holders of our securities in the United States (which may be in the form of ordinary shares or ADSs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new ordinary shares or other securities giving rights to acquire additional ordinary shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, holders of our securities in the United States will be unable to exercise any preferential subscription rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new ordinary shares or other securities. We intend to evaluate at the time of any rights offering the costs and potential liabilities associated with registering the rights, as well as the indirect benefits to us of enabling the exercise by holders of ADSs in the United States of the subscription rights, and any other factors we consider appropriate at the time, and then to make a decision as to whether to register the rights. We cannot assure you that we will file a registration statement.

For holders of our ordinary shares in the form of ADSs, the depositary may make these rights or other distributions available to ADS holders. If the depositary does not make the rights available to ADS holders and determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case the holders will receive no value for them. The section herein titled “American Depositary Shares—Dividends and Other Distributions” explains in detail the depositary’s responsibility in connection with a rights offering. See also “*Risk Factors—Your right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings*” in the Company’s Annual Report on Form 20-F to which this description is filed as an exhibit.

Assignment and Transfer of Shares

Shares are freely negotiable, subject to applicable legal and regulatory provisions. French law notably provides for standstill obligations and prohibition of insider trading.

Repurchase and Redemption of Ordinary Shares

Under French law, we may acquire our own ordinary shares. Such acquisition may be challenged on the ground of market abuse regulations. However, Market Abuse Regulation 596/2014 of April 16, 2014 and its delegated regulations, or MAR, provides for safe harbor exemptions when the acquisition is made (i) under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and with the General Regulations of the French Financial Markets Authority, or AMF and (ii) for the following purposes:

- to decrease our share capital, with the approval of the shareholders at an extraordinary general meeting; in this case, the ordinary shares repurchased must be cancelled within one month from the expiry of the purchase offer;
- to meet obligations arising from debt securities that are exchangeable into equity instruments;
- to provide ordinary shares for distribution to employees or managers under a profit-sharing, free ordinary share or share option plan; or
- we benefit from a simple exemption when the acquisition is made under a liquidity contract complying with the General Regulations of, and market practices accepted by, the AMF.

All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L. 22-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance with market manipulation and insider dealing rules.

Under MAR and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading value on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of ordinary shares may result in us holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. Ordinary shares repurchased by us continue to be deemed “issued” under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

Sinking Fund Provisions

Our bylaws do not provide for any sinking fund provisions.

General Meeting of Shareholders

General Meetings of shareholders are called by the Board. They can also be called by the auditor(s) or an officer appointed by a court upon request, by any interested party or by the Works Council in an emergency, by one or more shareholders holding at least five percent of the ordinary shares or by an association of our shareholders. Meetings are held at our registered offices or at any other location indicated in the convening notice.

The meeting is published in the French Bulletin of Mandatory Legal Notices (*Bulletin des Annonces Légales Obligatoires* or BALO) at least 35 days prior to the date of a General Meeting of shareholders. In addition to the information concerning us, the notice indicates in particular the agenda of the General Meeting of shareholders and the draft resolutions that will be presented.

In the 21 days preceding the meeting, we will publish the information and documents relating to the meeting on our web site.

The General Meeting of shareholders must be announced at least 15 days beforehand, by a notice placed in a journal that publishes legal announcements in the department where the headquarters are located, and in the BALO. Holders of registered ordinary shares who have owned them for at least one month as of the date on which the latest notice is published receive individual notices. When a General Meeting of shareholders is unable to take action because the requisite quorum is not present, a second meeting is called at least ten days in advance using the same procedure as the first one.

The General Meeting of shareholders may only take action related to items on the agenda. However, it may dismiss and replace one or more members of the Board any time. One or more shareholders representing at least the percentage of share capital fixed by law, and acting according to the legally required conditions and deadlines, are allowed to request that items and/or draft resolutions be added to the agenda of the General Meeting of shareholders. The work council may also request the entering of draft resolutions on the agenda of a General Meeting.

Each shareholder has the right to attend the meetings and take part in deliberation (i) personally; (ii) by granting proxy to another shareholder, his or her spouse or partner in a civil union or any other natural or legal person of his or her choice; (iii) by sending a proxy to the company without indication of the beneficiary; (iv) by voting by correspondence; or (v) by videoconference or another means of telecommunication, including internet, in accordance with applicable laws and regulations that allow identification; by presenting proof of identity and ownership of ordinary shares, subject to:

- for holders of registered ordinary shares, an entry in the shareholder registry at least two business days before the General Meeting of shareholders; and
- for holders of bearer ordinary shares, filing, under the conditions provided by law, of a certificate of participation issued by an authorized intermediary two days before the date of the General Meeting of shareholders.

The final date for returning voting ballots by correspondence is set by the Board and disclosed in the notice of meeting published in the BALO. This date cannot be earlier than three days prior to the meeting as provided in the bylaws.

A shareholder who has voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which we send to such shareholder either at the shareholder's request or at our initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting, for two meetings (an ordinary and an extraordinary meeting convened for the same day or within 15 days) or for successive meetings convened with the same agenda.

A shareholder may vote by correspondence by means of a voting form, which we send to such shareholder either at the shareholder's request or at our initiative, or which we include in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on our website at least 21 days before the date of the meeting. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

The above legislation provides that shareholders (and all the persons who may attend the general meeting of shareholders) may participate in the meeting by means of a teleconference or audio-visual conference call if this conference allows for the identification of the participants, transmits at least the voice of the participants and allows the continuous and simultaneous retransmission of the debates.

Our Bylaws and French Corporate Law Contain Provisions that May Delay or Discourage a Takeover Attempt

Provisions contained in our bylaws and French corporate law could make it more difficult for a third-party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of the share capital or voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the European Economic Area, or EEA, Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, a non-resident of France as well as any French entity controlled by non-residents of France may have to file a declaration for statistical purposes with the Bank of France (*Banque de France*) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold. See "Ownership of ADSs by Non-French Residents" herein;
- under French law, certain investments in a French company relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France of controlled by entities not French or not resident

in France are subject to prior authorization of the Ministry of Economy. See “Ownership of ADSs by Non-French Residents” herein;

- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our Board as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders may grant in the future our Board broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our ordinary shares;
- our shareholders have preferential subscription rights on a *pro rata* basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our Board has the right to appoint members of the Board to fill a vacancy created by the resignation or death of a member of the Board for the remaining duration of such member’s term of office, and subject to the approval by the shareholders of such appointment at the next shareholders’ meeting, which prevents shareholders from having the sole right to fill vacancies on our Board;
- our Board can be convened by the Chair, the Vice Chair, or the Lead Independent Member of the Board or by our Chief Executive Officer. One-third of the members of the Board may send a written request to the Chair to convene the Board if there has not been a meeting for more than two months;
- our Board meetings can only be regularly held if at least half of its members attend either physically or by way of videoconference or teleconference enabling the members’ identification and ensuring their effective participation in the Board’s decisions;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders’ general meeting is required to remove members of the Board with or without cause;
- the crossing of certain ownership thresholds has to be disclosed and can impose certain obligations; see “Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares” herein;
- specific items are required in the shareholders’ meeting agenda for nominations to the Board or for proposing matters to be acted upon at said shareholders’ meeting, except that a vote to remove and replace a member of the Board can be proposed at any shareholders’ meeting without notice;
- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Regulation 596/2014 of April 16, 2014; and
- pursuant to French law, our bylaws, including the sections relating to the number of members of the Board, and election and removal of members of the Board from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

Shareholder Identification

Ordinary shares may be registered or bearer ordinary shares, at the option of the shareholder, subject to the applicable legal requirements.

To identify the holders of bearer ordinary shares, we are authorized to ask in accordance with current legal and regulatory requirements, the central depository that maintains the records of the issue of these ordinary shares, in

exchange for a fee, for the holders’ name or business name, year of birth or year of incorporation, address and nationality, e-mail address, number of securities held giving immediate or future access to the capital and any restrictions to which the securities are subject.

Modification of the Bylaws

Our bylaws may only be amended by approval at an extraordinary shareholders’ meeting. Our bylaws may not, however, be amended to increase shareholder commitments without the approval of each shareholder. Decisions are made by a two-thirds majority of the votes held by the shareholders present, represented by proxy, or voting by mail.

Crossing the Threshold Set in the Bylaws

Without prejudice to the legal or regulatory stipulations, any natural person or legal entity who goes above or below, directly or indirectly, acting alone or in concert (*de concert*), a percentage of the share capital or voting rights equal to or higher than 2% or a multiple of this percentage, must inform us of the total number of ordinary shares, voting rights and securities giving access to capital or voting rights that it, he or she owns immediately or eventually, within four trading days of the date on which such ownership threshold is crossed.

If shareholders fail to comply with these obligations, shares or voting rights exceeding the fraction that should have been declared are deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the Commercial Code, if the failure to declare has been determined and one or several shareholders holding at least 2% of the capital make a request thereof, as recorded in the minutes of the General Meeting.

These requirements are without prejudice to the threshold crossing declarations provided for under French law in Articles L. 233-7, L. 233-9 and L. 233-10 of the French Commercial Code, which impose a declaration to us and to the French Financial Markets Authority (AMF) upon crossing of the following thresholds in share capital or voting rights no later than the fourth trading day following the crossing: 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% and 95%.

Furthermore, any shareholder crossing, alone or acting in concert, these 10%, 15%, 20% or 25% thresholds shall file a declaration pursuant to which it shall set out its intention for the following 6 months, including notably whether it intends to continue acquiring shares of the company or to acquire control over the company and its intended strategy for the company.

In addition, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 30% threshold shall file a mandatory public tender offer. Also, any shareholder holding directly or indirectly a number between 30% and 50% of the capital or voting rights and who, in less than 12 consecutive months, increases their holding of capital or voting rights by at least 1% of the company’s capital or voting rights, shall file a mandatory public tender offer.

Differences in Corporate Law

We are a *société européenne à conseil d’administration*, or S.E., incorporated under the laws of France. The laws applicable to French S.E. differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to us and the Delaware General Corporation Law, the law under which many public companies in the United States are incorporated. This summary is not intended to be a complete discussion of the respective rights.

	France	Delaware
Number of directors	Under French law, a <i>société européenne à conseil d'administration</i> must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the bylaws. In addition, the composition of the board of directors endeavors to seek a balanced representation of women and men. Since January 1, 2017, the number of directors of each gender may not be less than 40% when the company is listed on a regulated market or when the company meets certain criteria of turnover and number of employees, if not listed on a regulated market. Any appointment made in violation of this limit that is not remedied as well as the deliberations taken by the director irregularly appointed will be null and void. The directors are appointed by the shareholders' general meetings.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws, unless the certificate of incorporation fixes the number of directors.
Director qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, directors of a corporation may be legal entities (with the exception of the chair of the board of directors), and such legal entities must designate an individual to represent them and to act on their behalf at meetings of the board of directors.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.

	France	Delaware
Removal of directors	Under French law, directors may be removed from office, with or without cause, by the shareholders at any shareholders' general meeting without notice or justification, by a simple majority vote of the shareholders present and voting at the meeting in person or by proxy.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death or resignation, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification at the next shareholders' general meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by newly created directorships, may be filled by a majority of the remaining directors (even though less than a quorum).
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months following the end of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be provided by the certificate of incorporation or by the bylaws, or by the board of directors if neither the certificate of incorporation or the bylaws so provide.

General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing that, by the statutory auditors, or by a court appointed agent (<i>mandataire ad hoc</i>) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	A meeting announcement is published in the French Bulletin of Mandatory Legal Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the shareholders' general meeting. Subject to special legal provisions, the meeting notice is sent out at least 15 days prior to the date of the shareholders' general meeting, by means of a notice inserted both in a newspaper for legal notices (journal d'annonces légales) of the registered office department and, if relevant, in the BALO. Further, shareholders holding registered shares for at least a month at the time of the latest insertion of the notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice to shareholders holding registered shares may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying their e-mail address. When the shareholders' general meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice. The convening notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Trade and Companies (registre du commerce et des sociétés), the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote, the record date for voting if it is different from the record date determining notice and, in the case of a special meeting, purpose or purposes for which the meeting is called.

Proxy

France	Delaware
<p>Each shareholder has the right to attend the shareholders' general meetings and participate in the discussions (i) personally, or (ii) by granting proxy to his/her spouse, his/her partner with whom he/she has entered into a civil union or to another shareholder or to any individual or legal entity of his choice; or (iii) by sending a proxy to the company without indication of the beneficiary (in which case, such proxy shall be cast in favor of the resolutions supported by the board of directors and against all other resolutions), or (iv) by voting by correspondence, or (v) by videoconference or another means of telecommunication in accordance with applicable French laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two shareholders' general meetings, one ordinary, and the other extraordinary, held on the same day or within a period of 15 days.</p>	<p>Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.</p>

	France	Delaware
Shareholder action by written consent	Under French law, shareholders' action by written consent is not permitted in a <i>société européenne</i> .	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.
Preemptive Rights	Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights (<i>droits préférentiels de souscription</i>) to these securities on a pro rata basis of his/her share ownership unless such rights are waived by a two-thirds majority of the votes held by the shareholders present or represented at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such preferential subscription rights have not been waived by the shareholders' extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Further, preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period cannot be less than five trading days in duration. Preferential subscription rights are transferable during the subscription period, but starting two business days prior to the start of the subscription period and ending two business days prior to its closing.	Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock or to any security convertible into such stock.

Sources of Dividends

France	Delaware
<p>Under French law, dividends may only be paid by a French <i>société européenne</i> out of distributable profits (<i>bénéfices distribuables</i>) plus any distributable reserves and “distributable premium” that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law. “Distributable profits” (<i>bénéfices distribuables</i>) consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years. “Distributable premium” refers to the contribution paid by the shareholders in addition to the par value of their ordinary shares for their subscription that the shareholders decide to make available for distribution. Except in case of a share capital reduction, no distribution can be made to the shareholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the company's bylaws.</p>	<p>Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus as defined in and computed in accordance with Delaware law or (2) in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.</p>

Repurchase of Ordinary Shares

Under French law, a corporation may acquire its own ordinary shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes:

- to decrease its share capital, provided that such decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at the extraordinary general meeting deciding the capital reduction, in which case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;
- with a view to distributing within one year of their repurchase the relevant shares to employees or managers under a profit-sharing, free share or share option plan; not to exceed 10% of the share capital, in which case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or
- to meet obligations arising from debt securities, that are exchangeable into equity instruments.

A simple exemption is provided when the acquisition is made under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and in accordance with the General Regulation of the Financial Markets Authority (*Règlement Général de l'AMF*).

All other purposes, and especially share buy-backs for external growth operations pursuant to Article L. 22-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulations and insider dealing rules. Under the MAR and in accordance with the General Regulation of the AMF, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form. By exception, a company shall provide to the AMF, on a monthly basis, and to the public on a biannual basis, a summary report of the transactions made under a liquidity contract.

No such repurchase of ordinary shares may result in the company holding, directly or through a person acting on its behalf, more than 10% of its issued share capital.

Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.

	France	Delaware
Liability of directors and officers	Under French law, a company's bylaws may not include any provisions limiting the liability of directors. Civil liabilities of the directors may be sought for (1) an infringement of laws and regulations applicable to a company, (2) breach of the bylaws and (3) management failure.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: <ul style="list-style-type: none"> • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	French law provides that, unless otherwise provided in the bylaws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder. Double voting rights are automatically granted to the shares held in registered form (<i>au nominatif</i>) for more than two years, unless provided otherwise in the bylaws.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

	France	Delaware
Shareholder Vote on Certain Transactions	<p>Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires:</p> <ul style="list-style-type: none"> • the approval of the board of directors; and • approval by a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant shareholders' meeting or, in the case of a merger that will result in an increase of the shareholders' commitments or with a non-EU company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the board of directors authority to decide a merger-absorption or to determine the terms and conditions of the merger plan). 	<p>Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:</p> <ul style="list-style-type: none"> • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.
Dissent or Dissenters' Appraisal Rights	<p>French law does not provide for any such right but provides that a merger is subject, depending on the circumstances of the merger, to shareholders' approval by a two-thirds majority vote, or unanimous decisions of the shareholders, as stated above.</p>	<p>Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock.</p>

	France	Delaware
Standard of Conduct for directors	<p>French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty of loyalty, a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest (intérêt social) taking into consideration the social and environmental aspects of their activity, where applicable.</p>	<p>Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of a merger or consolidation requires the holders to accept for their shares anything other than:</p> <ul style="list-style-type: none"> • shares of stock of the surviving corporation; • shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders; • cash in lieu of fractional shares of the stock described in the two preceding bullet points; or • any combination of the above. <p>In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.</p> <p>Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.</p>

	France	Delaware
Shareholder Suits	<p>French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's corporate interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders.</p> <p>The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation.</p> <p>A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.</p>	<p>Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:</p> <ul style="list-style-type: none"> • state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or • state the reasons for not making the effort. <p>Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.</p>
Amendment of Certificate of Incorporation	<p>Under French law, corporations are not required to file a certificate of incorporation with the French Registry of Trade and Companies (registre du commerce et des sociétés) and only have bylaws (statuts) as organizational documents. As indicated in the paragraph below, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws.</p>	<p>Under Delaware law, generally a corporation may amend its certificate of incorporation if:</p> <ul style="list-style-type: none"> • its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and • the amendment is adopted by the affirmative votes of a majority (or greater percentage as may be specified by the corporation) of the outstanding shares entitled to vote on the amendment and a majority (or greater percentage as may be specified by the corporation) of the outstanding shares of each class or series of stock, if any, entitled to vote on the amendment as a class or series.

France

Delaware

Amendment of Bylaws

Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws. The extraordinary shareholders' meeting may authorize the board of directors to amend the bylaws to comply with legal provisions, subject to the ratification of such amendments by the next extraordinary shareholders' meeting. The board of directors is authorized to amend the bylaws as a result of a decision to relocate the company's registered office in France, subject to ratification by the next ordinary shareholders' meeting.

Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal bylaws. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors.

AMERICAN DEPOSITARY SHARES

Citibank is the depositary for the ADSs representing our ordinary shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank Europe plc, located at 1 North Wall Quay, Dublin 1 Ireland.

We have appointed Citibank as depositary pursuant to a deposit agreement. The form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website (www.sec.gov). Please refer to registration number 333-255301 when retrieving such copy. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, two ordinary shares that are on deposit with the depositary and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-Share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as an owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of France, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations. The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary's services are made available to you.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs, you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC, which nominee will be the only "holder" of such ADSs for purposes of the deposit agreement and any applicable ADR. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Distributions

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of France.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.*, the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary will *not* distribute the rights to you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- We fail to deliver satisfactory documents to the depositary; or
- It is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in France would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be

made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide to the depositary all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to you and will sell the property if:

- We do not request that the property be distributed to you or if we request that the property not be distributed to you; or
- We do not deliver satisfactory documents to the depositary; or
- The depositary determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depositary may not lawfully distribute such property to you, the depositary may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

Issuance of ADSs upon Deposit of Ordinary Shares

The depositary may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by U.S. and French legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary. As such, you will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- You are duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, “restricted securities” (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, Combination, and Split Up of ADRs

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Ordinary Shares Upon Cancellation of ADSs

As a holder, you will be entitled to present your ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian’s offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and French legal considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders’ meeting or a payment of dividends.
- Obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

Voting Rights

As a holder, you generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by your ADSs. At our request, the depositary will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary may distribute to holders of ADSs instructions on how to retrieve such materials upon request.

If the depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary in a timely manner.

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-ordinary share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. 5¢ per ADS issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to ordinary share ratio, or for any other reason)	Up to U.S. 5¢ per ADS cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. 5¢ per ADS held
ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary
Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and <i>vice versa</i> , or for any other reason)	Up to U.S. 5¢ per ADS (or fraction thereof) transferred
Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and <i>vice versa</i>).	Up to U.S. 5¢ per ADS (or fraction thereof) converted

As an ADS holder, you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;

- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary and/or service providers (which may be a division, branch or affiliate of the depositary) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom the ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

Amendments and Termination

We may agree with the depositary to modify the deposit agreement at any time without your consent. We undertake to give holders of ADSs 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses). In connection with any termination of the deposit agreement, the depositary may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Transmission of Notices, Reports and Proxy Soliciting Material

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. Subject to the terms of the deposit agreement, the depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to accurately determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs or other deposited property, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice or for any act or omission of or information provided by DTC or any DTC participant.
- The depositary shall not be liable for acts or omissions of any successor depositary in connection with any matter arising wholly after the resignation or removal of the depositary.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation including regulations of any stock exchange, or by reason of present or future provision of any provision of our Articles of Incorporation, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.

- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Incorporation or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder or beneficial holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- We and the depositary disclaim liability arising out of losses, liabilities, taxes, charges or expenses resulting from the manner in which a holder or beneficial owner of ADSs holds ADSs, including resulting from holding ADSs through a brokerage account.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary and you as ADS holder.

Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

As the above limitations relate to our obligations and the depositary's obligations to you under the deposit agreement, we believe that, as a matter of construction of the clause, such limitations would likely to continue to apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred under the deposit agreement before the cancellation of the ADSs and the withdrawal of the ordinary shares, and such limitations would most likely not apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred after the cancellation of the ADSs and the withdrawal of the ordinary shares and not under the deposit agreement.

In any event, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder. In fact, you cannot waive our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Taxes

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

Foreign Currency Conversion

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law/Waiver of Jury Trial

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of France.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY.

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. *If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.*

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) is the type that the registrant treats as private or confidential.

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER 1000166785		PAGE 1 OF 8	
2. CONTRACT NO. SPE2DP-23-D-0004		3. AWARD/EFFECTIVE DATE 2023 SEP 22		4. ORDER NUMBER		5. SOLICITATION NUMBER SPE2DP-23R-0001	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME		b. TELEPHONE NUMBER (No collect calls)		8. OFFER DUE DATE/ LOCAL TIME 2023 JUL 20	
9. ISSUED BY		CODE SPE2DP		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR SMALL BUSINESS HUBZONE SMALL BUSINESS SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS EDWOSB 8 (A)		SET ASIDE: ____ % FOR: WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS: 325414 SIZE STANDARD:	
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED SEE SCHEDULE		12. DISCOUNT TERMS Net 30 days		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
15. DELIVER TO		CODE		16. ADMINISTERED BY		14. METHOD OF SOLICITATION RFQ IFB <input checked="" type="checkbox"/> RFP	
17a. CONTRACTOR/ OFFEROR		CODE 43FM1 FACILITY CODE		18a. PAYMENT WILL BE MADE BY		CODE SL4701	
VALNEVA USA, INC. DBA INTERCELL USA INC 4650 MONTGOMERY AVE BETHESDA MD 20814-3254 USA TELEPHONE NO. 5165679329				DEF FIN AND ACCOUNTING SVC SSM P O BOX 182317 COLUMBUS OH 43218-2317 USA			
17b. CHECK IF REMITTANCE IS DIFFERENT AND OUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a INLESS BLOCK BELOW IS CHECKED. SEE ADDENDUM			
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY		22. UNIT	
See Schedule						23. UNIT PRICE	
						24. AMOUNT	
25. ACCOUNTING AND APPROPRIATION DATA				26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$[***]			
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA						ARE	
27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA						ARE	
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN <u>1</u> COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED				29. AWARD OF CONTRACT REF. Valneva's OFFER DATED <u>2023 Aug 15</u> YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH, HEREIN IS ACCEPTED AS TO ITEMS: All items			
30a. SIGNATURE OF OFFEROR/CONTRACTOR [***]				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)			
30b. NAME AND TITLE OF SIGNER (Type or Print) [***]		30c. DATE SIGNED 9/21/2023		31b. NAME OF CONTRACTING OFFICER (Type or Print) [***]		31c. DATE SIGNED 9/22/2023	
AUTHORIZED FOR LOCAL REPRODUCTION PREVIOUS EDITION IS NOT USABLE						STANDARD FORM 1449 (REV. 2/2012) Prescribed by GSA - FAR (48 CFR) 53.212	

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
32a. QUANTITY IN COLUMN 21 HAS BEEN RECEIVED					
INSPECTED		ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____			
32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE			
		32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE			
33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT		37. CHECK NUMBER
PARTIAL FINAL			COMPLETE PARTIAL FINAL		
38. S/R ACCOUNT NO.	39. S/R VOUCHER NUMBER	40. PAID BY			
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY <i>(Print)</i>			
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER		41c. DATE	42b. RECEIVED AT <i>(Location)</i>		
			42c. DATE REC'D (YYMM/DD)		42d. TOTAL CONTAINERS

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED: SPE2DP-23-D-0004	PAGE 3 OF 8 PAGES
<div>1. Contract SPE2DP-23-D-0004 is the result of Valneva's proposal submission dated August 15, 2023 in response to solicitation SPE2DP-23-R-0001. Valneva's offer was revised via correspondences dated August 28, 2023 and a response to the Final Proposal Revision (FPR) dated September 14, 2023.</div> <div>2. This document represents the basic contract against which delivery orders may be placed.</div> <div>3. Schedule of Supplies Item Identification: Japanese Encephalitis Virus (JEV), Purified, Inactivated Vaccine, EA (1 pre-filled syringe), NOC 42515-0002-01, "IXIARO" National Stock Number: (NSN 6505-01-607-7018) Item: 0001 Description - Base Year Minimum Quantity: [***] each Maximum Quantity: [***] each Unit Price: \$[***] Minimum Contract Price (Base Year): \$[***]</div> <div>4. The effective ordering period shall be from the date of award through one year thereafter.</div> <div>5. Delivery shall be FOB Destination and delivered within 120 days from date of the delivery order.</div> <div>6. [***]</div> <div>7. Delivery destination (to be indicated on each delivery order): Defense Logistics Agency Distribution, Susquehanna PA (DDSP) Unit Set Assembly Operation Bldg 89, Avenue U, Door 6 New Cumberland, PA 17070-5000 Attention: [***] Defense Logistics Agency Distribution, Yokosuka Japan (DOY J) FLT ACT YOKOSUKA PH 01181468168344 HONCHO 1 CHOME YOKOSUKA SHI B 5010 YOKOSUKA JP 238-0041</div> <div>8. Inspection and acceptance shall be at destination.</div> <div>9. The guaranteed minimum (GM) quantity to be ordered during the base year is [***] each.</div> <div>10. Valneva's offer on solicitation SPE2DP-23-R-0001, (including Amendment 0001, Amendment 0002), along with Valneva and DLA correspondence dated August 25, 2023; August 28, 2023 and the Final Proposal Revision (FPR) letter and response dated September 14, 2023, are made part of this contract and incorporated by reference.</div> <div>CONTINUED ON NEXT PAGE</div>		

Part 12 Clauses

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS --- COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (SEP 2023) FAR

As prescribed in 12.301(b)(4), insert the following clause:

- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:
- (1) 52.203 -19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113 -235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (2) 52.204 -23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021) (Section 1634 of Pub. L. 115 -91).
- (3) 52.204 -25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (NOV 2021) (Section 889(a)(1) of Pub. L. 115 -232).
- (4) 52.209 -10, Prohibition on Contracting with Inverted Domestic Corporations (NOV 2015).
- (5) 52.232 -40, Providing Accelerated Payments to Small Business Subcontractors (MAR 2023) (31 U.S.C. 3903 and IO U.S.C. 380 I).
- (6) 52.233 -3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
- (7) 52.233 -4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108 -77 and 108 -78 (19 U.S.C. 3805 note)).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services.

[Contracting Officer check as appropriate.]

- X 52.203-6, Restrictions on Subcontractor Sales to the Government (JUN 2020), with Alternate I (NOV 2021) (41 U.S.C. 4704 and IO U.S.C. 4655).
- X (2) 52.203 -13, Contractor Code of Business Ethics and Conduct (NOV 2021) (41 U.S.C. 3509).
- (3) 52.203 -15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 20 10) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- X (4) 52.204 -10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 610 I note).
- (5) [Reserved]
- (6) 52.204 -14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
- (7) 52.204 -15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
- (8) 52.204 -27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section I 02 of Division R of Pub. L. 117-328).
- X (9) 52.209 -6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (NOV 2021) (31 U.S.C. 6101 note).
- X (10) 52.209 -9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
- (11) [Reserved]
- (12) 52.219 -3, Notice of HUBZone Set-Aside or Sole Source Award (OCT 2022) (15 U.S.C. 657a).
- (13) 52.219 -4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2022) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
- (14) [Reserved]
- (15)(i) 52.219 -6, Notice of Total Small Business Set-Aside (NOV 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219 -6.
- (16)(i) 52.219 -7, Notice of Partial Small Business Set-Aside (NOV 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219 -7.
- X (17) 52.219 -8, Utilization of Small Business Concerns (SEP 2023) (15 U.S.C. 637(d)(2) and (3)).
- X (18)(i) 52.219 -9, Small Business Subcontracting Plan (SEP 2023) (15 U.S.C. 637(d)(4)).
- (2) Alternate I (NOV 2016) of 52.219 -9.
- (3) Alternate II (NOV 2016) of 52.219 -9.
- (4) Alternate III (JUN 2020) of 52.219 -9.
- (5) Alternate IV (SEP 2023) of 52.219 -9.
- (19)(i) 52.219 -13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- (ii) Alternate I (MAR 2020) of 52.219 -13.
- (20) 52.219 -14, Limitations on Subcontracting (OCT 2022) (15 U.S.C. 657s).
- X (21) 52.219 -16, Liquidated Damages --Subcontracting Plan (SEP 2021) (15 U.S.C. 637(d)(4)(F)(i)).
- (22) 52.219 -27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (OCT 2022) (15 U.S.C. 657f).
- X (23)(i) 52.219 -28, Post-Award Small Business Program Representation (SEP 2023) (15 U.S.C. 632(a)(2)).
- (ii) Alternate I (MAR 2020) of 52.219 -28.
- (24) 52.219 -29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (OCT 2022) (15 U.S.C. 637(m)).
- (25) 52.219 -30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (OCT 2022) (15 U.S.C. 637(m)).
- (26) 52.219 -32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
- (27) 52.219 -33, Nonmanufacturer Rule (SEP 2021) (15 U.S.C. 657s).
- X (28) 52.222 -3, Convict Labor (JUN 2003) (E.O. 11755).

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Part 12 Clauses (CONTINUED)

- X** (29) 52.222-19, Child Labor --Cooperation with Authorities and Remedies (DEC 2022) (E.O. 13126).
- X** (30) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- X** (31)(i) 52.222-26, Equal Opportunity (SEPT 20 16) (E.O. 11246).
- (ii) Alternate I (Feb 1999) of 52.222-26.
- X** (32)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- X** (ii) Alternate I (July 2014) of 52.222-35.
- X** (33)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- (ii) Alternate I (July 2014) of 52.222-36.
- X** (34) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- X** (35) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- X** (36)(i) 52.222-50, Combating Trafficking in Persons (NOV 2021) (22 U.S.C. chapter 78 and E.O. 13627).
- (ii) *Alternate I* (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (37) 52.222-54, Employment Eligibility Verification (JAY 2022) (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial products or commercial services as prescribed in FAR 22.1803.)
- (38)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (39) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).
- (40) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).
- (41)(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (OCT 2015) of 52.223-13.
- (42)(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-14.
- (43) 52.223-15, Energy Efficiency in Energy-Consuming Products (MAY 2020) (42 U.S.C. 8259b).
- (44)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-16.
- X** (45) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).
- (46) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).
- (47) 52.223-21, Foams (JUN 2016) (E.O. 13693).
- (48)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- (ii) Alternate I (JAN 2017) of 52.224-3.
- (49) 52.225-1, Buy American - Supplies (NOV 2021)) (41 U.S.C. chapter 83).
- (50)(i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (Dec 2022) (19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, 19 U.S.C. chapter 29 (sections 4501-4732), Public Law 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
- (2) Alternate I [RESERVED].
- (3) Alternate II (DEC 2022) of 52.225-3.
- (4) Alternate III (JAN 2021) of 52.225-3.
- (51) 52.225-5, Trade Agreements (DEC 2022) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).
- X** (52) 52.225-13, Restrictions on Certain Foreign Purchases (FEB 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- (53) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).
- (54) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150).
- (55) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).
- (56) 52.229-12, Taxon Certain Foreign Procurements (FEB 2021).
- (57) 52.232-29, Terms for Financing of Purchases of Commercial Products and Commercial Services (NOV 2021) (41 U.S.C.4505, 10 U.S.C. 3805).
- (58) 52.232-30, Installment Payments for Commercial Products and Commercial Services (NOV 2021) (41 U.S.C. 4505, 10 U.S.C. 3805).
- X** (59) 52.232-33, Payment by Electronic Funds Transfer --System for Award Management (OCT 2018) (31 U.S.C. 3332).
- (60) 52.232-34, Payment by Electronic Funds Transfer --Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).
- (61) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
- (62) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).
- (63) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(3)).
- (64)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (NOV 2021) (46 U.S.C. 55305 and 10 U.S.C. 2631).
- (ii) Alternate I (Apr 2003) of 52.247-64.
- (3) Alternate II (NOV 2021) of 52.247-64.
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services: *[Contracting Officer check as appropriate.]*
- (1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).
- (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.

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Part 12 Clauses (CONTINUED)

S.C. 206 and 41 U.S.C. chapter 67).

- (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards --Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment --Requirements (MAY 2014) (41 U.S.C. chapter 67).
- (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services --Requirements (MAY 2014) (41 U.S.C. chapter 67).
- (7) 52.222-55, Minimum Wages Under Executive Order 13658 (JAN 2022).
- (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).
- (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792).

(d) *Comptroller General Examination of Record.* The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records --Negotiation.

(i) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(c)(i) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1), in a subcontract for commercial products or commercial services. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause --

- (a) 52.203-13, Contractor Code of Business Ethics and Conduct (NOV 2021) (41 U.S.C. 3509).
- (b) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(c) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021) (Section 1634 of Pub. L. 115-91).

- (d) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (NOV 2021) (Section 889(a)(1) of Pub. L. 115-232).

(5) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).

- (6) 52.219-8, Utilization of Small Business Concerns (SEP 2023) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(7) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

(8) 52.222-26, Equal Opportunity (SEP 2016) (E.O. 11246).

(9) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

(10) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

(11) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

(12) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(13) 52.222-41, Service Contract Labor Standards (AUG 2018)(41 U.S.C. chapter 67).

(14) (A) 52.222-50, Combating Trafficking in Persons (NOV 2021) (22 U.S.C. chapter 78 and E.O. 13627).

(B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(15) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

(16) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services --Requirements (MAY 2014) (41 U.S.C. chapter 67).

(17) 52.222-54, Employment Eligibility Verification (MAY 2022) (E.O. 12989).

(18) 52.222-55, Minimum Wages Under Executive Order 13658 (JAN 2022).

(19) 52.222-62 Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).

(xx)(A) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(B) Alternate I (JAN 2017) of 52.224-3.

(21) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).

(22) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(23) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (MAR 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801). Flow down required in accordance with paragraph (c) of 52.232-40.

(24) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (NOV 2021) (46 U.S.C. 55305 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

CONTINUED ON NEXT PAGE

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED: SPE2DP-23-D-0004	PAGE 7 OF 8 PAGES
<div>Part 12 Clauses (CONTINUED)</div> <div>(2) While not required, the Contractor may include in its subcontracts for commercial products and commercial services a minimal number of additional clauses necessary to satisfy its contractual obligations.</div> <div>(End of Clause)</div> <div>52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS (DEC 2014) FAR</div> <div>52.204-25 PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (NOV 2021) FAR</div> <div>252.204-7009 LIMITATIONS ON THE USE OR DISCLOSURE OF THIRD-PARTY CONTRACTOR REPORTED CYBER INCIDENT INFORMATION (JAN 2023) DFARS</div> <div>252.232-7010 LEVIES ON CONTRACT PAYMENTS (DEC 2006) DFARS</div> <div>52.247-34 F.O.B. DESTINATION (NOV 1991) FAR</div> <div>52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (MAR 2023) FAR</div> <div>252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (JAN 2023) DFARS</div> <div>As prescribed in 232.7004 (b), use the following clause:</div> <div>Definitions. As used in this clause -</div> <div>Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.</div> <div>Document type means the type of payment request or receiving report available for creation in Wide Area Workflow (WAWF).</div> <div>Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.</div> <div>Payment request and receiving report are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.</div> <div>Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation System (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.</div> <div>WAWF access. To access WAWF, the Contractor shall -</div> <div>(1) Have a designated electronic business point of contact in the System for Award Management at HYPERLINK "http://www.sam.gov/" \h https://www.sam.gov and</div> <div>(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this Web site.</div> <div>WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.</div> <div>WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.</div> <div>WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:</div> <div>(1) Document type. The Contractor shall submit payment requests using the following document type(s):</div> <div>(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.</div> <div>(ii) For fixed price line items -</div> <div>(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.</div> <div>(Contracting Officer: insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)</div> <div>Invoice and Receiving Report Combo</div> <div>For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.</div> <div>N/A</div> <div>(Contracting Officer: insert either "Invoice 2in 1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)</div> <div>(iii) For customary progress payments based on costs incurred, submit a progress payment request.</div> <div>(iv) For performance based payments, submit a performance based payment request.</div> <div>(v) For commercial financing, submit a commercial financing request.</div> <div>(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.</div> <div>[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]</div> <div>Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.</div> <div>Routing Data Table *</div> <div>Field Name in WAWF</div> <div>Data to be entered in</div> <div>WAWF</div> <div>Pay Official DoDAAC</div> <div>SL4701</div> <div>Issue By DoDAAC</div> <div>SPE2DP</div> <div>Admin DoDAAC</div> <div>SPE2DP</div> <div>Inspect By DoDAAC</div> <div>Ship To Code</div> <div>SEE DELIVERY ORDER</div> <div>Ship From Code</div> <div>Mark For Code</div> <div>Service Approver</div> <div>(DoDAAC)</div> <div>Service Acceptor</div> <div>(DoDAAC)</div> <div>CONTINUED ON NEXT PAGE</div>		

Part 12 Clauses (CONTINUED)

Field Name in WAWF

Data to be entered in WAWF

Accept at Other DoDAAC

LPO DoDAAC

DCAA Auditor DoDAAC

Other DoDAAC(s)

(* Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(** Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact. (I) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(***)

(Contracting Officer: Insert applicable information or "Not applicable.")

(2) Contact the WA WF helpdesk at 866-618-5988, if assistance is needed.

52.233-3 PROTEST AFTER AWARD (AUG 1996) FAR

252.204-7018 PROHIBITION ON THE ACQUISITION OF COVERED DEFENSE TELECOMMUNICATIONS EQUIPMENT OR SERVICES (JAN 2023) DFARS

52.253-1 COMPUTER GENERATED FORMS (JAN 1991) FAR

252.244-7000 SUBCONTRACTS FOR COMMERCIAL PRODUCTS OR COMMERCIAL SERVICES (JAN 2023) DFARS

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO.3 TO GERMANY DISTRIBUTION AGREEMENT,
AMENDMENT NO.2 TO SWITZERLAND DISTRIBUTION AGREEMENT,
AMENDMENT NO.3 TO UK DISTRIBUTION AGREEMENT,
AND TERMINATION AGREEMENT

This Amendment (this “**Amendment**”) is entered into on the date of the last signature by and between:

- (A) **Valneva Sweden AB**, [***], organised under the laws of Sweden, with its registered office at SE-105 21 Stockholm, Sweden (“**Valneva Sweden**”);
- (B) **Valneva UK Limited**, organised under the laws of the United Kingdom, with its principal place of business at Centaur House, Ancells Business Park, Ancells Road, Fleet, Hampshire GU51 2UJ, United Kingdom (“**Valneva UK**”);
- (C) **Valneva France SAS**, [***], a simplified joint stock company with share capital of EUR 1,000, organised under the laws of France, with its principal place of business at 6 Îlot Saint-Joseph 12, Ter Quai Perrache Bureaux Convergence, Bâtiment A, 69002 Lyon, France (“**Valneva France**”);
- (D) **Valneva Canada, Inc.**, [***], organised under the laws of Canada, with its registered office at 3535 Saint-Charles Blvd., Suite 600, Kirkland (Quebec) H9H 5B9, Canada (“**Valneva Canada**”);
- (E) **Valneva Austria GmbH**, [***], organised under the laws of Austria, with its registered office at Campus Vienna Biocenter 3, AT-1030 Vienna, Austria (“**Valneva Austria**” and, together with Valneva Sweden, Valneva UK, Valneva France, and Valneva Canada, “**Valneva**”);
- (F) **Bavarian Nordic A/S**, [***], organised under the laws of Denmark, with its principal place of business at DK 2900 Hellerup, Denmark (“**Bavarian Denmark**”); and
- (G) **Bavarian Nordic Switzerland AG**, [***], organised under the laws of Switzerland, with its principal place of business at Zug Spaces Grafenauweg, Grafenauweg 8, CH-6301 Zug, Switzerland (“**Bavarian Switzerland**” and, together with Bavarian Denmark, “**Bavarian Nordic**”);

Each of Valneva and Bavarian Nordic are referred to as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, Valneva Sweden and Bavarian Denmark entered into a Distribution Agreement dated 18 November 2020, as amended on 18 November 2020 and 16 December 2021 regarding the rights of Bavarian Nordic to distribute Valneva’s proprietary cholera vaccine DUKORAL (“**DUKORAL**”) in Germany (“**Germany Distribution Agreement**”);

WHEREAS, Valneva Sweden and Bavarian Switzerland entered into a Distribution Agreement dated 20 January 2021, as amended on 1 November 2021 regarding the rights of Bavarian Nordic to distribute DUKORAL in Switzerland (“**Switzerland Distribution Agreement**”);

WHEREAS, Valneva Canada, Inc. and Bavarian Nordic A/S entered into a Distribution Agreement dated 27 November 2020, as amended on 16 December 2021 and 1 October 2022, regarding the rights of Valneva Canada to distribute Bavarian Nordic’s proprietary rabies vaccine RABAVERT in Canada (“**Canada Distribution Agreement**”);

WHEREAS, Valneva UK, Ltd. and Bavarian Nordic A/S entered into a Distribution Agreement dated 18 December 2020, as amended on 16 December 2021 and 22 August 2022, regarding the rights of Valneva

UK to distribute Bavarian Nordic's proprietary rabies vaccine RABIPUR in the United Kingdom ("UK Distribution Agreement");

WHEREAS, the Parties entered into other Distribution Agreements (as defined below) regarding the distribution of certain products in certain territories; and

WHEREAS, the Parties desire to amend the Germany Distribution Agreement, the Switzerland Distribution Agreement, and the UK Distribution Agreement, and terminate all Distribution Agreements with effect from the respective Termination Effective Date(s) (as defined below).

NOW THEREFORE, in consideration of the premises and mutual promises and covenants contained in this Amendment, and for other good and valuable consideration, the Parties hereto agree as follows.

The provisions of this Amendment shall apply with effect from 15 May 2023 (the "Amendment Effective Date").

1. **Germany Distribution Agreement.** The Parties hereto agree to amend the Germany Distribution Agreement with effect from the Amendment Effective Date as follows:

a. Section 1.8 shall be deleted in its entirety and replaced by the following:

"1.8 Not used."

b. The Parties have agreed to convert the exclusive distribution rights to non-exclusive distribution rights. Consequently, Sections 2.1.1 and 2.1.5 shall be deleted in their entirety and replaced by the following:

"2.1 Distribution and Supply

2.1.1 Distribution Rights. Subject to the terms and conditions of this Agreement, and with effect from the 15 May 2023, SUPPLIER hereby appoints DISTRIBUTOR, and DISTRIBUTOR accepts such appointment, as SUPPLIER's non-exclusive distributor to market, promote, sell, offer to sell, import and distribute the Product in the Territory (subject to SUPPLIER's retained rights in Section 2.1.2 below) without the right to grant sub-licenses or appoint sub-distributors except in cases where SUPPLIER has provided its prior written consent."

"2.1.5 Appointment of Distributors Outside the Territory. DISTRIBUTOR acknowledges that SUPPLIER may grant exclusive and/or non-exclusive marketing rights for the Product to third parties in countries outside the Territory, or non-exclusive rights for the Product within the Territory, for itself or its Affiliates. For clarity, DISTRIBUTOR shall not be entitled to receive any compensation for sales of Product made in the Territory over the Internet or by any other third party within the Territory."

c. The Heading of Article 3 and Section 3.1 shall be deleted in its entirety and replaced by the following:

"3 Non-Competition Covenants

3.1 No Manufacturing of Product. DISTRIBUTOR covenants not to copy, decompile, modify, reverse engineer, or create derivative works out of any Valneva Confidential Information or manufacture the Product or cause the Product to be manufactured directly or indirectly by third parties without the prior written consent of SUPPLIER."

For the avoidance of doubt, Section 3.1.1 shall continue in full force and effect.

d. Section 3.2 shall be deleted in its entirety and replaced by the following:

“3.2 Not used.”

e. Section 6.1 shall be deleted in its entirety and replaced by the following:

“6.1 Minimum Purchase Quantities and Sales Target

6.1.1 Minimum Purchase Quantities. Subject to Section 6.1.3, in any full calendar year following the Start Date, DISTRIBUTOR shall purchase the Minimum Annual Purchase Quantities.

6.1.2 Failure to fulfill Minimum Annual Purchase Quantities. Subject to Section 6.1.3, if, at the end of any full calendar year, DISTRIBUTOR has failed to purchase the Minimum Annual Purchase Quantity, DISTRIBUTOR shall [***].

6.1.3 Third Party Distributor. Notwithstanding the foregoing, if SUPPLIER appoints any third party as a distributor of the Product in the Territory at any time during the Term, SUPPLIER shall notify DISTRIBUTOR of such appointment in writing promptly, and in any event within two (2) Business Days of such appointment becoming effective (regardless of whether such third party has commenced distribution of the Product in the Territory). [***]

f. Section 10.1 shall be deleted in its entirety and replaced by the following:

“10.1 Sales Records. DISTRIBUTOR shall, and shall ensure that its Sub-Contractors where applicable maintain and retain all records relating to Product sales, contracts, invoices, customers, accounts, complaints and other transactions concerning Product for [***] from the date on which such records arose or for the period required by Applicable Law. SUPPLIER may request such sales figures and sale figure estimates and such other reporting information, in each case in aggregate form, as SUPPLIER may reasonably require, and DISTRIBUTOR will use Reasonable Commercial Efforts to provide such information to SUPPLIER as promptly as possible.”

g. Section 10.2 shall be deleted in its entirety and replaced by the following:

“10.2 Reports. DISTRIBUTOR shall keep SUPPLIER informed through [***] market reports. Each such [***] report shall include for each Product (1) the amount of inventory of Product [***] by Distributor and each of its Subcontractors, together with the remaining shelf-life of such Product inventory, and (2) the [***] volume sold in terms of both doses and Net Sales of Product. The report shall also include significant market developments in the Territory [***] and relevant updates of DISTRIBUTOR's activities to commercialize and market the Product in the Territory. The [***] report provided by DISTRIBUTOR in January of each calendar year shall cover in addition the full calendar year and serve as an annual report. Reports shall comply with the format provided by SUPPLIER in ANNEX J, or in a format otherwise agreed upon between the Parties, and shall be due on the [***] of the month following the month to which the report relates. Reports are to be sent to SUPPLIER's email address: [***]. DISTRIBUTOR shall cause its Sub-Contractors, where applicable, to prepare and submit to DISTRIBUTOR, on a timely basis, reports including such information and shall include information from such reports in the reports provided by DISTRIBUTOR hereunder. In case of major volume shortfalls, DISTRIBUTOR will immediately inform SUPPLIER about the reasons of such deviation and propose corrective actions. Commencing on January 2021, and every [***] thereafter, the Parties shall meet and discuss DISTRIBUTOR's marketing efforts performed in relation to the Product during the preceding [***] period including

DISTRIBUTOR's planned marketing activities in relation to the Product in the Territory over the forthcoming [***].

2. [***]

3. [***]

4. **Termination of Distribution Agreements.** The Parties agree that each of the following agreements (together the “**Distribution Agreements**”) shall terminate in accordance with its terms with effect from 31 December 2024 (“**Termination Effective Date 2024**”) or 31 December 2025 (“**Termination Effective Date 2025**”) as set forth below, provided that (i) no Party shall be required to give any written notice of such termination to another Party, and (ii) any provisions in such Distribution Agreements which are stated to survive such termination shall continue in full force and effect and the Parties shall comply with the provisions of Section 17 (*Effects of Termination*) of the relevant Distribution Agreement:

Termination Date 2024:

- a. Canada Distribution Agreement;
- b. UK Distribution Agreement;

Termination Date 2025:

- c. Germany Distribution Agreement;
 - d. Switzerland Distribution Agreement;
 - e. The distribution agreement between Valneva France SAS and Bavarian Nordic A/S dated 17 December 2020, as amended on 16 December 2021 and 22 August 2022, regarding the distribution by Valneva France of the product RABIPUR in France, certain French overseas territories, Belgium, Luxembourg and The Netherlands, and the product ENCEPUR Adults in France and certain French overseas territories;
 - f. The distribution agreement between Valneva Austria GmbH and Bavarian Nordic A/S dated 19 August 2020, as amended on 16 December 2021, regarding the distribution by Valneva Austria of the products RABIPUR, ENCEPUR Adults and ENCEPUR Children in Austria;
 - g. The distribution agreement between Valneva Austria GmbH and Bavarian Nordic A/S dated 18 November 2020, as amended on 16 December 2021, regarding the distribution by Bavarian Nordic A/S of the product IXIARO in Germany; and
 - h. The distribution agreement between Valneva Austria GmbH and Bavarian Nordic Switzerland AG dated 20 January 2021, as amended on 16 December 2021, regarding the distribution by Bavarian Nordic Switzerland AG of the product IXIARO in Switzerland.
5. The Parties agree that, upon termination or expiry of each Distribution Agreement, notwithstanding any transition plan agreed by the Parties in accordance with Section 17.7 of each Distribution Agreement, at the request of SUPPLIER on an agreement-by-agreement or tender-by-tender basis, DISTRIBUTOR shall [***].
6. Except as expressly set forth in this Amendment, all other terms and conditions of the Distribution Agreements shall remain in full force and effect until the Termination Date.

7. This Amendment may be executed in seven (7) or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Alternatively, this Agreement may be executed and transmitted by advanced electronic signatures (e.g. ValidSign or DocuSign), which shall have the same force and effect as an original.

[Signature page follows]

IN WITNESS WHEREOF, this Amendment shall take effect as of the date first written above when it has been executed below by the duly authorized representatives of the Parties.

Valneva Austria GmbH

By: /s/ By: /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Valneva Sweden AB

By: /s/ By: /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Valneva UK Limited

By: /s/ By: /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Valneva France SAS

By: /s/ By: /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Valneva Canada, Inc.

By: /s/ By: /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Bavarian Nordic A/S

By: /s/

Name: [***]

Title: [***]

Bavarian Nordic Switzerland AG, by Bavarian Nordic A/S authorised by and acting on its behalf

By: /s/

Name: [***]

Title: [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

**AMENDMENT No. 1
to Distribution Agreement
effective as of 15 December 2022
by and between Valneva Austria GmbH and VBI Vaccines B.V.**

This Amendment No. 1 to the Agreement (as defined below) is entered into,

BY AND BETWEEN

VBI Vaccines B.V., with [***] organized under the laws of the Netherlands, with its principal place of business at Queen's Tower #714, Delflandlaan 1, 1062EA Amsterdam, The Netherlands, hereinafter referred to as "**SUPPLIER**",

and

Valneva Austria GmbH, [***], organized under the laws of Austria, with its registered office at Campus Vienna Biocenter 3, AT-1030 Vienna, Austria, hereinafter referred to as "**DISTRIBUTOR**",

(hereinafter each referred to as a "**Party**", and collectively as the "**Parties**").

W I T N E S S E T H:

WHEREAS, The Parties have entered into a Distribution Agreement, with the Effective Date of 15 December 2022 and delegated responsibilities under the Distribution Agreement ("**Delegation**") to Valneva Austria's affiliates Valneva France SAS, Valneva UK, Ltd. And Valneva Sweden AB pertaining to the sale of, and the rights of DISTRIBUTOR through its Affiliates to commercialize and distribute SUPPLIER's proprietary hepatitis-B vaccine PreHevbri® ("**Product**") in Belgium, the Netherlands, the United Kingdom and Sweden, Norway, Denmark and Finland, as further defined therein (hereinafter referred to as the ("**Agreement**")); and

WHEREAS, The Parties have discussed and agreed upon new Minimum Annual Purchase Quantities and a new Price (as defined in the Agreement) for 2024 as well clarifying certain information requirements, and now wish to amend the Agreement accordingly.

NOW, THEREFORE, it is agreed as follows:

1. To the extent not explicitly defined herein, capitalised terms used in this Amendment No. 1 shall have the same meaning as set forth in the Agreement.
2. The Parties have agreed to clarify information requirements pertaining to Regulatory Approvals and have agreed to amend Section 5.1.2 accordingly. After the change Section 5.1.2 will read as follows (changes in *italics*):

"5.1.2 **Marketing Authorization and Interactions with Governmental Authorities.**

SUPPLIER undertakes that it holds and shall maintain, at SUPPLIER's cost, throughout the Term of this Agreement and for a period of [***] thereafter a Marketing Authorization necessary for the marketing and sale of the Product in the Territory. On written request by the DISTRIBUTOR, SUPPLIER shall provide DISTRIBUTOR with information in its possession which is needed for the promotion and distribution of the Product. The SUPPLIER will be in charge of the regulatory submissions required to maintain the Marketing Authorizations for the Product in the Territory. *The SUPPLIER will provide the approved Product Information (English version and translations for the countries in the Territory) to the DISTRIBUTOR within [***] after receipt of European Commission and/or European Medicines Agency approval. The DISTRIBUTOR undertakes to use Reasonable Commercial Efforts to notify SUPPLIER as soon as DISTRIBUTOR identifies that there is a potential risk of a Stock-Out-Situation in the Territory, or within [***] prior to an identified Stock-Out-Situation.* SUPPLIER shall be responsible for informing the European Medicines Agency and/or the applicable Governmental Authority in the Territory of any Stock-Out Situations to the extent required by Applicable Law, unless the Applicable Law in the Territory requires the DISTRIBUTOR to communicate with the applicable Governmental Authority regarding Stock-Out Situations, in which case DISTRIBUTOR shall inform the applicable Governmental Authority using correspondence approved by SUPPLIER. SUPPLIER shall promptly inform DISTRIBUTOR of the loss of, or on becoming aware of the threat of the loss of, its Marketing Authorization(s) in the Territory. The failure of SUPPLIER to maintain such Marketing Authorization(s) shall give DISTRIBUTOR the right, in its sole discretion, to terminate this Agreement, in accordance with Section 16.2.1, by giving [***] prior written notice to SUPPLIER, unless SUPPLIER has obtained the necessary Marketing Authorization within that [***] cure period. DISTRIBUTOR shall upon request provide assistance to SUPPLIER at DISTRIBUTOR'S cost and expense as may be reasonably required by SUPPLIER in connection with the maintenance of the Marketing Authorizations. DISTRIBUTOR shall seek SUPPLIER's approval prior to initiation of and provide SUPPLIER with prior written notice of its contacts, liaisons, discussions, meetings, and correspondence with, and submissions to, any Government Authority to the extent relating to, or otherwise affecting, the Market Authorization of the Product ("Regulatory Correspondence") and shall provide details of what will be, and what was, covered in such Regulatory Correspondence. SUPPLIER shall have the opportunity to provide comments and advice in connection with such Regulatory Correspondence and DISTRIBUTOR shall, on request from SUPPLIER, provide SUPPLIER with details of such Regulatory Correspondence. DISTRIBUTOR shall promptly but not later than [***] from receipt of a question regarding the Product(s) from any Governmental Authority inform the SUPPLIER of such question including providing reasonable details of the question. SUPPLIER shall be responsible for responding to any such questions if permitted by the Government Authority or if not permitted by the Government Authority, DISTRIBUTOR shall respond to the Government Authority as instructed by SUPPLIER."

- 3. The Parties have agreed to include a new Price for [***]. As of the Amendment Date ANNEX C will be deleted in its entirety and replaced by a new ANNEX D, attached hereto as Exhibit 1.
- 4. The Parties have agreed on new Minimum Annual Purchase Quantities. As of the Amendment Date ANNEX D will be deleted in its entirety and replaced by a new ANNEX D, attached hereto as Exhibit 2.
- 5. Except as set forth herein, (a) all terms and conditions of the Agreement are ratified and confirmed in all respects and shall continue in full force and effect, (b) the Agreement and this Amendment No. 1 shall be read and construed as a single agreement, and all references to the Agreement, as previously amended, shall hereafter refer to the Agreement, as amended hereby, and (c) nothing contained herein shall constitute a waiver of, impair or otherwise affect any obligation or right of either party under the Agreement.
- 6. This Amendment No. 1 shall be effective as of 1 January 2024 (the "Amendment Effective Date").

7. Section 20 of the Agreement shall apply to this Amendment No. 1 and be incorporated herein by reference.

Signature page follows

IN WITNESS WHEREOF, this Amendment No. 1 has been executed on behalf of each Party by its duly authorised representatives.

Valneva Austria GmbH VBI Vaccines B.V.

By: /s/	By: /s/
Name: [***]	Name: [***]
Title: [***]	Title: [***]

Valneva Austria GmbH

By: /s/
Name: [***]
Title: [***]

Exhibit 1

ANNEX C Price Schedule; Minimum Order Quantities; Payment Terms; Forecasts; Orders; Handling Requirements

Initial price schedule for PRODUCT

PreHevbri™ Hepatitis B vaccine (recombinant, adsorbed), Injectable suspension, for intramuscular use, will be supplied in either one (1) package consisting of 1x1 (1,0ml) dose of Product, or one (1) package consisting of 10x1 (1,0ml) dose of Product, as ordered by the DISTRIBUTOR.

Table 1:

Country	Product name	Price in %/dose	Minimum Order Quantity (per shipment)/doses
Sweden Norway Denmark Finland	PreHevbri™	***	***

The UK	PreHevbri™	***	***
Belgium and the Netherlands	PreHevbri™	***	***

The Floor Price have been established by [***].

It is agreed that the Floor Price is applicable for Products for sale and distribution [***]. Specific terms and conditions will be agreed upon between the Parties for Products intended to be sold and distributed under a Tender.

Reconciliation of Average Net Selling Price For Doses sold by DISTRIBUTOR

Within [***] following December 31 2024, and thereafter following December 31 each year, DISTRIBUTOR shall provide SUPPLIER with sufficient evidence of the number of doses sold, inventory on stock as of December 31, the ASP charged to customers during the previous calendar year as well as a detailed stock report in order to enable the Parties to define and agree upon the ASP of Products for that year, together with a reconciliation between the EASP and the ASP and a calculation of the amount that a Party must pay to the other in settlement for such reconciliation. For clarity, the first true-up reconciliation will be performed in January 2025 to cover the years 2023 and 2024.

If the balance of the reconciliation is negative, such amount will be paid by SUPPLIER to DISTRIBUTOR. If the balance is positive, such amount will be paid by DISTRIBUTOR to SUPPLIER. Payment will take place within [***] upon receipt of the invoice which will be issued upon agreement of the reconciliation and calculation by the Parties. [***] In case of termination or expiration of this Agreement, the balance for the last calendar year will be settled between the Parties by a credit note issued by the relevant Party. In the event of a dispute, the dispute resolution provisions in Section 19, shall apply.

Revaluation of stock

The true up mechanism needs to take into account all inventory on stock as of the end of the respective year. For the avoidance of doubt, inventory which was scrapped during the year will not be included in the true up mechanism.

For the purpose of this Agreement and as way of example, the reconciliation shall be calculated as follows:

[***]

Currency Conversion for Countries within the Territory not having EUR as Invoicing Currency

For the purpose of reconciliation in EUR the in-market Net Sales for countries not using EUR as invoicing currency shall be as follows:

If the reconciled calculated True-up Price is below the PreHevbri™ Floor Price due to the fluctuation in exchange rate the PreHevbri™ Floor Price shall not apply.

Rolling Purchase Forecasts

DISTRIBUTOR will submit to SUPPLIER a [***] rolling monthly forecast to be submitted not later than the [***] of each calendar month covering the next [***] (“**Forecast**”). The first [***] of each Forecast shall constitute a binding commitment (the “**Binding Portion**”) for the DISTRIBUTOR to purchase forecasted quantities. If DISTRIBUTOR wishes to increase the quantities of Product to be delivered as compared with the Binding Portion of any Forecast, the Parties shall discuss in good faith the possibility for SUPPLIER to manufacture and supply such excess. However, SUPPLIER shall not have any obligation to manufacture and/or supply in excess of the Binding Portion of such Forecast.

In respect of the [***] through to and including the [***] calendar months of each Forecast DISTRIBUTOR may decrease or increase the quantities set forth during such period in the Forecast by [***][***]. If DISTRIBUTOR requests for valid business, and in good faith, to alter the Forecast for such months by more than [***], SUPPLIER will use its Reasonable Commercial Efforts to satisfy such request.

In respect of the [***] through to the [***]of each Forecast DISTRIBUTOR may decrease or increase the quantities set forth during such period by [***]. If DISTRIBUTOR requests for valid business reasons, and in good faith, to alter the Forecast for such months by more than [***], SUPPLIER will use its Reasonable Commercial Efforts to satisfy such request.

For the avoidance of doubt, a Forecast shall have no bearing on the Minimum Annual Purchase Quantities referred to in Section 6.1.

Firm Purchase Orders

Firm purchase orders shall be placed with a lead-time of [***].

Exhibit 2

ANNEX D Business Plan - Minimum Annual Purchase Quantities

Country	Minimum Annual Purchase Quantities/Doses		
	2023 Quantity	2024 Quantity	2025 Quantity
Sweden			
Norway		[***]	[***]
Finland			
Denmark	[***]		
The United Kingdom	[***]	[***]	[***]
Belgium		[***]	[***]
The Netherlands	[***]		

In the event of significant changes in the market and such changes are likely to have an impact on or does actually affect the sales of the Products in the Territory, including but not limited to significant changes to trends in travel or competing products (including parallel imports) entering the relevant market in the Territory, the Parties agree to discuss in good faith commercially viable adjustments to the Minimum Annual Purchase Quantities for the relevant calendar year(s) reflecting such changes. In case of supply issues the Minimum Annual Purchase Quantities will be adapted by mutual agreement.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

for 1,5 ml sterile water for injection syringes with 0,5 ml fill volume

effective as of April 1, 2023

by and between

VALNEVA AUSTRIA GMBH

and

VETTER PHARMA INTERNATIONAL GMBH

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ARTICLES

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ANNEXES

- ANNEX 1: PRODUCT, SERVICES AND PRICES
- ANNEX 2: SPECIAL FORECASTING
- ANNEX 3: EXPANDED TERRITORY
- ANNEX 4: QUALITY AGREEMENT

This Commercial Supply Agreement (the “Agreement”), is made and entered into with effect as of April 1, 2023 (“Effective Date”), by and between Valneva Austria GmbH, a company duly organized and existing under the laws of Austria and having its principal place of business at Campus Vienna Biocenter 3, 1030 Vienna, Austria (“Valneva”), and Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany, and having its principal place of business at Eywiesenstraße 5, 88212 Ravensburg, Germany (“Vetter”), with Valneva and Vetter hereinafter individually referred to as a “Party” and collectively as the “Parties”.

WITNESSETH:

WHEREAS, Valneva desires to engage Vetter in the Manufacture of a 1,5 ml syringe pre-filled with 0,5 ml sterile water for injection, intended by Valneva to use for commercial purposes and in performing specific Services with respect thereto;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements above and hereinafter set forth, and subject to this Agreement, Valneva and Vetter agree as follows:

ARTICLE 1 : DEFINITIONS.

For the purposes of this Agreement and any supplements or amendments hereto and thereto, the following capitalized terms, whether used in the singular or plural, shall have the same and uniform meanings assigned to them below, unless a particular context otherwise requires:

- (1) “Additional Quantity” has the meaning set forth in Section 2(4)(h).
- (2) “Additional Requirements” has the meaning set forth in Section 2(2).
- (3) “Affiliate” means, with respect to a Party, any person, firm, company or other entity which controls, is directly or indirectly controlled by, or is under common control with such Party; as used herein, “control” means either (i) direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors or more than fifty percent (50%) interest in the income of the entity in question; or (ii) the possession, directly or indirectly, of the power to manage, direct or cause the direction of the management and policies of such entity.
- (4) “Annex” means an annex to this Agreement.
- (5) “Annual Reference Quantity” means the aggregate Valneva Product demand for months January to December of the following year as set forth in Section 2(4)(d).
- (6) “Appendix” means an appendix to the Quality Agreement.
- (7) “Article” means an article of this Agreement (and excludes, unless otherwise specified, that of the Quality Agreement).
- (8) “Assistance” means all support or assistance provided under this Agreement or a separate agreement, including any activities set forth in Sections 2(2), 4(1), and 6(5).
- (9) “Background IP” means any IP that (i) is owned or controlled by a Party or any of its Affiliates as of the Effective Date; or (ii) is developed by or for, or otherwise comes to be owned or controlled by a Party or any of its Affiliates, separately from and independently of any activities performed under this Agreement.
- (10) “Batch Document Package” has the meaning set forth in the Quality Agreement.
- (11) “Binding Period” has the meaning set forth in Section 2(4)(b).
- (12) “Business Day” means any calendar day other than a Saturday, a Sunday or a calendar day on which commercial banks located in Baden-Württemberg, Germany, or at the principal place of business of Valneva, are authorized or required by law to be closed.
- (13) “Capacity Agreement” has the meaning set forth in Section 2(4)(e).

- (14) “Change of Control” means, with respect to an entity, a transaction or series of related transactions as a result of which a person or entity or group of persons or entities acting in concert directly or indirectly acquires control of the entity or acquires ownership of all or substantially all of its assets. The transaction(s) may be in any form or combination of forms, including an issuance of voting securities, a grant of one or more proxies, a merger (whether or not the entity survives), a consolidation, a share exchange, a reorganization or a transfer of shares or assets. As used in this definition, “control” of an entity means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the entity, whether through the ownership of more than 50% of voting securities, by contract or otherwise.
- (15) “Confidential Information” means any and all information of a confidential or proprietary nature, including but not limited to any scientific, technical, financial or business information, material, samples and know-how in whatever form (written, oral or visual) that is directly or indirectly furnished or made available to the receiving Party or its Affiliates by or on behalf of the disclosing Party or its Affiliates under this Agreement that (a) if in tangible form, is labeled in writing as proprietary or confidential; or (b) if disclosed in oral or visual form or, if disclosed in writing without an appropriate letter, label or legend shall constitute Confidential Information that would be apparent to a reasonable person, familiar with the disclosing Party’s business and the industry in which it operates, that such information is of a confidential or proprietary nature the maintenance of which is important to the disclosing Party.
- (16) “Conforming Product” means Product Manufactured in accordance with the Process Specifications, subject to Section 5(2).
- (17) “Costs” means any and all monetary obligations, including, but not limited to, damages, liabilities, judgements, losses, and costs and/or expenses (including reasonable attorneys’ fees and court costs).
- (18) “CTD” has the meaning set forth in the Quality Agreement.
- (19) “Defect Notification Period” has the meaning set forth in Section 5(2).
- (20) “Delivery Date” means the date upon which Product will be delivered in accordance with Section 4(1), such date to be provided by Vetter in the Purchase Order confirmation pursuant to Section 2(4)(f).
- (21) “Developments” means inventions (whether patentable or not), improvements, discoveries, enhancements or other technical developments which arise from the Parties’ activities under this Agreement or are made, conceived or reduced to practice by either Party during the course of its performance hereunder.
- (22) “Deviation” has the meaning set forth in the Quality Agreement.
- (23) “Effective Date” has the meaning set forth in the preamble.
- (24) “EMA” means the European Medicines Agency or any successor agency.
- (25) “Expanded Territory” has the meaning set forth in Section 6(4).
- (26) “Facility” means, with respect to a Product, any facility used by or on behalf of Vetter in performing Vetter’s Services under this Agreement and located in Ravensburg or Langenargen, Germany.
- (27) “FDA” means the United States Food and Drug Administration or any successor agency.
- (28) “Force Majeure” means, with respect to circumstances affecting a Party’s ability to perform its obligations hereunder, any unforeseen event beyond the reasonable control of a Party, including, but not limited to, acute labor and/or supply chain disruption; violent storm or other severe weather event; earthquake, tsunami, volcanic eruption or other natural disaster; epidemic, plague or other biological event or outbreak, and other Acts of God and/or of human origin such as acts of war or terrorism.

- (29) “Future Developments” has the meaning set forth in Section 12(7).
- (30) “GMP” and “cGMP” have the meaning set forth in the Quality Agreement.
- (31) “Initial Term” has the meaning set forth in Section 9(1).
- (32) “Intellectual Property” and “IP” means all worldwide (i) patent or patent application, and any patent issuing there from, together with any extensions, reissues, reexaminations, substitutions, renewals, divisions, continuations and continuations-in-part thereof, and any patent or patent application claiming priority to any application in common with any such patent containing a disclosure substantially similar to that of any such patent, all to the extent the foregoing contain claims covering such invention; (ii) copyright registrations and applications and all renewals and extensions thereof; (iii) discoveries, inventions, trade secrets, know-how, techniques, methodologies, modifications, improvements, works of authorship, designs and data (whether or not protectable under patent, copyright, trade secrecy or similar laws); and (iv) Confidential Information, including all applications and registrations with respect to the items identified in clauses (iii)-(iv) (if any), but excluding all trademarks, trade names, service marks, logos and other corporate identifiers.
- (33) “Inspection” has the meaning set forth in Section 5(2).
- (34) “Inventory” has the meaning set forth in Section 3(4).
- (35) “Legal Requirements” means with respect to each Party, any and all laws, rules and regulations of any governmental body or regulatory authority, in each case solely to the extent applicable to such Party’s business and activities. For clarification, the Legal Requirements for Vetter and any of its Affiliates shall be limited to such applicable laws, rules and regulations applicable at the Facility, i.e. the laws, rules and regulations of Germany and the European Union (as directly applicable in Germany). Any Legal Requirements applicable to Valneva, to which Vetter and its Affiliates are to adhere (as in the case of such requirements being considered essential for the Product), shall be provided by Valneva to Vetter in detail and shall, subject to Vetter’s prior written consent, be incorporated into the agreed-upon Process Specifications all as set forth in Section 2(2).
- (36) “Long Range Forecast” has the meaning set forth in Section 2(4)(a).
- (37) “Manufacture” and “Manufacturing” means any steps, processes, operations and activities required to produce Product for and on behalf of Valneva at the Facility and specified in the Process Specifications, which might include manufacturing, processing, primary packaging, labeling, preparation for transport, sampling and testing of the Product, Materials and intermediates, receipt of Materials, as well as related Product in-process control, quality control testing, quality assurance and certification activities or the generation of stability data of Product.
- (38) “Materials” means any components, excipients and materials used for Manufacture and supply of Product, including but not limited to Sourced Materials.
- (39) “Maximum Quantity” has the meaning set forth in Section 2(4)(h).
- (40) “Minimum Quantity” has the meaning set forth in Section 2(4)(h).
- (41) “Non-conforming Product” means Product not Manufactured in accordance with the Process Specifications, subject to Section 5(2).
- (42) “Omitted Product Quantity” has the meaning set forth in Section 2(4)(g).
- (43) “Party” and “Parties” have the respective meaning set forth in the preamble.
- (44) “Preferred Subcontractor” has the meaning set forth in Section 2(3).
- (45) “Preferred Supplier” has the meaning set forth in Section 3(1)(b).
- (46) “Prices” has the meaning set forth in Annex 1.
- (47) “Process Specifications” means the mutually agreed Manufacturing process specifications, generated by Vetter Pharma as contemplated in the Quality Agreement, and agreed upon for the

Manufacture of the Product, that define and detail all Manufacturing, Service or Regulatory Services activities performed at the Facility, including all criteria applicable to the Sourced Materials and instructions agreed to be relevant for such Manufacture, but not including any additional Product acceptance and release requirements.

- (48) “Product” has the meaning set forth in the Quality Agreement.
- (49) “Product Costs” has the meaning set forth in Section 8(2)(i).
- (50) “Purchase Order” means a purchase order issued by Valneva specifying the quantity of Product ordered or a specific service and the required Delivery Date.
- (51) “Quality Agreement” means the quality agreement entered into by and between Valneva and Vetter Pharma with respect to the Services performed and/or the Product Manufactured under this Agreement, to be attached as Annex 4 hereto. The Quality Agreement may be modified from time to time by mutual written agreement. Once executed by Valneva and Vetter Pharma, the Quality Agreement shall be incorporated into and made part of this Agreement by this reference.
- (52) “Recall” has the meaning set forth in Section 11(6).
- (53) “Regulatory Approval” means any approval, consent, notice or permission required from (or, in the case of a notice, given to) a regulatory authority in order to comply with applicable Legal Requirements, including for purposes of Manufacturing, performance of Services, marketing, importing, exporting, testing, distributing, selling or otherwise using the Product.
- (54) “Regulatory Filing” has the meaning set forth in the Quality Agreement.
- (55) “Regulatory Services” means providing Valneva with the CTD of Product.
- (56) “Replacement Product” has the meaning set forth in Section 5(4).
- (57) “Representatives” has the meaning set forth in Section 12(2).
- (58) “Rolling Forecast” has the meaning set forth in Section 2(4)(b).
- (59) “Rules” means the Rules of Arbitration of the German Institute for Arbitration (Deutsche Institution für Schiedsgerichtsbarkeit e.V. [DIS]).
- (60) “Section” means any subsection of an Article.
- (61) “Semi-Binding Period” has the meaning set forth in Section 2(4)(c).
- (62) “Services” has the meaning set forth in Section 2(1).
- (63) “SKU” means the stock keeping unit of filled Product as set forth in Section 2(4)(b).
- (64) “SOPs” means such standard operating procedures of Vetter Pharma as are applicable to the Services under this Agreement.
- (65) “Sourced Materials” means any of the Materials, that under this Agreement, are sourced or procured by Vetter or its Affiliates from Preferred Suppliers on behalf of Valneva or at the direction of Valneva (which direction is deemed to be provided by Valneva signing off on the Process Specifications), as further determined in the Quality Agreement, provided for in the Process Specifications and/or agreed upon in writing.
- (66) “Sourced Services” has the meaning set forth in Section 2(3).
- (67) “Term” has the meaning set forth in Section 9(1).
- (68) “Territory” means all countries under the jurisdiction of the FDA and/or the European Commission (EMA). Subject to mutual agreement by and between the Parties and subject to the provisions of Section 6(4), the Territory may be expanded.
- (69) “Valneva” has the meaning set forth in the preamble.

- (70) “Valneva Indemnites” means Valneva, any of Valneva’s Affiliates, and their respective officers, directors, agents and employees.
- (71) “Valneva Product Information” has the meaning set forth in the Quality Agreement.
- (72) “Vetter” has the meaning set forth in the preamble.
- (73) “Vetter Competitor” means [***].
- (74) “Vetter Indemnites” means Vetter and any of its Affiliates, Vetter Subcontractors and any of their trustees and/or executors, and their respective officers, directors, agents and employees.
- (75) “Vetter Maximum Liability Cap” means [***].
- (76) “Vetter Pharma” means Vetter Pharma-Fertigung GmbH & Co. KG, an Affiliate of Vetter that is duly organized and existing under the laws of Germany and has its principal place of business at Schützenstraße 87, 88212 Ravensburg, Germany.
- (77) [***].
- (78) “Vetter Subcontractor” has the meaning set forth in Section 2(3).

ARTICLE 2 : SERVICES.

- (1) *Performance of Services.* Vetter shall cause Vetter Pharma to (i) perform the Manufacture, and provide the respective Batch Document Package, pursuant to the Process Specifications; (ii) provide Regulatory Services (as further determined in Article 6); and (iii) subject to written agreement by Valneva and Vetter provide certain services for Valneva related to the Manufacture of Products and other, accompanying services (each, a “Service”), all such Manufacture, Regulatory Services, and Services as specified in this Agreement and Annex 1, and subject to the terms of this Agreement, and, if the Services and/or Regulatory Services are to be performed in accordance with GMP, those of the Quality Agreement executed between Vetter Pharma and Valneva that addresses all of the Parties’ respective technical responsibilities for GMP Manufacturing and quality of the Product. Except as otherwise agreed to in writing by Valneva, all Manufacture, Services and Regulatory Services will be performed at the Facilities.
- (2) *Process Specifications.* The Manufacturing process for the Product complies with current specifications on the Effective Date, and has been successfully validated in accordance with GMP (if applicable), and finally approved by Valneva. Valneva and Vetter shall agree in writing to the final Process Specifications for performance of any Services under this Agreement, and written documentation of such Process Specifications shall be attached to or referenced in the Quality Agreement and incorporated therein by reference. Valneva shall ensure that the Process Specifications comply with the Regulatory Approvals, Regulatory Filings and any applicable Legal Requirements. If the Valneva requires Vetter to adhere to any additional good manufacturing practices of countries outside the Territory or any requirements coming from Valneva Legal Requirements, Regulatory Approvals, Regulatory Filings or any Product-specific GMP (either thereof “Additional Requirements”), any such Additional Requirements may be, after Vetter review and by mutual prior written agreement of the Parties (including on regulatory, technical, commercial, quality and/or certain other provisions and documents applicable to such Products) be incorporated into the agreed Process Specifications. Valneva shall provide Vetter Pharma with, included in any such request of Additional Requirements, the country-specific legislation, rules and regulations and practices or requirements of the regulatory authorities and governmental bodies, which may affect the Services (including the set-up, content and use of the CTD), the Manufacture and/or any Assistance, and shall inform Vetter of the effect of any thereof. Valneva shall keep Vetter informed of any changes of any thereof after the Effective Date and shall meet all notice and information requirements as set forth in the Quality Agreement. Valneva shall also provide Vetter with all information reasonably necessary for the performance of the Services and any technical support reasonably requested by Vetter in connection with the same. Vetter shall keep Valneva informed of Vetter’s positive knowledge, if any, of any specific legislation, rules and regulations and practices or requirements of the generally applicable regulatory requirements of German authorities, EMA and FDA, which may affect the set-up, content and use of the CTD, and shall inform Valneva of the effect thereof known to Vetter.

- (3) *Subcontracting and Delegation.* Vetter may, subject to Valneva's prior written consent - such consent not to be unreasonably withheld - , delegate its responsibilities under this Agreement to any of its Affiliates, including Vetter Pharma (which is with regard to Vetter Pharma herewith provided). Furthermore, Vetter and Valneva may agree on the performance of certain Services (or part thereof) by third parties. If Vetter accepts to assist Valneva in receiving such Services by third parties, subject to Vetter's prior written consent in this Agreement and the Quality Agreement - such consent not to be unreasonably withheld - ("Sourced Services"), Vetter shall either (i) source any such Sourced Services from third party service providers mutually agreed upon by the Parties or approved by Valneva in the Quality Agreement or the Process Specifications ("Preferred Subcontractors"); or (ii) directly communicate to and manage such Preferred Subcontractors under Valneva contracts in the name and on behalf of Valneva. Third party service providers, including Preferred Subcontractors shall be approved by Valneva and listed in or attached to the Quality Agreement to the extent they are going to perform any GMP relevant activities. Valneva shall provide all information that is necessary and/or reasonably requested by Vetter and hereby provides the required power of attorney for Vetter and/or its Affiliates for the purpose of such assistance.

In addition, Valneva agrees and hereby consents that Vetter and its Affiliates might use own subcontractors for its internal logistic and warehousing operations (currently [***]) and second source laboratories for material qualification (each a "Vetter Subcontractor"). Vetter shall be and remain fully and solely responsible for performance or non-performance of any Vetter Affiliate and Vetter Subcontractors, subject to and to the extent set forth in this Agreement, including Article 11, whether under this Agreement or Quality Agreement, or under any other agreement or any theory of law. Valneva shall be and remain fully responsible for performance or non-performance of Valneva, its Affiliates and its Preferred Subcontractors, unless otherwise set forth in this Agreement.

- (4) *Forecasting.* The forecasting, ordering, scheduling and other related parameters of Manufacture of Product, shall be as specified below and set forth in Annex 2, provided however, the following shall apply:

(a) *Long Range Forecast.* Valneva shall provide its good faith estimate of the total Product demand for the next [***] and shall reflect therein each anticipated Product quantity [***] (hereinafter the "Long Range Forecast"). The Long Range Forecast shall be submitted to Vetter annually in writing by [***]. The Long Range Forecast is non-binding and only for mutual planning purposes. Significant forecast changes should be indicated to Vetter as soon as they are known to Valneva and need to be discussed together with its impact and Vetter will inform Valneva about potential measures to allow for such demand at Valneva's cost [***]. Based on the Long Range Forecast, Vetter will inform Valneva in writing [***] of each calendar year about Vetter's capacity for the [***] of the Long Range Forecast.

(b) *Rolling Forecast.* Valneva shall provide for each Product to be Manufactured by Vetter a [***] Rolling Forecast (hereinafter the "Rolling Forecast") and submit such Rolling Forecast to Vetter, initially no later than [***] before the first intended Product Manufacture, and thereafter, on or before [***] of each calendar month. The Rolling Forecast shall reflect the Product demand requested to be delivered in each calendar month, [***].

Each Rolling Forecast must therefore include the requested Product volume (in stock keeping units of filled Product, each a "SKU") per delivery month and volumes are to be routinely ordered in increments of [***] pre-filled syringes. The Product volumes presented in the initial Rolling Forecast and each monthly revised or updated Rolling Forecast are subject to Vetter's written approval. Any attempts by Valneva to engage in "rear-loading", "front loading" or other demand peaks, such as for Valneva stock building, have to be communicated to Vetter and is subject to Vetter's approval. In the event Vetter cannot accommodate the Rolling Forecast, the Parties will cooperate to draft an agreed upon Rolling Forecast.

Binding Period. Months [***] of each Rolling Forecast shall constitute a firm and binding commitment by Valneva and any Product demand volumes submitted for the first [***] months of each Rolling Forecast cannot be modified by Valneva or cancelled in any way without full compensation ("Binding Period").

(c) *Semi-Binding Period.* Months [***] of each Rolling Forecast are partly-binding ("Semi-Binding Period"), meaning that Valneva may adjust the Product volumes forecasted for such [***] period in accordance with the following limitations:

Rule 1: The aggregate Product volumes set out in all monthly Rolling Forecasts in a calendar year may not deviate by more than [***] (SKUs) from the Annual Reference Quantity (as defined below) for such calendar year.

Rule 2: Product volumes set out in any revised monthly Rolling Forecast may not deviate by more than [***] (SKUs) from the previous Rolling Forecast submitted by Valneva for the Semi-Binding Period.

The amount of SKUs will be rounded-off pursuant to common rounding to whole batch numbers (integers), provided however, if the variance of SKUs is between [***] batches Valneva will be granted a minimum flexibility of one full Product batch.

[***]

(d) *Annual Reference Quantity.* The Parties hereby agree on an “Annual Reference Quantity” for each calendar year, covering January through December of such year, to allow for precise capacity planning. The Rolling Forecast of [***] shall represent the Annual Reference Quantity (= aggregate Valneva Product demand for months January to December) of the following year.

[***]

Within [***] Business Days of receipt of the Rolling Forecast, Vetter will inform Valneva in writing about Vetter’s capacity for the full [***] of the Rolling Forecast.

(e) *Capacity Agreement.* The Parties may agree to have certain Facility capacity reserved for Manufacture of Product for certain years (“Capacity Agreement”), especially if the capacity on a certain line or cleanroom is scarce or the Valneva Product demand is considered high as may be indicated by the Long Range Forecast.

(f) *Ordering.* Valneva is required to issue firm, binding Purchase Orders with Vetter at least [***] months prior to the requested Delivery Date. Vetter will send during the month following the receipt of such Purchase Order a written confirmation with respect to Product volumes which can be Manufactured and will notify Valneva of the Delivery Date no later than [***] ahead of the scheduled delivery.

(g) *Annual Reconciliation, Compensation.* The Parties will in December of each year jointly review and compare if Valneva ordered and paid for all of its Product commitments under this Agreement.

In the event that any such review reveals that Valneva has failed to provide Purchase Orders or has failed to pay for binding commitments of the Rolling Forecast and/or the Capacity Agreement in the applicable calendar year, has reduced its Product demand other than allowed under this Agreement and/or has cancelled at any time Purchase Orders, then Valneva shall compensate Vetter for each Omitted Product Quantity (“Omitted Product Quantity”) as follows:

[***]

Valneva shall pay the compensation as determined hereunder for the respective calendar year within [***] of such joint review.

(h) *Minimum and Maximum Quantity.* Valneva shall order at least [***] of the Annual Reference Quantity (“Minimum Quantity”) and may order up to [***] of the Annual Reference Quantity (“Maximum Quantity”), subject to Vetter’s written approval. However, Valneva hereby acknowledges and agrees that the Maximum Quantity in each calendar year may not exceed a total of [***] batches without Vetter’s consent. To the extent that quantities ordered in any Purchase Order exceed the quantities forecasted (i) for the Binding Period; or (ii) for the Semi-Binding Period by more than [***]; or (iii) the Maximum Quantity (individually and collectively “Additional Quantity”), such Purchase Order shall be considered a binding commitment of Valneva to pay for the Product quantity reflected in the Purchase Order and Vetter shall respond to Valneva if such Additional Quantity can be supplied, subject to the Facility’s manufacturing and equipment capacities and other supply commitments, provided, however, that Vetter’s failure to supply any such Additional Quantity (or part thereof) shall not constitute a breach of this Agreement by Vetter. Vetter’s acceptance to deliver Additional Quantities set out in an individual Purchase Order shall in no event (i) oblige Vetter to accept Additional Quantities in future Purchase Orders; nor (ii) be construed as acceptance by Vetter of quantity increases in future Rolling Forecasts or increased Maximum Quantities. Furthermore, it is agreed and understood by the Parties that any Additional Quantity will not be considered as Annual Ordered Quantity (as defined below) and not included therein during the annual reconciliation review by the Parties and will not be credited against the Minimum Quantity.

(i) *Service and batch size.* This Rolling Forecast model is designed for filling Services of a Product batch size of [***] prefilled syringes per Product batch as specified in the Agreement and the Parties hereby agree that Valneva shall order and forecast full Product batches. If the amount of Conforming Product available for delivery of a given batch is determined to be below [***] prefilled syringes, Vetter will proactively contact and consult with Valneva to determine if e.g. the production of an additional batch or earlier production of subsequent batches is required to fulfill the volume requirements of Valneva.

If after alignment with Vetter other Services (e.g. secondary packaging) or batch sizes are forecasted or ordered, this Rolling Forecast model shall be adjusted accordingly, including pricing.

(j) *Japan quality.* The Rolling Forecast model set forth in this Section 2(4) shall not cover any Product intended by Valneva for distribution or use, or both, in the Japanese market. In the event, Valneva requests Product to be distributed in Japan, the Parties shall amend this Section 2(4) to include supply chain terms that provide for adequate capacity reservation and adjust specifications, pricing and include other terms as required.

(l) *Scheduling of Manufacture.* Based on the information provided in the Rolling Forecast, Vetter will schedule the Manufacture. Scheduling will not be communicated to Valneva. Vetter will try to prioritize Purchase Orders with critical shelf-life, and Valneva allows Vetter to advance order requests for Manufacture, up to a maximum of [***] in addition to the required cycle time, to build manufacturing campaigns and most efficiently use available capacity for all of its customers. Consideration will be taken to ensure that the Remaining Shelf-Life as defined under Section 4(2) is upheld.

ARTICLE 3 : MATERIALS.

(1) *Supply of Materials.*

(a) Vetter shall Manufacture the Product in the quantities and according to the confirmed delivery dates and routinely deliver to Valneva not less than [***] vials per Batch considered the standard Batch Size. Material allocated towards Valneva's Purchase Orders will only be fulfilled in standard Batch Size quantities of [***] vials as reflected in requested quantities of Valneva's Purchase Orders. Planned deviations from this standard Batch Size are subject to the Parties' written agreement.

(b) *Sourced Materials.* Vetter shall procure or cause to procure the Sourced Materials for use in the Manufacture in accordance with this Agreement and the Quality Agreement or otherwise directed or approved by Valneva (which direction or approval is deemed to be provided by Valneva signing off on the Process Specifications). If Vetter and Valneva make alternative arrangements for sourcing of Materials to be directly supplied by third parties to Vetter, and if Vetter agrees to assist Valneva in such sourcing of Sourced Materials and as provided for in Annex 1 or otherwise agreed upon in writing, Vetter shall (i) order any such Sourced Materials directly from third party suppliers mutually agreed upon, in the Quality Agreement or otherwise directed or approved by Valneva (which direction or approval is deemed to be provided by Valneva signing off on the Process Specifications) ("Preferred Supplier"), or (ii) call off and take delivery of such Sourced Materials under Valneva contracts with such Preferred Supplier, in each case in quantities and with lead times appropriate to maintain an Inventory as provided for in Annex 1. Valneva shall provide all information that is necessary and/or reasonably requested by Vetter, complete associated Vetter request form and hereby provides the required power of attorney for Vetter and/or its Affiliates for the purpose of such sourcing assistance.

(2) *Inadequate Delivery.* Any inadequate delivery of Materials (whether such inadequacy is one of quality, quantity, missing documents or otherwise) may result in delays in the Manufacture of the Product and the postponement of any associated Delivery Date. In the event of such inadequate delivery, Vetter shall be permitted, in its sole discretion, to reasonably reschedule the Manufacture and determine a new Delivery Date, following good faith consultation with Valneva. Vetter shall use commercially reasonable efforts to ensure that the new Delivery Date is no later than the earlier of the following: [***]. Any such postponement of Manufacture due to inadequate delivery of Valneva and Sourced Materials shall be deemed a cancellation of Manufacture under the respective Purchase Order, for which Vetter shall be compensated as set forth in Section 2(4)(g) and Annex 1, if not solely caused by Vetter.

- (3) *Testing of Materials.* Prior to use by Vetter in performance of the Services, all Materials used for the Manufacture, shall be tested in accordance with the Process Specifications or, in the absence of specific testing requirements, with the SOPs, including an incoming inspection upon delivery to verify correct quantity and labeling and visual inspection to identify obvious defects due to transport. With respect to the quality and the condition of any Materials used in the Services, Vetter may rely on the accuracy of any certificates and information provided for such Materials. Other than set forth in this Agreement, Vetter shall have no obligation to undertake any quality assurance or other activity with regard to Materials, including any additional testing or certification of the same, and Vetter shall not be liable for any defects in the Materials which have not been established or are not determined by Vetter performing its testing Services hereunder.
- (4) *Inventory.* Based on the Binding Period or the Rolling Forecast (or, to the extent commercially practicable, on any updates), Vetter may have placed, in accordance with its customary business practices, binding orders for Materials for the Products not supplied by Valneva. Valneva is hereby informed and accepts that for some Materials there are minimum order requirements (e.g. because of long lead-time or minimum batch sizes) and Vetter will have to order Material quantities that exceed the demand required for the Binding Period or the Rolling Forecast. In addition, Vetter will maintain a stock of Sourced Materials at [***] ahead for Delivery Date of confirmed orders in accordance with Section 1(4) and Annex 2, but no less than the quantity required for the Manufacture of [***] (all Materials ordered in accordance with any of the foregoing collectively hereinafter the “Inventory”) at any time. To the extent such Inventory is ordered in accordance with the foregoing, Valneva shall be responsible and liable for any related costs incurred by Vetter and/or any of its Affiliates, including, but not limited to, related to storage and disposal of and staff planning and working capital costs for any excess and/or obsolete Inventory, not being fit for use due to (a) reduced Rolling Forecast or capacity reservation; (b) cancellation or postponement of any Purchase Orders; (c) changes to the Process Specifications or the specifications of Material, including to Legal Requirements; or (d) expiry or termination of this Agreement) provided that, in any case, despite Vetter’s best efforts the Inventory cannot be used for other products or customers and Vetter provides reasonably detailed written evidence thereof. If requested, Valneva shall provide Vetter with a written authorization to purchase any Inventory. Vetter may request (a) to retain a higher Inventory volume against down payment by Valneva, or (b) if feasible, will ask Preferred Suppliers for their Assistance to keep an additional rolling safety consignment stock available at Valneva’s risk and cost, if Vetter’s expenditures for Inventory are significant due to Valneva’s Product demand.

ARTICLE 4 : PRODUCT DELIVERY.

- (1) [***]. Any Product to be delivered by Vetter shall be delivered [***]. Vetter shall provide Valneva with reasonable advance notice of the Delivery Date, [***] and Valneva shall arrange for Product pick up and shipment on such date. In the event that Vetter or its Affiliates or subcontractors or external service providers give incidental support or Assistance to Valneva, in a manner or extent exceeding Vetter’s obligations set forth in the preceding sentence, such support or Assistance shall be made on behalf of Valneva (and not of Vetter) and Valneva shall remain fully liable and responsible for the same. Any major support or Assistance by Vetter shall be separately agreed upon in writing. Valneva shall, at Vetter’s request, provide information required for taxation or reporting purposes in respect of export of the Product.
- (2) *Remaining Shelf-Life* means, with respect to Product ordered by Valneva and delivered by Vetter, the period of time from the Delivery Date until the expiration date of such Product consistent with the shelf-life approved by the relevant regulatory authority.

For the Product the Parties agree a Remaining Shelf-Life of at least [***]. During the Term of the Agreement, the Parties may adjust the agreed Remaining Shelf-Life, as appropriate. If a delay is solely caused by Vetter which results in the Remaining Shelf-Life being less than [***], Valneva shall be under no obligation to accept any Delivery of Product where the Remaining Shelf-Life requirement is not met.

- (3) *Late Pick-Up.* Unless otherwise agreed between the Parties, if Product is not collected by Valneva on the Delivery Date, Vetter shall store such Product at the Facility at Valneva’s risk and in accordance with the SOPs. For Products not collected within [***] of the Delivery Date, Valneva shall pay to Vetter such compensation of storage as set forth in Annex 1, unless Valneva has declined to collect the Product based on a claim of Non-conforming Product accepted by Vetter or substantiated by an independent laboratory as provided for by Section 5(3).

- (4) *Quarantine Shipment.* Product not yet released to Valneva by Vetter may be shipped under quarantine upon prior written request of Valneva and Valneva by such request assumes all risks, responsibilities and costs associated with the quarantine shipment.
- (5) *Late Delivery.* Vetter will use commercially reasonable efforts to deliver Product on the Delivery Date. Vetter shall promptly inform Valneva as soon as Vetter becomes aware that it will not be able to meet the Delivery Date. Vetter shall provide Valneva, to the extent known, reasonable and subject to Vetter's other contractual and statutory obligations, with details regarding the reason for the delay and the efforts that Vetter has made and will make to deliver the Product as soon as possible by using commercially reasonable efforts. [***]

ARTICLE 5 : NON-CONFORMING PRODUCT, INSPECTION, REPLACEMENT.

- (1) *General.* Vetter shall promptly inform Valneva of any Non-conforming Product discovered during or after Manufacture, and launch an investigation subject to the Quality Agreement and its SOPs. Vetter shall have the discretion to withhold the release of any Product pending the resolution of any potential quality issues. Product that is affected by deviation (of which Valneva shall be notified in writing in accordance with the Quality Agreement) shall not be deemed Non-conforming Product so long as any such deviation has been processed in accordance with the Quality Agreement and does not materially affect the quality of the Product.
- (2) *Inspection.* Valneva shall without undue delay perform or have performed an inspection and testing of Product received, and conduct a review and approval of associated Batch Document Package, all as required by Legal Requirements (including GMP) and as necessary for the intended purpose but in no event later than [***] following delivery of each ("Inspection"). Valneva shall notify Vetter in writing upon discovery of any Product or any part of a shipment of Product to Valneva or its designee or of the associated batch documentation alleged to be Non-conforming, and/or of its rejection of Product based upon defect, such notice to be provided within [***] of delivery ("Defect Notification Period"), provided, however, that such Defect Notification Period shall be (i) reduced to [***] if Valneva is rejecting such shipment due to transport or obvious external physical damage or quantity discrepancies that are, or would be, evident upon reasonable visual inspection of such packaged Product; and (ii) extended to [***] following the Delivery Date if Valneva's rejection is based upon a latent defect, that is, defect of a Product that cannot be detected or would not be evident upon reasonable Inspection (in which case Valneva must provide notification immediately upon discovery of such latent defect). Any notification by Valneva of a Non-conforming Product must include a detailed explanation of the alleged defect. In the event Valneva's notice of Non-conforming Product is not timely delivered as provided hereunder, the Product in question shall be conclusively presumed satisfactory and deemed accepted by Valneva.
- (3) *Investigation, Dispute.* Vetter shall have the right to investigate any alleged Non-conforming Product. If, during any calendar quarter, [***] batches are rejected by Valneva, Vetter shall notify Valneva and, upon receipt of such notification by Valneva, the Parties shall meet to discuss, evaluate and analyze the reasons for and implications of the failure of the Manufacture to meet the Process Specifications and the rejection by Valneva. Pending the same, Vetter shall have the right to cease all Manufacturing and not be deemed in default or breach under this Agreement, with all scheduled or other Manufacture not to recommence until such time as final disposition of the rejected batches has been decided upon, and complete investigations (with root cause analysis and corrective action to prevent further batch rejections) have been finalized, which disposition, analysis and corrective action shall be agreed to in writing by the Parties. Vetter shall perform or have performed such investigation, root cause analysis and any corrective action diligently and expeditiously. Prior to the completion thereof, Valneva may request in writing the recommencement of Manufacture, subject to Valneva's assumption of responsibility in the event of further batch rejection for the same or similar reasons. If the Parties disagree as to final disposition, analysis or corrective action, and, if Vetter disagrees with Valneva's determination, the Parties shall attempt to resolve such disagreement through direct management discussions, failing of which the Parties shall appoint a mutually agreed-upon, independent pharmaceutical laboratory in the European Union to evaluate and determine whether the Product's Manufacture was in accordance with the Process Specifications as of the Delivery Date. The laboratory's determination thereof shall be binding upon both Parties as to the facts evaluated, and the laboratory's charges and related expenses shall be borne by the Party against whom the determination is made.

- (4) *Replacement.* In the event that (i) Vetter agrees that Product is Non-conforming Product; or (ii) Product is determined to be Non-conforming Product pursuant to Section 5(3), and provided that Valneva has given Vetter timely notice of defect in accordance with Section 5(2), Vetter shall reimburse Valneva by issuing a credit of the amount paid for the Non-conforming Product or replace any Non-conforming Product with Conforming Product ("Replacement Product"). Vetter shall use commercially reasonable efforts to deliver to Valneva such Replacement Product [***]. If the Non-conforming Product has been caused by the negligence of Vetter, Vetter Affiliates or Vetter Subcontractors, any such Manufacture of Replacement Product, including the Batch Documentation Package, will be rendered at the cost and expense of Vetter and without additional charge to Valneva, and in this event Vetter shall be liable, whether for itself and/or any of its Affiliates and/or any Vetter Subcontractors, for any related loss of Materials, and shall arrange for return or disposal of the rejected Non-conforming Product, and supply of Replacement Product, all at the cost and expense of Vetter (but subject to the limitations of Article 11, including Section 11(5)).

ARTICLE 6 : REGULATORY SERVICES.

- (1) *Regulatory Services; Document Update.* Vetter shall cause Vetter Pharma to assist Valneva in preparing its regulatory filings with regard to the Product in any country of the Territory (and Expanded Territory, as the case may be) by providing Regulatory Services, all in accordance with the provisions of this Agreement, the Process Specifications and the Quality Agreement. Valneva shall have the right to use the CTD (or part and/or updates thereof), including all stability data as set forth in the Quality Agreement, in its regulatory submission for Product. Valneva shall pay for any updates of the CTD pursuant to Annex 1 of this Agreement.
- (2) *Information.* Valneva shall keep Vetter informed of any specific legislation, rules and regulations and practices or requirements of the regulatory authorities and governmental bodies within the Territory (other than the generally applicable regulatory requirements of German authorities, EMA and FDA) and Expanded Territory, as the case may be, which may affect the setup, content and use of the CTD and shall inform Vetter of the effect of any thereof. Vetter shall be responsible for compliance of the CTD with the applicable general requirements of the EMA, the FDA and German authorities, as the case may be.
- (3) *Contact with Governmental and Regulatory Bodies, Communication.* Valneva shall be solely responsible for all documentation, submission and communication with governmental, health and regulatory authorities or agencies with respect to all matters relating to the Product and the Regulatory Approvals, and shall keep the documentation submitted to such governmental and regulatory bodies updated as required by law, applicable regulation and regulatory practices (with copies to the regulatory affairs department of Vetter Pharma). Neither Vetter nor any of its Representatives shall have any obligation to directly contact or communicate with any such governmental, health and regulatory bodies regarding the Product unless required by GMP. In such case Vetter shall promptly notify Valneva and provide a copy of Vetter's communications with governmental, health and regulatory authorities or agencies relating to the Product.
- (4) *Territory.* Valneva shall at its own discretion, register or file the Product in the Territory and shall therefore use the CTD, including all stability data set forth or referred to in the Quality Agreement. In amplification of the foregoing, it is understood that Valneva shall neither sell, nor distribute nor otherwise use, whether directly or indirectly, the Product outside of the Territory and Expanded Territory, as the case may be. Subject to the provisions of Section 2(2), the Territory may be expanded by countries outside the Territory ("Expanded Territory"), and any such countries of an Expanded Territory shall be listed in and/or added to Annex 3, as the case may be.
- (5) *Regulatory Assistance.* Any regulatory Assistance consisting of services other than the Regulatory Services set forth in Section 6(1) and/or any additional support, including but not limited to regulatory services and/or any document adaptations required for an Expanded Territory, or any other activity regarding requests or enquiries by governmental, health and regulatory authorities or agencies of the Territory or an Expanded Territory and/or of Valneva, as the case may be, shall separately agreed upon in writing, especially with regard to regulatory, technical, commercial, quality and/or certain further particular provisions and will be charged separately. Any request for any such regulatory Assistance shall include complete instructions and any other information that is reasonably necessary for Vetter to evaluate required regulatory Assistance, calculate costs and provide Valneva with an offer for such regulatory Assistance.

- (6) *Confidentiality.* All information, materials, documents, and data provided by Vetter and/or any of its Affiliates to Valneva with respect to Regulatory Services, regulatory Assistance, document updates or in support of the preparation, completion or updating to the Regulatory Filings of Valneva, including the CTD shall be deemed to be proprietary Confidential Information of Vetter and/or its Affiliates. Valneva shall have the right to disclose Confidential Information to the regulatory authorities in the Territory (and Expanded Territory as the case may be) to the extent needed for, and solely for the purpose of its Regulatory Filing of the Products, on a need to know basis upon prior written notification of Vetter. Vetter and/or its Affiliates shall continue to own and shall retain all title and interest in and to the Product and to all Confidential Information provided and related therewith.

ARTICLE 7 : REGULATORY FILINGS, INSPECTIONS AND CHANGES.

- (1) *Product Approval.* Valneva shall ensure all Regulatory Filings and obtain and maintain, at its own cost and risk, all Regulatory Approvals needed for the Product, the Services which are particular to the Product and/or required in accordance with the Legal Requirements. Valneva shall not distribute or otherwise use the Product without first securing such Regulatory Approvals. Vetter shall cooperate and make every commercially reasonable effort, at the cost and/or expense of Valneva, to provide such information and other Assistance as Valneva may reasonably request in connection with such Regulatory Filings and Regulatory Approvals, all in accordance with and subject to the terms of the Quality Agreement. If approvals by regulatory authorities are needed for the Manufacture (other than set forth in Section 7(2)), all risks, costs and/or expenses thereof shall be borne by Valneva and neither Vetter nor any of its Affiliates shall pay for or warrant such approvals.
- (2) *Facility Approval.* Vetter has caused and shall cause Vetter Pharma to obtain and maintain, with respect to the Facility, any necessary manufacturing authorization(s) issued by the applicable German health authority and, upon written request of Valneva, Vetter shall make available a copy of such authorization(s).
- (3) *Inspections and Audits.* Any costs and/or expenses associated with any inspections or audits performed by Valneva or third party auditors engaged by Valneva and by any regulatory authority with respect to the Services and/or the Product shall be borne by Valneva, except for costs incurred from inspections by the German health authorities, FDA and/or EMA directly and solely associated with the CTD, which shall be borne by Vetter (excluding Valneva costs and expenses, as the case may be). Valneva shall ensure that Valneva annual GMP inspections shall not exceed two (2) Business Days with no more than two sub-groups of inspectors or auditors, that inspectors and auditors are bound by confidentiality and non-use obligations similar to those agreed hereunder and shall follow all procedures, instructions and SOPs applicable at the Facility, all to the extent and subject to the terms of the Quality Agreement.
- (4) *Change Control, Costs.* Any changes to the agreed-upon process of Manufacture or the Process Specifications hereunder shall be carried out in accordance with this Section and the change control procedures set forth in the Quality Agreement, if applicable. The Parties agree that:
- (i) for changes that arise from a regulatory requirements of the EMA and/or the FDA that is generally applicable to Vetter or that is directly and solely associated with the CTD, and subject to the remaining provisions of this Section 7(4) and those of Section 8(2) below, Vetter shall implement such changes (except to the extent commercially unreasonable or in conflict with the business operation of the Facility), and Vetter shall bear all reasonable costs and/or expenses directly related thereto; and
 - (ii) for any other changes not described in subsection (iii) hereof, for changes related to Product, Materials, Facility or any Manufacturing process that arise from Legal Requirements (including Product-specific GMP), and for changes made at the discretion or based upon the preference of Valneva, Vetter shall implement such changes as are mutually agreed upon (except to the extent commercially unreasonable or in conflict with the business operation of the Facility), and Valneva shall bear all reasonable costs related thereto; and
 - (iii) the Parties will during the Term adhere to the change control procedures set forth herein and in the Quality Agreement; provided, however, that in the event that in any year no Product batch is Manufactured under this Agreement, Vetter and its Affiliates may cease the change control procedures, and Vetter will notify Valneva thereof.

- (5) *Disputes.* With respect to any changes, Vetter and Valneva shall mutually agree on their respective obligations and the allocation of associated costs (consistent with the above) and on any necessary or desired amendments to this Agreement. In the event of a dispute regarding a change, Valneva and Vetter shall discuss in good faith how to proceed, provided, however, that Vetter shall not be required to (i) to accept or cause Vetter Pharma to accept any changes with regard to or having impact on the Product Specifications and/or the CTD; and (ii) to continue or cause Vetter Pharma to continue the Manufacture of the Product (which Manufacture may be immediately ceased without it being deemed a breach of this Agreement) if Vetter believes that a course of action urged by Valneva, whether calling for incorporation or non-incorporation of a change, constitutes a violation of any Legal Requirement. If Vetter reasonably believes such course of action does not constitute a possible violation as set forth in the preceding sentence, but creates an increased risk that Vetter and/or any of its Affiliates is or could be held responsible or liable under a third-party claim, then upon Valneva's request Vetter shall cause Vetter Pharma to continue the Manufacture of the Product and to take such course of action, and Valneva shall indemnify, defend and hold Vetter and/or any of its Vetter Indemnitees harmless from and against any and all Costs resulting from or arising out of such course of action.

ARTICLE 8 : PRICES, INVOICES, PAYMENTS AND ADJUSTMENTS.

- (1) *Prices, Invoices.* Vetter's charges for the Services shall be the Prices set forth in Annex 1, plus any taxes (including, but not limited to, value added tax), customs, fees and other duties, if and to the extent applicable. Vetter will invoice upon (i) rendering a Service; and (ii) delivery of Product (including CoA or CoC, as agreed in the QA); and (iii) as further set forth in Annex 1; or (iv) if not contained in Annex 1, as defined in a respective quotation by Vetter and agreed upon by Valneva. Services rendered are generally invoiced in full upon completion of the Services. Since Vetter provides its Manufacturing Services in certain stages, Vetter shall be allowed to invoice Valneva also for any Manufacturing Service fully rendered to Valneva, of which ownership and control of the in-process Product has passed to Valneva, and for which payment by Valneva is due. A Manufacturing Service is deemed to be fully rendered upon successful release of the in-process Product for further manufacturing (next process step), following a successful in process control (in accordance with SOPs) and provided that such in process control revealed that there is no critical Deviation. Any Assistance shall be separately agreed upon and either incorporated into the Product Prices or separately invoiced. [***]. Payments by Valneva shall not be deemed to have been made until Vetter has received such payment. If Vetter receives payment later than [***] of invoice date, Vetter may [***]. With respect to payments due for Product as to which Valneva has initiated in good faith an investigation or dispute under Section 5(3), Valneva's withholding of payment shall not be considered a breach during the pendency of such investigation or dispute, provided, however, that if such investigation demonstrates no Non-conforming Product or failure by Vetter, or Valneva does not prevail in such dispute [***]. Any payments shall be made without any reduction, set-off or counterclaim.
- (2) *Price Adjustments, Disputes.* [***] Vetter may adjust its Prices as follows:
- (i) In the event of increases in the cost of (a) the Product; or (b) the Services as arising from general changes to Vetter's cost structure including, but not limited to, Materials supplied or Services provided by any third party, wages, insurance, energy costs and other associated costs and expenses affecting Vetter and/or any of its Affiliates (collectively, "Product Costs"), Vetter shall be permitted to adjust its Prices as a matter of right and without justification, provided, that the percentage increase of any such adjustment shall not exceed [***] of the Price (including Product unit price and other Service fee) agreed for the period preceding the effective date of such Price increase. For a proposed adjustment in excess of such percentage, Vetter shall provide Valneva with reasonable evidence in support of such increase and the Parties shall negotiate in good faith regarding whether to include such excess in the adjustment.
 - (ii) In the event of increases in costs of Materials supplied or Services provided by any third party, Vetter shall be permitted to adjust its Prices accordingly, and any increases shall be borne by Valneva, provided, however, that Vetter shall provide reasonable evidence in support of such increase (such as, by way of non-limiting example, a written statement by such third party showing the increase).
 - (iii) In the event of changes to the Services including, but not limited to, changes in scope or Material, regulatory, GMP or Legal Requirements (including GMP), or of increased production or overhead costs which arise from changes pursuant to Section 7(4) above, Vetter

may reasonably request price adjustments, which shall be mutually agreed upon and set forth in an amendment to this Agreement.

- (3) Should a dispute arise regarding a price adjustment, the Parties shall discuss the same in good faith for a period of [***]. If the Parties cannot agree on a price adjustment within such period, they shall appoint an independent certified public accountant as mediator who shall review the Parties' respective proposals for the adjustment sought, evaluate the factual and methodological bases for the proposals, and recommend an appropriate price adjustment. The Parties shall ensure that such mediator (i) is bound to each Party by obligations of confidentiality equally restrictive to those referred to in this Agreement; (ii) has not been employed by either Party at any time during the ten (10) years prior to appointment hereunder; (iii) has professional experience in the pharmaceutical industry, preferably in the field of contract manufacturing (sterile pre-filling and the outsourcing thereof); and (iv) renders a recommendation within a further [***]. The Parties shall adopt the recommendation of the mediator, and all fees and expenses of the mediator and related proceedings shall be borne by the Party whose proposed price adjustment was furthest removed from that recommended by the mediator.

ARTICLE 9 : TERM, TERMINATION, CONSEQUENCES, SURVIVAL.

- (1) *Term and Termination of this Agreement.* The Term of this Agreement shall commence as of the Effective Date and shall continue for an initial period of five (5) full calendar years ("Initial Term") after the Effective Date, however, minimum until all Services under this Agreement (including all Manufacture called for in the most recent Rolling Forecast approved or accepted by Vetter) have been completed, unless this Agreement is earlier terminated in accordance with Section 9(2). Upon the expiration of the Initial Term and any subsequent term thereafter, this Agreement shall automatically be renewed for subsequent terms of [***] (Initial Term and any subsequent term collectively, the "Term"), unless a Party notifies the other Party [***] prior to the end of any Term in writing of its intention to not renew this Agreement.
- (2) This Agreement shall remain in full force and effect until the earliest of (i) its termination for breach under Section 9(3); or (ii) its special termination pursuant to Sections 9(4) or 9(5).
- (3) *Termination for Breach.* In the event of a material breach of this Agreement by a Party, the non-breaching Party may terminate this Agreement for cause by giving written notice of breach and termination to the breaching Party, such termination to take effect if the breaching Party has not cured such breach within [***] of its receipt of such notice.
- (4) *Special Termination by Vetter.* Vetter may terminate this Agreement if (i) Valneva is the subject of a Change of Control involving a Vetter Competitor – Vetter may exercise such termination right only within [***] of the notification to Vetter of such Change of Control event, or if (ii) in a dispute pursuant to Section 7(5) hereof the Parties fail to establish mutual agreement within [***]; or (iii) in a dispute pursuant to Section 8(3) hereof the Parties fail to establish mutual agreement in accordance with such Section within [***].
- (5) *Special Termination by Either Party.* Either Party may terminate this Agreement by written notice to the other Party and with immediate effect, if (i) the other Party makes a general assignment (novation) for the benefit of its creditors and not in accordance with Section 12(3); or (ii) proceedings are commenced in any court of competent jurisdiction by or against such Party (by any third party but not by the other Party) seeking (a) such Party's reorganization, liquidation, dissolution, arrangement or winding up, or the composition of readjustment of its debts; (b) the appointment of a receiver or trustee for or over such Party's property; or (c) similar relief in respect of such Party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, wherein any such proceedings continue undismissed, or an order with respect to any of the foregoing is entered and continues unabated, for a period of more than [***].
- (6) *Consequences.* Upon termination of this Agreement, neither Vetter nor Valneva shall have any further obligations (exceeding this Section 9(6)) thereunder except that (i) Vetter shall terminate the Services in progress in an orderly manner as soon as practicable and in accordance with a schedule set forth by Vetter and provided to Valneva; (ii) Vetter shall deliver to Valneva or dispose of, at Valneva's option and expense, any Sourced Materials in its possession or control dedicated for Manufacture and all Product Manufactured up to the effective date of expiration or termination; (iii) Vetter shall invoice Valneva, and Valneva shall pay Vetter, for any amounts due and owed Vetter, at the effective date of expiration or termination, for Services and

Assistance performed and all expenses incurred (as specified in this Agreement); (v) Vetter shall, in its sole discretion, sell to Valneva, and Valneva shall purchase at the Prices herein provided, any Product for which Purchase Orders have been or are required to be placed at the time of expiration or termination in accordance with a then-current Rolling Forecast or capacity reservation and, at the purchase Prices thereof, any and all Inventory ordered as contemplated in or permitted under this Agreement; and (vi) each Party shall return to the other Party any and all documentation (including copies thereof) constituting Confidential Information of the other Party and/or any of its Affiliates, provided, however, that, subject to Section 12(2), a Party may retain such documentation (and Vetter may cause Vetter Pharma to retain such limited quantity of the Product, Sourced Materials, all sufficient for two (2) analyses) as may be necessary for proper record keeping (including Section 12(2)(ii)) in satisfaction of Legal Requirements. Valneva shall be responsible and liable to Vetter for any non-cancellable expenses incurred by Vetter related to, based upon or arising out of such expiry or termination, including for an orderly cessation of the Manufacture and any related activities, as well as such other amounts accruing prior to termination; provided, however, any and all expenditures scheduled under the Manufacture not actually made, due to such termination, shall be deducted from any of the foregoing amounts.

- (7) *Licenses.* Upon the effectiveness of termination of this Agreement, all licenses granted by Vetter and/or any of its Affiliates to Valneva under this Agreement or due to this Agreement shall automatically be deemed revoked unless expressly stated otherwise. However, for the avoidance of doubt, this shall not affect the Products already supplied and sold by Vetter to Valneva under this Agreement.
- (8) *Survival.* The following provisions of this Agreement shall survive termination and expiry hereof: Section 9(6) (Consequences), Article 10 (Intellectual Property), Article 11 (Indemnification, Liability and Limitations), Section 12(1) (Insurance), Section 12(2) (Confidentiality), and Sections 12(4) (Conflicts) through 12(18) (Governing Law).

ARTICLE 10 : INTELLECTUAL PROPERTY.

- (1) *Background IP.* Each Party and/or any of its Affiliates shall continue to own all of its Background IP and, except as herein provided, neither a Party nor any third party shall as a result of this Agreement acquire any right, title or interest in or to such Background IP.
- (2) *Developments.* Any Developments in respect of or related to the Manufacture and/or the Product (including but not limited to any production process and/or testing method) shall be owned by Vetter and/or its Affiliates, without any restrictions, including the right to assign, transfer and sublicense and Valneva shall be granted a non-exclusive license to said IP according to Section 10(3).
- (3) *Licenses.* Vetter hereby grants to Valneva a temporary (for the duration of this Agreement), royalty-free, fully paid up, non-exclusive license with respect to all Intellectual Property under Vetter's and/or its Affiliates ownership or control, which is used by Vetter and/or its Affiliates in performing activities and services under this Agreement, to file with regulatory authorities, distribute or otherwise use within the Territory (and Expanded Territory, as the case may be) the Product Manufactured by Vetter under this Agreement with the right to grant and authorize sublicenses solely to the extent needed for, and solely for the purpose to allow any third party to distribute or otherwise use within the Territory (and Expanded Territory, as the case may be) the Product Manufactured by Vetter for Valneva. Valneva shall ensure that any such third party shall fully comply with the terms of this Agreement and the Quality Agreement, it being agreed and understood that Valneva shall take full and unlimited liability for any such third Party.
- (4) *No Other Licenses.* Except as provided for in this Article 10, nothing in this Agreement shall be construed as a grant of license or covenant under, a waiver of rights in, or a transfer of ownership of, any Intellectual Property owned or controlled by a Party, either expressly or by implication.
- (5) *Trademark.* Any trademarks of Vetter and/or its Affiliates shall remain their respective property, as the case may be, and Valneva shall have the right to use such trademarks only in connection with the sale and distribution within the Territory (and Expanded Territory, as the case may be) of the Product Manufactured.

ARTICLE 11 : INDEMNIFICATION, LIABILITY AND LIMITATIONS.

- (1) *Indemnification of Valneva by Vetter.* Vetter shall indemnify and hold harmless and/or, upon Valneva's request, defend Valneva Indemnitees from and against any Costs that arise out of or result from (i) a third party claim that (a) any Manufacturing process owned by Vetter or its Affiliates, and used under this Agreement; or (b) the CTD, in both events (a) and (b) infringes a third Party's Intellectual Property under the patent or intellectual property laws of the United States and/or the European Union or any member state thereof; or (ii) third party product liability claim, producer liability claim or tort claim for personal injury, and in both events (i) and (ii) if and to the extent such Costs have been caused by negligent failure of a Vetter Indemnatee, and are not attributable in any way to Valneva Indemnitees or third parties. Any such Vetter indemnification obligation is subject to the limitations of this Article generally and reduced by any obligations of indemnification owed by Valneva pursuant to Section 11(2).
- (2) *Indemnification of Vetter by Valneva.* Valneva shall indemnify and hold harmless and/or, upon Vetter's request, defend Vetter Indemnitees from and against any Costs that arise out of or result from (i) any infringement of a third party's Intellectual Property in connection with any Sourced Materials, Intellectual Property and information or other deliverable received from or on behalf of Valneva and used by Vetter or Vetter Indemnitees under this Agreement and/or the Product; (ii) the negligence or willful misconduct of a Valneva Indemnatee; (iii) any actions undertaken by a Vetter Indemnatee in compliance with this Agreement hereunder, the Process Specifications, Valneva Product Information and/or a direction by or on behalf of a Valneva Indemnatee or Valneva designee; (iv) any use of Materials supplied or approved by a Valneva Indemnatee and/or use of any information or other deliverable received by or on behalf of Valneva; (v) any breach by a Valneva Indemnatee of this Agreement; (vi) the distribution, sale or use of a Product; (vii) the use of the CTD; or (viii) any Assistance rendered. Any such Valneva indemnification obligation is subject to the limitations of this Article generally and reduced by any obligations of indemnification owed by Vetter pursuant to Section 11(1).
- (3) [***].
- (4) *Cooperation.* Each Party agrees to notify the other within [***] of receipt of any claim made for which the other Party might be liable under this Article 11, as the case may be. Subject to the rights of any insurer, the indemnifying Party shall have the right, but not the obligation, to defend, negotiate and settle such claim. The indemnified Party shall be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein, provided, however, that if the indemnifying Party elects to defend the indemnified Party, the indemnifying Party shall have final decision-making authority regarding all aspects of the defense of any claim. The Party seeking indemnification shall provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. Neither Party shall be responsible under or bound by any settlement of any claim or suit made without its prior written consent, provided, however, that the indemnified Party shall not unreasonably withhold or delay such consent. If a settlement contains an absolute waiver of liability for the indemnified Party, and each Party has acted in compliance with the requirements of this Section 11(3), then the indemnified Party's consent shall be deemed given. The foregoing notwithstanding, neither Party shall agree to settle any claim on such terms or conditions as would impair the other Party's ability or right to research, develop, manufacture, market, sell or otherwise use the Product, or as would impair Vetter's ability, right or obligation to perform its obligations under this Agreement or its ability to provide services of a similar nature to other customers.
- (5) [***]
- (6) [***]
- (7) [***]
- (8) *Maximum Liability.* All other provisions of this Agreement notwithstanding, Vetter's annual aggregate liability and indemnity obligations to Valneva, regardless of the legal grounds, for any Costs arising from or in connection with this Agreement, shall not exceed the Vetter Maximum Liability Cap.
For the avoidance of doubt, any Vetter liability under this Section is subject to the limitations of this Article generally and Vetter shall be liable in unlimited amounts, for itself and any other

Vetter Indemnatee, if Costs are incurred as a consequence of willful misconduct by a Vetter Indemnatee.

- (9) *Assertion.* All claims under this Agreement shall be brought within one (1) year after the cause of action incurred or shall be deemed waived, if not otherwise agreed in this Agreement.
- (10) *No Warranty.* Neither Vetter nor any of its Affiliates makes or has made any representation, warranty or covenant, whether written or oral, direct, implied or statutory, other than the covenant under German law as stipulated in and subject to Article 5, and hereby expressly disclaims any other representation, warranty, covenant or agreement, written or oral, direct, implied or statutory, including but not limited to warranties of merchantability, quality or fitness for a particular purpose.
- (11) *Other Limitation.* No Affiliate of Vetter shall incur any liability in connection with this Agreement, and Valneva shall seek payment or other remedy solely from Vetter in accordance with this Agreement and not from any Vetter Affiliate. Vetter shall not be liable for errors, defects or shortcomings in the Process Specifications provided or approved by Valneva, in the Materials, or in any instruction or direction given to Vetter by Valneva.
- (12) *Special Damages Excluded.* In no event shall a Party or its Affiliates be responsible to the other Party for any reason whatsoever for loss of profits, loss of goodwill, loss of business, delay in or cancellation, interruption or suspension of any Product supply, or for any indirect, incidental, exemplary, punitive, special or consequential damages, provided, however, the foregoing shall not apply in case of fraud, willful misconduct or to breaches of the confidentiality provisions in this Agreement or any third party indemnification claims hereunder as set forth in this Article.

ARTICLE 12 : MISCELLANEOUS.

- (1) *Insurance.* During the Term and for a period of at least one (1) year thereafter:

Valneva shall carry with a reputable insurance company a policy of insurance for product liability claims with a per-occurrence limit of at least [***] (or the equivalent thereof in U.S. Dollars) or such higher amount as may be required by applicable law in any of the jurisdictions of Product use. Valneva shall, at Vetter's request, provide Vetter with a copy of the certificate for such policy, and shall immediately inform Vetter in the event that such policy is cancelled or rendered void, or if coverage thereunder fails to meet the above standards.

Vetter shall carry with a reputable insurance company a policy of insurance for product liability claims (to the extent commercially reasonable and practicable or, if otherwise, shall self-insure and remain personally responsible and liable for such coverage) in an aggregate amount [***], which coverage shall include (namely be reduced by) attorneys' fees and/or court fees.

Either Party's violation of this Section 12(1) shall be deemed a material breach of this Agreement.

- (2) *Confidentiality, Press.* Each Party shall keep Confidential Information disclosed to it by the other Party and/or its Affiliates strictly confidential and shall use such Confidential Information solely for the purpose of exercising its rights and fulfilling its obligations under or in connection with this Agreement. The receiving Party shall not publish, disseminate or otherwise disclose the other Party's Confidential Information to any third party without the prior written consent of the other Party, except as herein provided. The receiving Party shall confine its dissemination of the disclosing Party's Confidential Information only to those of its or its' Affiliates officers, directors, employees, consultants, advisors, agents and subcontractors (hereinafter: "Representatives") who have a strict need to know the Confidential Information for the purposes of this Agreement and who are bound with the receiving Party to obligations of confidentiality and non-use at least as strict as those contained herein. The receiving Party shall procure compliance by such Representatives with this Agreement and be liable to the disclosing Party for any breach of this Agreement by any such Representatives. Such confidentiality and limited use obligation shall remain in full force and effect during the Term and for a period of eight (8) years thereafter. The receiving Party's obligations hereunder shall not apply to any part of the disclosure which: (a) is or becomes publicly known other than through breach of this Agreement by the receiving Party or its Representatives; (b) is received by the receiving Party or its Representatives in good faith from any third party, which, to the receiving Party's knowledge, is not under obligation of confidentiality to the disclosing Party; (c) is in the rightful possession of

the receiving Party or its Representatives prior to disclosure by the disclosing Party hereunder; or (d) is independently developed by the receiving Party or its Representatives as evidenced by contemporaneous written records. Notwithstanding anything in this Agreement to the contrary, the receiving Party shall be permitted to disclose any Confidential Information of the disclosing Party that it is compelled by any law, regulation, judicial or administrative process, to disclose (after providing the disclosing Party with reasonable notice of such requirement to disclose and with an opportunity to obtain a protective order and by limiting such disclosure as far as possible under applicable law). The receiving Party agrees that the disclosing Party's Confidential Information shall at all times remain the property of the disclosing Party. The receiving Party further acknowledges that by furnishing the Confidential Information, the disclosing Party does not make any express or implied representation or warranty as to the accuracy or completeness of the Confidential Information, and that the disclosing Party expressly disclaims any and all liability that may be based on the Confidential Information, errors therein or omissions therefrom. Nothing in this Agreement shall be construed as a license or grant to the receiving Party of any rights in or to the disclosing Party's Confidential Information, unless expressly stated otherwise. For clarity purposes only, (i) data storage in a third party cloud system or maintenance/structural work on the IT-system or landscape by third parties shall not be deemed a disclosure of information to a third party, provided that such storage/activities are subject to industry standard data security, data privacy and confidentiality obligations; and (ii) backups may be maintained provided that such backups are generated automatically from time to time, are not generally accessible and remain subject to the confidentiality and non-use obligations. Neither Party shall issue a press release or make a public statement of any type that mentions the other Party, unless the other Party provides prior written approval of such press release or public statement.

- (3) *Assignments.* Unless expressly provided for herein, neither Party shall be permitted to assign or transfer any of its rights and obligations under this Agreement without the prior written consent of the other Party, subject to the following exceptions:

Each Party may assign or transfer any such rights (and, for the avoidance of doubt, to grant of security interests in the same) to any of its Affiliates, or to lenders, shareholders, investors or financial underwriters, so long as such assignment or transfer does not impair or materially diminish the assigning Party's ability to perform its obligations under this Agreement, provided, however, that the assigning Party shall not be relieved, by action of such assignment or transfer of rights, of any of its obligations hereunder, and the assignee shall, in addition to the assignor, assume confidentiality obligations to the same extent as set forth in this Agreement and accepted by the assignor.

Valneva may assign this Agreement and all rights and obligations hereunder, to a successor in connection with a merger, consolidation or the sale of all or substantially all of Valneva's business to which this Agreement relates, provided, however, that (a) Valneva shall provide prior written notice to Vetter of any such assignment, merger, consolidation or sale; (b) Valneva shall not be released of obligations already accrued including confidentiality obligations which, for the sake of clarity, shall be assumed by such successor in addition to being retained by Valneva; and (c) such successor shall have agreed in writing to be bound by this Agreement and have the financial capacity (at least commensurate with that of Valneva as of the Effective Date) to perform the obligations to be assumed by such assignee.

- (4) *Conflicts.* In the event of a conflict between the terms of this Agreement (excluding Annex 4) and those of an associated Quality Agreement, the terms of such Quality Agreement shall exclusively govern and control with respect to all technical, pharmaceutical and/or quality-related aspects of the Services, and the terms hereof (excluding Annex 4) shall exclusively govern and control with respect to all other matters.

- (5) *Amendments.* Any amendment or alteration to this Agreement, specifically including this Section, or of any attachment thereto, shall take effect only by a written document signed and duly executed by both Parties.

- (6) *Notices.* All legal notices and other legal communication hereunder shall be in writing and addressed to the other Party at its address first written above, or to such other address as may be stated in a Party's written notice provided under this Section, and shall be deemed duly given upon receipt when such receipt is on a Business Day during normal business hours of the recipient and, otherwise, on the next Business Day.

- (7) *Force Majeure.* No Party shall be responsible or liable to the other Party and/or any of its representatives, and no breach shall be deemed to have occurred, for failure or delay in performing any obligation or for other non-performance if such failure, delay or other non-performance is caused by or arises from Force Majeure. A Party shall be under no obligation to settle a strike, labor stoppage, lockout, or any other labor trouble by entering into any agreement to settle any thereof, and such matter shall continue to be deemed Force Majeure until settled to the satisfaction of the affected Party. Any and all of the foregoing shall also apply to a Party to the extent that an Affiliate of such Party or Vetter Subcontractor is performing or providing any service or work in connection with the obligations of a Party. A Party claiming Force Majeure shall notify the other Party specifying the cause and probable duration of the failure, delay or other non-performance. Neither Vetter nor any of its Affiliates shall be under any obligation to fulfill any Purchase Order which has been, or should have been scheduled to be performed during a time period of Force Majeure, provided, however, that a Party so affected shall undertake every reasonable effort to fulfill its contractual obligations to the extent reasonably possible under the circumstances.

To the extent that any such event is threatened or has already commenced at the time of execution of this Agreement, the Parties (i) shall be deemed to be equally informed as to the current scope of such event and its potential impact on the subject matter hereof; (ii) acknowledge that the future course of such event and the extent of its impact (“Future Developments”) are unknowable and cannot be foreseen; and (iii) agree that such Future Developments shall, prior threat or commencement of the event notwithstanding, themselves be regarded as Force Majeure events excusing a Party’s failure of or delay in performance, subject in any case to the above obligations of timely notice and estimate of effect and duration, mitigation and/or recommencement.

- (8) *No Waiver.* Any failure by either Party to request performance or non-performance by the other Party and/or any of its Affiliates, or to claim a breach of this Agreement, shall neither be construed as a waiver of any right under Agreement, nor affect any subsequent failure to request performance or non-performance or to claim a breach, nor affect the effectiveness, the validity and/or the enforceability of this Agreement or any part thereof, nor prejudice or preclude such Party with respect to any subsequent action. Any request for performance or non-performance by either Party and/or any of its Affiliates or claim of a breach of this Agreement shall be effective, valid and enforceable only if such request or claim is reduced to writing.
- (9) *Debarment.* Neither Party nor any of their Affiliates shall be debarred by the FDA, nor shall they knowingly employ or use the services of any individual or organization (including subcontractors) who are debarred.
- (10) *Compliance.* Valneva shall ensure (i) not to misuse any payment made under this Agreement in any manner that constitutes a criminal offence or otherwise constitutes a material violation of any applicable Legal Requirements or any way that could have an adverse effect on Vetter and/or its Affiliates; and (ii) compliance with and Legal Requirements, including any anticorruption and antitrust laws; and (iii) compliance of its Affiliates, designees, subcontractors and suppliers with this Section; and (iv) not infringe the *Vetter Code of Conduct* as officially published.
- Valneva shall immediately notify Vetter of any possible violation of this Section and of any initiation of investigation by public authorities against Valneva or its Affiliates relating to any subject matter covered by this Section.
- A violation of this Section 12(10) shall be deemed a material breach of this Agreement.
- (11) *Relationship.* Each of the Parties and their respective Affiliates are independent parties and independent contractors, and nothing herein creates a partnership, agency, employment, joint venture or similar relationship between any of them.
- (12) *Severability.* If a provision of this Agreement is held void, invalid or unenforceable, it shall be replaced constructively by a mutually agreed provision that is effective, valid and enforceable and consistent with the lawful purposes manifest in or determinable from the remainder of this Agreement as a whole. Any matter not initially or fully addressed in this Agreement shall be resolved by incorporating into the same such reasonable provisions as are necessary to complete this Agreement in a manner which accomplishes to the maximum extent possible such lawful purposes and intentions. The effectiveness, validity and enforceability of this Agreement shall remain, independent of any provision which might be or has become void, invalid or unenforceable unless constructive replacement thereof is not possible and, in the absence of such provision, this Agreement would not reasonably have been entered into.

- (13) *United Nations Convention.* The United Nations Convention on Contracts for the International Sale of Goods shall have no application to, and shall be of no force and effect with respect to, the matters set forth or contemplated in this Agreement.
- (14) *Entire Agreement.* This Agreement, including the Quality Agreement, as amended and together with any attachments thereto (whether Annexes, Exhibits or Appendices), constitute the entire agreement with respect to the matters set forth or contemplated in this Agreement, and supersedes in any and all respects any prior proposal, quotation, negotiation, conversation, discussion, agreement or other communication concerning such matters, the purported terms and conditions of any of which shall be null and void. The terms of the Quality Agreement (being an Annex hereto and any Appendices thereto form an integral part of this Agreement, and shall have the same force and effect as if expressly set forth therein. Any reference to this Agreement includes its Annexes, and any breach thereof shall be deemed a breach of this Agreement.
- (15) *Execution.* This Agreement, and any amendments or addenda thereto, may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Execution may be carried out conventionally (by handwritten ink signature of all counterparts) or electronically (with e-signature by all Parties using the DocuSign® electronic signature system). Documents executed conventionally may be exchanged by (i) physical delivery of signed originals or (ii) electronic transmission of scanned or other images of the same, with physical delivery of the signed originals to follow; the Parties intend such transmitted images to have the same meaning, validity and enforceability as original documents bearing a handwritten signature, and a Party receiving a document so signed may rely upon it as if the original had been received. Documents executed electronically shall be deemed fully executed and legally binding upon all Parties' completion of the DocuSign® protocol, and the Parties hereby acknowledge their intent to be so bound, provided, however, that the Parties hereby reject use of the DocuSign® Electronic Record and Signature Disclosure or any similar DocuSign-generated collateral agreement ("ERSD") and further jointly agree that, in the event such ERSD is used and consent thereto is needed for completion of the electronic signature process, all provisions thereof are hereby anticipatorily repudiated and shall be void, inapplicable and unenforceable as between the Parties, even if consented to.
- (16) *Interpretation.* Any titles or headings, of Articles or Sections or otherwise, are for convenience and reference only and shall not be relied upon in the construction hereof. Any meaning or interpretation of legal terms contained or referred to in this Agreement and its associated documents shall be defined and interpreted solely in accordance with the governing law specified in Section 12(18) below, irrespective of any other meanings or interpretations under any other source or body of law. In this Agreement the words "herein", "hereunder" and similar words refer to this Agreement as a whole; terms used in the plural include the singular, and vice versa, unless the context requires otherwise; the words "including", "include" and variations thereof are deemed to be followed by "without limitation"; reference to a document, including this Agreement, also refers to any Annex, Exhibit, Appendix or other attachment thereto; and reference to any regulatory authority includes any successor thereto.
- (17) *Disputes.* Each Party's sole remedy for any dispute, controversy or claim arising out of, relating to or in connection with this Agreement shall be binding arbitration under the Rules. The arbitration shall be adjudicated by three (3) arbitrators appointed in accordance with the Rules. The Parties agree that (i) such arbitration shall be conducted exclusively in Frankfurt/Main, Germany; (ii) all arbitral proceedings (including, but not limited to, their existence, content and results) shall be kept confidential by all persons involved (including, but not limited to, the Parties and any Affiliates, witnesses, experts and adjudicators); and (iii) the language used in the arbitral proceedings shall be English.
- (18) *Governing Law.* This Agreement (including any applicable Quality Agreement), or other agreement incorporated herein by reference, and any amendments to any of the above, and all terms and provisions of the same, shall be construed, enforced and governed exclusively by and according to the substantive laws of Germany, without reference to any conflict-of-laws-rules or any then current rules on general terms and conditions.

(Remainder of page intentionally left blank, followed by the signatures page.)

IN WITNESS WHEREOF, and intending to be bound hereby, each of the Parties has caused this Agreement to be executed by its duly authorized representatives at the place(s) and on the date(s) set forth below, with effect as of the Effective Date.

VALNEVA AUSTRIA GMBH

Vienna, Austria, dated this _____ day of _____ (month), 2023

(signed) /s/ (signed) /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

VETTER PHARMA INTERNATIONAL GMBH

Ravensburg, Germany, dated this _____ day of _____ (month), 2023

(signed) /s/ (signed) /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

ANNEX 1 TO THE COMMERCIAL SUPPLY AGREEMENT:
PRODUCT, SERVICES and PRICES

[***]

ANNEX 2 TO THE COMMERCIAL SUPPLY AGREEMENT:

ANNUAL REFERENCE QUANTITIES (as per Section 2(4)(d))

ANNEX 3 TO THE COMMERCIAL SUPPLY AGREEMENT:
EXPANDED TERRITORY

Not applicable at the Effective Date.

ANNEX 4 TO THE COMMERCIAL SUPPLY AGREEMENT:
QUALITY AGREEMENT

Reference is made to the Quality Agreement entered into between Valneva SE (Valneva Austria GmbH's parent), a company duly organized and existing under the laws of France and having its principal place of business at 6 Rue Alain Bombard, 44800 Saint-Herblain, France and Vetter Pharma, effective as of May 28, 2018.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

THIS AMENDMENT ("Amendment"), of the Supply Agreement, effective as of April 1, 2023 (such agreement, as amended from time to time as described in the recitals below, the "Agreement"), by and between Valneva Austria GmbH, a company duly organized and existing under the laws of Austria, having its principal offices located at Campus Vienna Biocenter 3, 1030 Vienna, Austria ("Valneva"), and Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany, having its principal offices located at Eywiesenstraße 5, 88212 Ravensburg, Germany ("Vetter"), with Valneva and Vetter hereinafter individually also referred to as a "Party" and collectively as the "Parties",

WITNESSETH:

WHEREAS, in accordance with Section 12 (5) (Amendments), the Parties wish to amend the Agreement on the terms set forth herein;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements set forth above and below in this Amendment, and in the Agreement, subject to the terms and conditions hereof, each Party as follows:

ARTICLE 1: AMENDMENTS

With effect from January 1, 2024, the Agreement shall be deemed amended in accordance with the following:

Annex 1 shall be replaced in its entirety by an updated version of Annex 1, attached hereto as Exhibit 1.

ARTICLE 2: MISCELLANEOUS

(1) Capitalized terms not defined herein shall have the same meanings as specified in the Agreement, unless the context otherwise requires. A reference herein to an Article or a Section is to an Article or Section of the Agreement, unless the context otherwise requires. Each reference to the term Agreement, in the Agreement, shall be deemed to be a reference to the Agreement as amended or supplemented by this Amendment, unless the context otherwise requires.

(2) The provisions of the Confidentiality Agreement shall also govern this Amendment, except that each Party agrees to keep Confidential Information of the other Party confidential for a period of ten (10) years from the termination of the Agreement.

(3) Except as expressly modified by this Amendment, any and all terms and conditions of the Agreement shall remain in full force and effect, and shall be applicable to this Amendment. For the avoidance of doubt, anything which is not covered in this Amendment, shall be subject to the provisions of the Agreement.

(4) The Agreement (including the Quality Agreement and its Appendices and the Confidentiality Agreement) together with this Amendment, constitutes the entire agreement between the Parties with respect to Production of the Product by Vetter and supersedes in all respects all prior proposals, negotiations, conversations, discussions and agreements between the Parties in respect thereof.

(5) Section 12 (17) (Dispute) and Section 12 (18) (Governing Law) of the Agreement shall be deemed incorporated into this Amendment by this reference, save that any reference in any such Article to "this Agreement" shall be deemed to be a reference to this Amendment.

(Page remainder left blank intentionally, immediately followed by the signatures page.)

IN WITNESS WHEREOF, duly authorized representatives of each of the Parties have on the days and year at the places below written executed this Amendment to be effective on the respective dates as set forth above.

VALNEVA Austria GmbH

Vienna, Austria, dated _____(month) _____(day), 2023

(signed) /s/
Name: [***]
Title: [***]

VETTER PHARMA INTERNATIONAL GMBH

Ravensburg, Germany, dated _____(month) _____(day), 2023

(signed) /s/ (signed) /s/
Name: [***] Name: [***]
Title: [***] Title: [***]

Exhibit 1

ANNEX 1 TO THE COMMERCIAL SUPPLY AGREEMENT:
PRODUCT, SERVICES and PRICES

Product(s):

Sterile water for injection in a pre-filled syringe 1,5 ml, with approx. 0,5 ml fill volume, according to and specified in Quotation dated June 1, 2022.

Services:

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

THIS AMENDMENT NO. 2 (“Amendment #2”), of the Supply Agreement, effective as of April 1, 2023 (such agreement, as amended from time to time as described in the recitals below, the “Agreement”), by and between Valneva Austria GmbH, a company duly organized and existing under the laws of Austria, having its principal offices located at Campus Vienna Biocenter 3, 1030 Vienna, Austria (“Valneva”), and Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany, having its principal offices located at Eywiesenstraße 5, 88212 Ravensburg, Germany (“Vetter”), with Valneva and Vetter hereinafter individually also referred to as a “Party” and collectively as the “Parties”,

WITNESSETH:

WHEREAS, the Parties have agreed to expand the territorial scope under the Agreement and add Expanded Territories. In accordance with Section 12 (5) (Amendments), the Parties now wish to amend the Agreement on the terms set forth herein;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements set forth above and below in this Amendment #2, and in the Agreement, subject to the terms and conditions hereof, each Party agree as follows:

ARTICLE 1: AMENDMENTS

(1) With effect from January 1, 2024 (“**Amendment Effective Date**”), the Agreement shall be deemed amended in accordance with the following:

A. Annex 3 shall be replaced in its entirety by an updated version of Annex 3, attached hereto as Exhibit 1.

B. Article 10.3 shall be modified to clarify license grant under the Agreement. After the amendment Section 10.3 will read as follows (changes in *italics*):

“Article 10; INTELLECTUAL PROPERTY.

(3) Licenses. Vetter hereby grants to Valneva a temporary (for the duration of this Agreement), royalty free, fully paid up, non-exclusive license with respect to all Intellectual Property under Vetter’s and/or its Affiliates ownership or control, which is used by Vetter and/or its Affiliates in performing activities and services under this Agreement, to file with regulatory authorities, *commercialize*, distribute or otherwise use within the Territory (and Expanded Territory, as the case may be) the Product Manufactured by Vetter under this Agreement with the right to grant and authorize sublicenses solely to the extent needed for, and solely for the purpose to allow any third party to *file with regulatory authorities, commercialize*, distribute or otherwise use within the Territory (and Expanded Territory, as the case may be) the Product Manufactured by Vetter for Valneva. Valneva shall ensure that any such third party shall fully comply with the terms of this Agreement and the Quality Agreement, it being agreed and understood that Valneva shall take full and unlimited liability for any such third Party.”

ARTICLE 2: MISCELLANEOUS

(1) Capitalized terms not defined herein shall have the same meanings as specified in the Agreement, unless the context otherwise requires. A reference herein to an Article or a Section is to an Article or Section of the Agreement, unless the context otherwise requires. Each reference to the term Agreement, in the Agreement, shall be deemed to be a reference to the Agreement as amended or supplemented by this Amendment #2, unless the context otherwise requires.

(2) Except as expressly modified by this Amendment #2, any and all terms and conditions of the Agreement shall remain in full force and effect, and shall be applicable to this Amendment #2. For the avoidance of doubt, anything which is not covered in this Amendment #2, shall be subject to the provisions of the Agreement.

(3) The Agreement (including the Quality Agreement and its Appendices) together with this Amendment #2, constitutes the entire agreement between the Parties with respect to Manufacture of the Product by Vetter and supersedes in all respects all prior proposals, negotiations, conversations, discussions and agreements between the Parties in respect thereof.

(4) Section 12 (2) (Confidentiality. Press), Section 12 (17) (Dispute) and Section 12 (18) (Governing Law) of the Agreement shall be deemed incorporated into this Amendment #2 by this reference, save that any reference in any such Article to “this Agreement” shall be deemed to be a reference to this Amendment #2.

(Page remainder left blank intentionally, immediately followed by the signatures page.)

IN WITNESS WHEREOF, duly authorized representatives of each of the Parties have on the days and year at the places below written executed this Amendment #2 to be effective on the Amendment Effective Date.

VALNEVA Austria GmbH

Vienna, Austria, dated _____(month) _____(day), 2024

(signed) /s/

Name: [***]

Title: [***]

(signed) /s/

Name: [***]

Title: [***]

VETTER PHARMA INTERNATIONAL GMBH

Ravensburg, Germany, dated _____(month) _____(day), 2024

(signed) /s/

(signed) /s/

Name: [***]

Name: [***]

Title: [***]

Title: [***]

ANNEX 3 TO THE COMMERCIAL SUPPLY AGREEMENT:
EXPANDED TERRITORY

[***]

***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

CREDIT AGREEMENT

dated as of February 3, 2020,
as amended by that First Amendment, dated as of as June 24, 2020,
as further amended by that Second Amendment, dated as of July 31, 2020,
as further amended by that Third Amendment, dated as of January 15, 2021,
as further modified by that Waiver, dated as of November 30, 2021,
as further amended by that Fourth Amendment, dated as of January 3, 2022,
as further amended by that Fifth Amendment, dated as of April 25, 2022,
as further amended by that Sixth Amendment, dated as of September 22, 2022,
as further amended by that Seventh Amendment, dated as of August 16, 2023,
as further amended by that Eighth Amendment, dated as of October 30, 2023
and as further amended by that Ninth Amendment and Waiver, dated as of March 18, 2024

among

VALNEVA AUSTRIA GMBH,
as the Borrower,

VALNEVA SE,
as Holdings

THE LENDERS FROM TIME TO TIME PARTY HERETO

and

WILMINGTON TRUST, NATIONAL ASSOCIATION,
as the Administrative Agent

THE LOANS HEREUNDER ARE BEING MADE WITH ORIGINAL ISSUE DISCOUNT ("OID") FOR U.S. FEDERAL INCOME TAX PURPOSES. THE ISSUE PRICE, AMOUNT OF OID, ISSUE DATE AND YIELD TO MATURITY OF THE LOANS MAY BE OBTAINED FROM THE BORROWER BY CONTACTING THE ADDRESS OF THE BORROWER SPECIFIED ON SCHEDULE 10.2.

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CREDIT AGREEMENT

THIS CREDIT AGREEMENT, dated as of February 3, 2020 (as amended, supplemented or otherwise modified from time to time, this "Agreement"), is entered into by and among VALNEVA AUSTRIA GMBH, a company organized and existing under the laws of Austria (the "Borrower"), having its principal place of business at Campus Vienna Biocenter 3, 1030, Vienna, Austria, with registration number FN 389960 x, VALNEVA SE, a *societas europaea* organized and existing under the laws of the European Union ("Holdings"), having its principal place of business at 6 rue Alain Bombard, 44800, Saint-Herblain, France, the Lenders (defined herein) and WILMINGTON TRUST, NATIONAL ASSOCIATION, a national banking association organized and existing under the laws of the United States of America (together with its Affiliates, successors, transferees and assignees) as the Administrative Agent. The Borrower and each Lender are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WITNESSETH:

WHEREAS, the Borrower engaged a financial advisor in the United States to solicit proposals from financial institutions located in the United States to provide the Borrower with a term loan credit facility;

WHEREAS, as a result of such solicitation process, the Borrower determined to obtain such term loan credit facility from the Lenders and has requested that the Lenders provide a senior term loan facility to the Borrower (with \$45,000,000 available on the Funding Date, \$15,000,000 available on or prior to the three-month anniversary of the Funding Date, \$12,500,000 available on or prior to the nine-month anniversary of the Funding Date, \$12,500,000 available on or prior to the twelve-month anniversary of the Funding Date, \$20,000,000 available on or prior to the Fourth Delayed Draw Commitment Termination Date, \$20,000,000 available on or prior to the Fifth Delayed Draw Commitment Termination Date, \$50,000,000 available on or prior to the Sixth Delayed Draw Commitment Termination Date and \$50,000,000 available on or prior to the Seventh Delayed Draw Commitment Termination Date, subject to the terms and conditions set forth herein); and

WHEREAS, the Lenders are willing, on the terms and subject to the conditions hereinafter set forth, to extend the Commitment and make the Loans to the Borrower (it being agreed that after giving effect to the Seventh Amendment (as defined below) on the Seventh Amendment Effective Date, the aggregate principal amount of Loans plus the aggregate principal amount of Commitments outstanding under this Agreement as of the Seventh Amendment Effective Date will be \$200,000,000).

NOW, THEREFORE, the parties hereto agree as follows.

ARTICLE I

DEFINITIONS AND ACCOUNTING TERMS

SECTION 1.1 Defined Terms. The following terms (whether or not underscored) when used in this Agreement, including its preamble and recitals, shall, except where the context otherwise requires, have the following meanings (such meanings to be equally applicable to the singular and plural forms thereof):

"Administrative Agent" means Wilmington Trust, National Association, in its capacity as administrative agent under any of the Loan Documents, or any successor administrative agent.

"Administrative Agent's Office" means the Administrative Agent's address and, as appropriate, account as set forth on Schedule 10.2 or such other address or account as the Administrative Agent may from time to time notify the Borrower and the Lenders.

"Affiliate" of any Person means any other Person which, directly or indirectly, Controls, is Controlled by or is under common Control with such Person. **"Control"** (and its correlatives) by any Person means (a) the power of such Person, directly or indirectly, (i) to vote 20% or more of the Voting Securities (determined on a fully diluted basis) of another Person or (ii) to direct or cause the direction of the management and policies of such other Person (whether by contract or otherwise); provided that, for purposes of this definition, Grimaud Group shall not be deemed to be an Affiliate of any Loan Party or other Subsidiary unless Grimaud Group has the power, directly or indirectly, (x) to vote 25% or more of the Voting Securities (determined on a fully diluted basis) of any Loan Party or other Subsidiary or (y) to direct or cause the direction of the management and policies of any Loan Party or other Subsidiary (whether by contract or otherwise), or (b) ownership by such Person of 20% or more of the Capital Securities of another Person; provided that, for purposes of this definition, Grimaud Group shall not be deemed to be an Affiliate of any Loan Party or another Subsidiary unless Grimaud Group owns 25% or more of the Capital Securities of such Loan Party or other Subsidiary. With respect to a Lender, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Lender shall, for purposes hereof, be deemed to an Affiliate of such Lender. None of the Administrative Agent, any Lender or any other Secured Party shall be deemed to be an Affiliate of any Loan Party or other Subsidiary hereunder as a result of being the Administrative Agent, a Lender or a Secured Party.

"Agency Fee Letter" means the fee letter, dated as of the Closing Date, between the Borrower and Wilmington Trust, National Association, as the Administrative Agent.

"Agreement" is defined in the preamble.

"Announcing Report" has the meaning assigned to such term in Section 7.15(b).

"Applicable Percentage" means, with respect to any Lender at any time, with respect to such Lender's portion of the outstanding Loans at any time, the percentage of the outstanding principal amount of the Loans held by such Lender at such time. The initial Applicable Percentage of each Lender is set forth opposite the name of such Lender on Schedule 2.1 or in the Assignment and Assumption pursuant to which such Lender becomes a party hereto, as applicable.

"Applicable Rate" means, subject to Section 3.5, 9.95% *per annum*.

"Applicable Securities Jurisdictions" means the United States, France, the European Union and any other jurisdiction in which any Capital Securities or other securities of Holdings are listed or traded on a securities exchange or over-the-counter market at any date of determination.

"Applicable Securities Laws" means the securities Laws in each of the Applicable Securities Jurisdictions (including the Exchange Act, the French *Règlement général de l'Autorité des marchés financiers*, the French *Code monétaire et financier*, the French *Code de commerce* and Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation)), and the applicable rules, policy statements, notices, blanket rulings, orders and all other regulatory instruments of the securities regulators and securities exchanges in each of the Applicable Securities Jurisdictions.

"Approved Fund" means any Fund that is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) an entity or an Affiliate of an entity that administers or manages a Lender.

"Assignment and Assumption" means an assignment and assumption entered into by a Lender and an Eligible Assignee (with the consent of any party whose consent is

required by Section 10.10(b)), and accepted by the Administrative Agent, in substantially the form of Exhibit F hereto or any other form approved by the Administrative Agent.

"Assignment Effective Date" is defined in Section 10.10(a).

"Austrian IO" means the Austrian Insolvency Code (*Insolvenzordnung*) as amended from time to time.

"Austrian Security Documents" means the Austrian law governed pledges over bank accounts, receivables, Capital Securities and Intellectual Property, in each case, to the extent such assets are required by the terms of the Loan Documents to constitute Collateral.

"Authorized Officer" means, relative to Holdings, the Borrower or any of the Subsidiaries, those of its officers, general partners or managing members (as applicable) whose signatures and incumbency shall have been certified to the Administrative Agent and the Lenders pursuant to Section 5.2.

"Autorité des marchés financiers" means the French Stock Markets regulator.

"Benefit Plan" means (i) any employee benefit plan, as defined in section 3(3) of ERISA, that: (a) is a "multiemployer plan," as defined in section 3(37) of ERISA (or equivalent provisions of non-U.S. law governing union-sponsored defined benefit pension plans), (b) is subject to section 412 of the Code, section 302 of ERISA or Title IV of ERISA (or equivalent provisions of non-U.S. law governing union-sponsored defined benefit pension plans), (c) provides welfare benefits to terminated employees, other than to the extent required by section 4980B(f) of the Code and the corresponding provisions of ERISA, or (d) provides medical, dental, vision or long-term disability benefits and is not fully insured by a third-party insurance company; or (ii) any Canadian Defined Benefit Plan.

"BLA" means a biologics license application, as that term is defined by section 351 of the PHSA, and any foreign equivalent.

"Borrower" is defined in the preamble.

"Borrower Materials" means information, reports, financial statements and other materials delivered by the Borrower to the Administrative Agent and the Lenders hereunder, as well as other reports and information provided by the Administrative Agent to the Lenders.

"Business Day" means any day which is neither a Saturday or Sunday nor a day on which banks are authorized or required to be closed in New York, New York or Vienna, Austria.

"Canadian Defined Benefit Plan" means each Canadian Pension Plan with a "defined benefit provision" as such term is defined in the *Income Tax Act (Canada)*.

"Canadian Insolvency Laws" means the *Bankruptcy and Insolvency Act (Canada)*, the *Companies' Creditors Arrangement Act (Canada)* or any similar Canadian federal or provincial insolvency law for the relief of debtors as now or hereinafter in effect.

"Canadian Pension Plan" means a "registered pension plan" as such term is defined in the *Income Tax Act (Canada)*.

"Canadian PPSA Loan Party" means any Loan Party that is existing under the Laws of any province of Canada (other than the Province of Quebec) or that has its registered office, its head office, its chief executive office, a place of business, any tangible or corporeal property or a Controlled Account in any province of Canada (other than the Province of Quebec).

"Canadian Security Documents" means any Deeds of Hypothec, Canadian security agreement or other security documents, account control agreements or blocked account agreements governed by the Laws of any province of Canada (in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders) and granted by any one or more Canadian PPSA Loan Parties or Quebec Loan Parties, which as of the date of this Agreement includes a Deed of Hypothec granted by Valneva Canada.

"Capital Securities" means, with respect to any Person, (a) all shares of, interests or participations in, or other equivalents in respect of (in each case however designated, whether voting or non-voting), such Person's capital stock, whether now outstanding or issued after the Closing Date, and (b) all securities convertible into, or exchangeable for, any other Capital Securities and all warrants, options or other rights to purchase, substitute for or otherwise acquire any other Capital Securities, whether or not presently convertible, exchangeable or exercisable.

"Capitalized Lease Liabilities" means, with respect to any Person, all monetary obligations of such Person and its Subsidiaries under any leasing or similar arrangement which have been (or, in accordance with IFRS, should be) classified as capitalized leases, and for purposes of each Loan Document the amount of such obligations shall be the capitalized amount thereof, determined in accordance with IFRS, and the stated maturity thereof shall be the date of the last payment of rent or any other amount due under such lease prior to the first date upon which such lease may be terminated by the lessee without payment of a premium or a penalty.

"Cash Equivalent Investment" means, at any time:

- (a) any direct obligation of (or unconditionally guaranteed by) France, Austria, Sweden, the United Kingdom, Canada and/or the United States (or any agency or political subdivision thereof, to the extent such obligations are supported by the full faith and credit of such country or state) maturing not more than one year after such time;
- (b) commercial paper maturing not more than one year from the date of issue, which is issued by a corporation (other than an Affiliate of Holdings, the Borrower or any of its Subsidiaries) organized under the Laws of France, Austria, Sweden, the United Kingdom, Canada and/or the United States, any state thereof or of the District of Columbia and rated A-1 or higher by S&P or P-1 or higher by Moody's; or
- (c) any certificate of deposit, demand or time deposit or bankers' acceptance, maturing not more than 180 days after its date of issuance, which is issued by or placed with any bank or trust company organized under the Laws of France, Austria, Sweden, the United Kingdom, Canada and/or the United States (or any state thereof) and which has (i) a credit rating of A2 or higher from Moody's or A or higher from S&P and (ii) a combined capital and surplus greater than €500,000,000; or
- (d) investments in money market mutual funds at least 95% of the assets of which are comprised of securities of the types described in clauses (a) through (c) of this definition.

"Casualty Event" means the damage, destruction or condemnation, as the case may be, of property of any Person or any of its Subsidiaries.

"CE Mark" means, with respect to any Product, the "CE" mark issued upon approval of such Product by the European Union Regulatory Authority.

"Centre of Main Interests" means the centre of main interests as that term is used in Article 3(1) of the Council of the European Union Regulation No 2015/848 on insolvency proceedings (recast).

"Change in Control" means and shall be deemed to have occurred if: (a) any "person" or "group" (within the meaning of Rule 13d-5 of the Exchange Act) shall acquire or own, directly or indirectly, beneficially or of record, determined on a fully diluted basis, more than 35% of the Voting Securities of the Borrower or Holdings; (b) a majority of the seats (other than vacant seats) on the board of directors of the Borrower or the Supervisory Board of Holdings shall at any time be occupied by persons who were neither (i) nominated by the board of directors of the Borrower or the Supervisory Board of Holdings, as applicable, nor (ii) appointed by directors or members, as applicable, so nominated; (c) Holdings shall cease to directly own, beneficially and of record, 100% of the issued and outstanding Capital Securities of the Borrower; or (d) Holdings shall cease to directly or indirectly own, beneficially and of record, 100% of the issued and outstanding Capital Securities of the Subsidiaries (other than directors' qualifying shares as required by applicable Laws and, with respect to any Subsidiaries of the Borrower, other than in connection with a sale or liquidation of 100% of any such Subsidiary in a transaction permitted by this Agreement).

"Change in Law" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking effect of any Law, rule, regulation or treaty; (b) any change in any Law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority; or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that, notwithstanding anything herein to the contrary, (i) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (ii) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law," regardless of the date enacted, adopted or issued.

"Closing Date" means the date of this Agreement.

"CMS" means the U.S. Centers for Medicare and Medicaid Services.

"Code" means the Internal Revenue Code of 1986, as amended from time to time.

"Collateral" means collectively, all of the real, personal and mixed property (including Capital Securities) in which Liens are purported to be granted pursuant to the Security Agreements as security for the Obligations, including as described on Schedule 1.1.

"Commitment" means, as to each Lender, such Lender's obligation (if any) to make Loans hereunder.

"Commitment Amount" means the Initial Commitment Amount plus the Delayed Draw Commitment Amounts.

"Compliance Certificate" means a certificate duly completed and executed by an Authorized Officer of the Borrower, substantially in the form of Exhibit C hereto or any other form approved by the Required Lenders.

"Confidential Information" means any and all information or material (whether written or oral, or in electronic or other form) that, at any time before, on or after the Closing Date, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party pursuant to this Agreement or in connection with the transactions contemplated hereby, but shall not include the existence or terms of this Agreement.

"Contingent Liability" means any agreement, undertaking or arrangement by which any Person guarantees, endorses or otherwise becomes or is contingently liable upon (by direct or indirect agreement, contingent or otherwise, to provide funds for payment, to supply funds to, or otherwise to invest in, a debtor, or otherwise to assure a creditor against loss) the Indebtedness of any other Person (other than by endorsements of instruments in the course of collection), or guarantees the payment of dividends or other distributions upon the Capital Securities of any other Person. The amount of any Person's obligation under any Contingent Liability shall (subject to any limitation set forth therein) be deemed to be the stated or determined amount of the outstanding debt, obligation or other liability guaranteed thereby, or if not stated or determinable, the maximum reasonably anticipated amount of such debt, obligation or other liability as determined by such Person in good faith; provided, however, that such amount shall not, in any event, exceed the maximum amount for which such Person may be liable under the applicable agreement, undertaking or arrangement.

"Control" is defined within the definition of **"Affiliate."**

"Control Agreement" means a springing account control agreement entered into by the applicable Loan Party, the Administrative Agent and the bank or other depository institution at which such account is located.

"Controlled Account" means an account of Holdings, the Borrower or any other Loan Party that is (i) in the case of accounts located in the United States, subject to a Control Agreement, (ii) in the case of accounts located in France, Austria or Sweden, subject to a pledge over bank accounts with a blockage clause, (iii) in the case of accounts located in Canada or the United Kingdom (including Scotland), subject to a perfected Lien in favor of the Administrative Agent, for the benefit of the Secured Parties, to secure the Obligations in accordance with applicable Law, or (iv) in the case of accounts located in any other jurisdiction reasonably acceptable to the Required Lenders, subject to a perfected Lien in favor of the Administrative Agent, for the benefit of the Secured Parties, to secure the Obligations in accordance with applicable Law.

"Copyrights" means all copyrights, whether statutory or common law, and all exclusive and nonexclusive licenses from third parties, along with any and all (a) renewals, revisions, extensions, derivative works, enhancements, modifications, updates and new releases thereof, (b) **income, royalties, damages, claims and payments now and hereafter due and/or payable with respect thereto, including damages and payments for past, present or future Infringements thereof**, (c) rights to sue for past, present and future Infringements thereof, and (d) foreign copyrights and any other rights corresponding thereto throughout the world.

"Copyright Security Agreement" means any Copyright Security Agreement executed and delivered by the Borrower or any of the Guarantors, substantially in the form of Exhibit C to the Security Agreement or any other form approved by the Required Lenders.

"Debtor Relief Laws" means the Bankruptcy Code of the United States and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief laws of the United States or other applicable jurisdictions from time to time in effect (including, without limitation, the Austrian IO, Canadian Insolvency Laws and the French *Code de commerce*).

"Deed of Hypothec" means the deed of hypothec governed by the Laws of the Province of Quebec granted by Valneva Canada, a Quebec Loan Party, in favor of the Administrative Agent, as hypothecary representative (within the meaning of Article 2692 of the Civil Code of Quebec) for the Secured Parties, and any other deed of hypothec granted after the Closing Date by Valneva Canada or any additional Quebec Loan Parties in favor of the Administrative Agent, as hypothecary representative for the Secured Parties, each in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders.

"Deerfield" means Deerfield Partners, L.P. and its Affiliates.

"Default" means any Event of Default or any condition, occurrence or event which, after notice or lapse of time or both, would constitute an Event of Default.

"Delayed Draw Commitment Amount" means each of the First Delayed Draw Commitment Amount, the Second Delayed Draw Commitment Amount, the Third Delayed Draw Commitment Amount, the Fourth Delayed Draw Commitment Amount, the Fifth Delayed Draw Commitment Amount, the Sixth Delayed Draw Commitment Amount and the Seventh Delayed Draw Commitment Amount.

"Delayed Draw Commitment Termination Date" means each of the First Delayed Draw Commitment Termination Date, the Second Delayed Draw Commitment Termination Date, the Third Delayed Draw Commitment Termination Date, the Fourth Delayed Draw Commitment Termination Date, the Fifth Delayed Draw Commitment Termination Date, the Sixth Delayed Draw Commitment Termination Date and the **Seventh Delayed Draw Commitment Termination Date**.

"Delayed Draw Funding Date" means each of the First Delayed Draw Funding Date, the Second Delayed Draw Funding Date, the Third Delayed Draw Funding Date, the Fourth Delayed Draw Funding Date, the Fifth Delayed Draw Funding Date, the Sixth Delayed Draw Funding Date and the **Seventh Delayed Draw Funding Date**.

"Delayed Draw Loan" means each of the First Delayed Draw Loan, the Second Delayed Draw Loan, the Third Delayed Draw Loan, the Fourth Delayed Draw Loan, the Fifth Delayed Draw Loan, the Sixth Delayed Draw Loan and the Seventh Delayed Draw Loan.

"Designated Jurisdiction" means any country or territory to the extent that such country or territory is the subject of any comprehensive Sanction (which, on the Closing Date, includes Crimea, Cuba, Iran, North Korea, and Syria).

"Disclosing Party" means the Party disclosing Confidential Information.

"Disposition" (or words of similar import such as **"Dispose"**) means any sale, transfer, lease, license, contribution or other conveyance (including by way of merger) of, or the granting of options, warrants or other rights to, any of Holdings's, the Borrower's or the Subsidiaries' assets (including accounts receivable and Capital Securities of Subsidiaries, but excluding the issuance of Capital Securities of Holdings (other than Disqualified Capital Securities)) to any other Person (other than to Holdings, the Borrower or any of the Guarantors) in a single transaction or series of transactions.

"Disqualified Capital Securities" means any Capital Securities that, by their terms (or by the terms of any security or other Capital Securities into which they are convertible or for which they are exchangeable) or upon the happening of any event or condition, (a) mature or are mandatorily redeemable (other than solely for Qualified Capital Securities), pursuant to a sinking fund obligation or otherwise (except as a result of a Change in Control or asset sale so long as any rights of the holders thereof upon the occurrence of a Change in Control or asset sale event shall be subject to the prior repayment in full of the Loans and all other Obligations that are accrued and payable and the termination of the Commitment), (b) are redeemable at the option of the holder thereof (other than solely for Qualified Capital Securities) (except as a result of a Change in Control or asset sale so long as any rights of the holders thereof upon the occurrence of a Change in Control or asset sale event shall be subject to the prior repayment in full of the Loans and all other Obligations that are accrued and payable and the termination of the Commitment), in whole or in part, (c) provide for the scheduled payment of dividends in cash or (d) are or become convertible into or exchangeable for Indebtedness or any other Capital Securities that would constitute Disqualified Capital Securities, in each case of clauses (a) through (d), prior to the date that is 181 days after the Seventh Amendment Tranche Maturity Date; provided that if such Capital Securities are issued pursuant to a plan for the benefit of employees of Holdings, the Borrower or any of its Subsidiaries, or by any such plan to such employees, such Capital Securities shall not constitute

Disqualified Capital Securities solely because they may be required to be repurchased by Holdings, the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations.

"Division/Series Transaction" means, with respect to any Person that is a limited liability company organized under the Laws of the State of Delaware, that any such Person (a) divides into two or more Persons (whether or not the original Person survives such division) or (b) creates, or reorganizes into, one or more series, in each case, as contemplated under the Laws of the State of Delaware.

"Dukoral" means the vaccine product indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in adults and children from 2 years of age who will be visiting endemic/epidemic areas, manufactured, distributed offered for sale or sold under the Dukoral brand or any successor product.

"EB-66" is defined in the definition of "Non-Core Assets".

"Eighth Amendment" means that Eighth Amendment, dated as of October 30, 2023, among the Borrower, Holdings, the Guarantors party thereto, the Lenders party thereto, and the Administrative Agent.

"Eighth Amendment Effective Date" has the meaning set forth in the Eighth Amendment.

"Eligible Assignee" means (i) a Lender, an Affiliate of a Lender, an Approved Fund or (ii) a commercial bank, insurance company, investment or mutual fund or other entity that is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans in the ordinary course of its business.

"English Debenture" means the Debenture executed and delivered by Valneva UK Limited (as chargor in respect of substantially all its assets), Holdings (as chargor in respect of its shares in Valneva UK Limited) and the Administrative Agent (as chargee).

"Environmental Laws" means all applicable U.S. and non-U.S. federal, state, provincial, local or other political subdivision laws, statutes, rules, regulations, codes, directives, treaties, requirements, ordinances, orders, decrees, judgments, injunctions, or binding agreements issued, promulgated or entered into by any Governmental Authority, relating in any way to the environment, natural resources, or Hazardous Material, including protection of human health and safety from exposure to Hazardous Materials.

"Environmental Liability" means any liability, loss, claim, suit, action, investigation, proceeding, damage or obligation, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of or affecting Holdings, the Borrower or any Subsidiary directly or indirectly arising from, in connection with or based upon (a) any violation of Environmental Law or Environmental Permit, (b) the generation, use, handling, transportation, storage, treatment, recycling, presence, disposal, Release or threatened Release of, or exposure to, any Hazardous Materials, or (c) any contract, agreement, penalty, order, decree, settlement, injunction or other arrangement (including operation of Law) pursuant to which liability is assumed, entered into, inherited or imposed with respect to any of the foregoing.

"Environmental Permit" is defined in [Section 6.7\(c\)](#).

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time.

"ERISA Affiliate" means, as applied to any Person, (a) any corporation that is a member of a controlled group of corporations within the meaning of section 414(b) of the Code of which that Person is a member, (b) any trade or business (whether or not incorporated) that is a member of a group of trades or businesses under common control within the meaning of section 414(c) of the

Code of which that Person is a member; (c) any member of an affiliated service group within the meaning of section 414(m) or 414(o) of the Code of which that Person, any corporation described in clause (a) above or any trade or business described in clause (b) above is a member; or (d) is similarly affiliated with any Person under equivalent provisions of non-U.S. law applicable to employer-sponsored defined benefit pension plans.

"Event of Default" is defined in Section 9.1.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Excluded Accounts" is defined in Section 7.13.

"Excluded Taxes" means any of the following Taxes imposed on or with respect to the Administrative Agent or a Lender or required to be withheld or deducted from a payment to the Administrative Agent or a Lender, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of such Administrative Agent or such Lender being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) any withholding Taxes attributable to such Lender's failure to comply with Section 4.6(a), and (c) any withholding Taxes imposed under FATCA.

"Existing Maturity Date" means March 3, 2027.

"Exit Fee" is defined in Section 3.8.

"FATCA" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

"FDA" means the U.S. Food and Drug Administration, any comparable state or local Governmental Authority, and comparable Governmental Authority in any non-United States jurisdiction and any successor agency of any of the foregoing.

"FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act (or any successor thereto) and any comparable state or local Law, and comparable Laws in any non-United States jurisdiction, as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Federal Funds Rate" means, for any day, the rate *per annum* equal to the weighted average of the rates on overnight federal funds transactions with members of the Federal Reserve System arranged by federal funds brokers on such day, as published by the Federal Reserve Bank of New York on the Business Day next succeeding such day; provided that, if such day is not a Business Day (assuming for purposes of this definition, that the definition of "Business Day" references only New York, New York and not Vienna, Austria), the Federal Funds Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day.

"Fifth Amendment" means that Fifth Amendment, dated as of April 25, 2022, among the Borrower, Holdings, the Guarantors party thereto, the Lenders party thereto, and the Administrative Agent.

"Fifth Amendment Effective Date" shall have the meaning set forth in the Fifth Amendment.

"Fifth Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the Fifth Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Fifth Delayed Draw Commitment Amount of all of the Lenders as in effect on the Fifth Amendment Effective Date is \$20,000,000.

"Fifth Delayed Draw Commitment Termination Date" means the earlier to occur of (a) the Fifth Delayed Draw Funding Date (immediately after the making of the Fifth Delayed Draw Loan on such date), and (b) September 30, 2022, if the Fifth Delayed Draw Loan shall not have been made hereunder prior to such date.

"Fifth Delayed Draw Funding Date" means the date of the making of the Fifth Delayed Draw Loan hereunder, which in no event shall be later than September 30, 2022.

"Fifth Delayed Draw Loan" is defined in Section 2.1.

"First Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the First Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the First Delayed Draw Commitment Amount of all of the Lenders as in effect on the Closing Date is \$15,000,000.

"First Delayed Draw Commitment Termination Date" means the earliest to occur of (a) the First Delayed Draw Funding Date (immediately after the making of the First Delayed Draw Loan on such date), (b) June 24, 2020, and (c) March 4, 2020, if the Initial Loan shall not have been made hereunder prior to such date.

"First Delayed Draw Funding Date" means the date of the making of the First Delayed Draw Loan hereunder, which in no event shall be later than June 3, 2020.

"First Delayed Draw Loan" is defined in Section 2.1.

"Fiscal Quarter" means a quarter ending on the last day of March, June, September or December.

"Fiscal Year" means any period of twelve consecutive calendar months ending on December 31; references to a Fiscal Year with a number corresponding to any calendar year (e.g., the "2018 Fiscal Year") refer to the Fiscal Year ending on December 31 of such calendar year.

"Foreign Lender" means a Lender that is organized under the laws of a jurisdiction outside of the United States.

"Fourth Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the Fourth Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Fourth Delayed Draw Commitment Amount of all of the Lenders as in effect on the Fifth Amendment Effective Date is \$20,000,000.

"Fourth Delayed Draw Commitment Termination Date" means the Fourth Delayed Draw Funding Date (immediately after the making of the Fourth Delayed Draw Loan on such date).

"Fourth Delayed Draw Funding Date" means the date of the making of the Fourth Delayed Draw Loan hereunder, which in no event shall be later than the Fifth Amendment Effective Date.

"Fourth Delayed Draw Loan" is defined in Section 2.1.

"French Security Documents" means the French law governed pledges over bank accounts, French law governed pledges over shares of Valneva France, French law governed pledge of intercompany loans and French law governed pledge over business/on-going concern, in each case, to be executed and delivered by Holdings or, as the case may be, the Borrower and the Administrative Agent with respect to the Collateral owned by Holdings or, as the case may be, by the Borrower.

"F.R.S. Board" means the Board of Governors of the Federal Reserve System or any successor thereto.

"FTC Act" means the Federal Trade Commission Act, as amended.

"Fund" means any Person (other than a natural Person) that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its activities.

"Funding Date" means the date on which the Initial Loan is made hereunder, which in no event shall be later than March 4, 2020.

"GCPs" means the then current good clinical practices that establish the national and international ethical and scientific quality standards for designing, conducting, recording and reporting clinical trials that are promulgated or endorsed for the United States by the FDA (including through ICH E6 and 21 CFR Parts 50, 54, 56 and 312) and for outside the United States by comparable Governmental Authorities.

"GLPs" means the then current good laboratory practices as set forth by FDA in 21 C.F.R. Part 58, and all applicable foreign equivalents.

"GMPs" means the then current good manufacturing practices, as that term is defined by FDA and as set forth in FDA's regulations at 21 C.F.R. Parts 210 and 211 and applicable FDA guidance, and all applicable foreign equivalents.

"Governmental Authority" means any national, supranational, federal, state, county, provincial, local, municipal, territorial or other government or political subdivision thereof, whether domestic or foreign, and any agency, authority, commission, ministry, instrumentality, regulatory body, securities exchange, court, tribunal, arbitrator, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to any such government.

"Grimaud Group" means, collectively, the Persons acting in concert and designated as the "Grimaud family group" ("*Groupe familial Grimaud*") in filings with the *Autorité des marchés financiers*, together with their successors and heirs.

"Guarantee" means the guarantee executed and delivered by an Authorized Officer of Holdings or an Authorized Officer of each Material Subsidiary (other than the Borrower), substantially in the form of Exhibit D hereto or any other form approved by the Administrative Agent and the Required Lenders.

"Guarantor" means any Person that signs a Guarantee, which shall include Holdings and each Material Subsidiary (other than the Borrower).

"Hazardous Material" means any material, substance, chemical, mixture or waste which is toxic or hazardous to any living organism, the environment or natural resources, including explosive, hazardous, polluting, toxic, biohazardous, infectious or radioactive substances, materials or wastes (including medical wastes), and including petroleum or petroleum products, byproducts or distillates, asbestos or asbestos-containing materials, urea formaldehyde, polychlorinated biphenyls, radon gas, ozone-depleting substances, greenhouse gases, and all other substances or wastes of any nature

regulated pursuant to any Environmental Law or as to which any Governmental Authority with applicable jurisdiction requires investigation, reporting or remedial action pursuant to any Environmental Law.

"Hedging Obligations" means, with respect to any Person, all liabilities of such Person under currency exchange agreements, interest rate swap agreements, interest rate cap agreements and interest rate collar agreements, and all other agreements or arrangements designed to protect such Person against fluctuations in interest rates or currency exchange rates.

"herein," "hereof," "hereto," "hereunder" and similar terms contained in any Loan Document refer to such Loan Document as a whole and not to any particular Section, paragraph or provision of such Loan Document.

"Holdings" has the meaning set forth in the preamble hereto.

"IFRS" means international financial reporting standards issued by the International Accounting Standards Board, as generally accepted in France and endorsed by the European Union.

"Impermissible Qualification" means any qualification or exception to the opinion or certification of any independent public accountant as to any financial statement of Holdings, the Borrower which (a) is of a "going concern" or similar nature (other than any "going concern" or like qualification or exception with respect to, or resulting from, the impending maturity of the Loans), (b) relates to the limited scope of examination of matters relevant to such financial statement, or (c) relates to the treatment or classification of any item in such financial statement and which, as a condition to its removal, requires an adjustment to such item the effect of which is to cause the Borrower to be in Default.

"including" and **"include"** means including without limiting the generality of any description preceding such term, and, for purposes of each Loan Document, the Parties agree that the rule of *ejusdem generis* shall not be applicable to limit a general statement, which is followed by or referable to an enumeration of specific matters, to matters similar to the matters specifically mentioned.

"IND" means an Investigational New Drug Application as defined in FDA's regulations at 21 C.F.R. Part 312, or any successor application or procedure filed with the FDA, or any foreign equivalent.

"Indebtedness" of any Person means:

- (a) all obligations of such Person for borrowed money or advances and all obligations of such Person evidenced by bonds, debentures, notes or similar instruments;
- (b) all obligations, contingent or otherwise, relative to the face amount of all letters of credit, whether or not drawn, and banker's acceptances issued for the account of such Person;
- (c) all Capitalized Lease Liabilities of such Person and all obligations of such Person arising under Synthetic Leases;
- (d) net Hedging Obligations of such Person;
- (e) all obligations of such Person in respect of Disqualified Capital Securities;

- (f) whether or not so included as liabilities in accordance with IFRS, all obligations of such Person to pay the deferred purchase price of property or services (excluding trade accounts payable in the ordinary course of business which are not overdue for more than 90 days or, if overdue for more than 90 days, as to which a dispute exists and adequate reserves in conformity with IFRS have been established on the books of such Person), and indebtedness secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) a Lien on property owned or being acquired by such Person (including indebtedness arising under conditional sales or other title retention agreements), whether or not such indebtedness shall have been assumed by such Person or is limited in recourse;
- (g) all indebtedness (including Indebtedness of other types covered by the other clauses of this definition) of such Person or another Person secured by any Lien on any assets or property of such Person, whether or not such indebtedness has been assumed or is recourse (with the amount thereof, in the case of any such indebtedness that has not been assumed by such Person, being measured as the lower of (y) fair market value of such property and (z) the amount of the indebtedness secured); and
- (h) all Contingent Liabilities of such Person in respect of any of the foregoing.

The Indebtedness of any Person shall include the Indebtedness of any other Person (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such Person, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor. Notwithstanding the foregoing, "Indebtedness" shall exclude any earn-out obligations, contingent deferred purchase price obligations, post-closing purchase price adjustments, working capital adjustments, holdback obligations or indemnification obligations incurred in connection with any Permitted Acquisition, permitted Investment or permitted Disposition, in each case, unless and until such obligation (i) is required to be included as a liability on the balance sheet of such Person in accordance with IFRS or (ii) is earned and becomes payable in accordance with the terms of the applicable documentation giving rise to such obligation and is not paid when due.

"Indemnified Liabilities" is defined in Section 10.4.

"Indemnified Parties" is defined in Section 10.4.

"Infringement" and **"Infringes"** mean the misappropriation or other violation of know-how, trade secrets, confidential information, or Intellectual Property.

"Initial Commitment Amount" as to each Lender, means its obligation to make a portion of the Initial Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Initial Commitment Amount of all of the Lenders as in effect on the Closing Date is \$45,000,000.

"Initial Lender" means each of Deerfield and OrbiMed.

"Initial Loan" is defined in Section 2.1.

"Inside Information" means any (a) "material non-public information" in respect of, or relating to, Holdings, any of its Affiliates, Capital Securities or other securities or any other publicly listed or traded company, or (b) any "insider information" or "inside information" or other

information (i) which, if used by any Person in connection with (or possessed by any Person while) purchasing, selling or otherwise trading in any Capital Securities or other securities of Holdings or any other publicly listed or traded company, could result in the violation of any Applicable Securities Laws, or (ii) the possession of which could otherwise restrict or limit trading by any Person in any Capital Securities or other securities of Holdings or any other publicly listed or traded company under any Applicable Securities Laws.

"Intellectual Property" means all: (a) Patents, all patent applications and invention disclosure documents of any type, registrations and renewals, reissues, reexaminations and patent rights in any lawful form thereof; (b) Trademarks; (c) Copyrights and other works of authorship (registered or unregistered), and all applications, registrations and renewals thereof; (d) computer software, databases, data and documentation; (e) trade secrets and confidential business information, whether patentable or unpatentable and whether or not reduced to practice, know-how, inventions, manufacturing processes and techniques, research and development information, data and other information included in or supporting Regulatory Authorizations; (f) other intellectual property or similar proprietary rights; and (g) any and all improvements to any of the foregoing which is at any time owned, assigned to or is by contract owned or assigned to Holdings, the Borrower, its Subsidiaries or their respective agents.

"Investment" means, relative to any Person, (a) any loan, advance or extension of credit made by such Person to any other Person, including the purchase by such Person of any bonds, notes, debentures or other debt securities of any other Person, (b) Contingent Liabilities in favor of any other Person, and (c) any Capital Securities held by such Person in any other Person. The amount of any Investment shall be the original principal or capital amount thereof less all returns of principal or equity thereon and shall, if made by the transfer or exchange of property other than cash, be deemed to have been made in an original principal or capital amount equal to the fair market value of such property at the time of such Investment.

"Ixiaro" means the vaccine product indicated for active immunization for the prevention of disease caused by Japanese encephalitis, manufactured, distributed, offered for sale or sold under the Ixiaro or Jespect brand or any successor product.

"Key Contracts" means the Defense Logistics Agency Firm Fixed Price Indefinite Delivery Indefinite Quantity (IDIQ) federal contract, pursuant to which Valneva USA provides Ixiaro to the United States Department of Defense.

"Key Permits" means all Permits relating to the Products, which Permits are material to the business of the Borrower and its Subsidiaries, taken as a whole.

"knowledge" of Holdings means the knowledge of any senior officer or executive officer of Holdings or any of its Subsidiaries.

"Laws" means all applicable federal, state, provincial, territorial, U.S. or non-U.S. laws, statutes, ordinances, rules, regulations, binding guidances, judgments, orders, injunctions, decrees, arbitration awards and Key Permits issued by any Governmental Authority.

"Lender" means each Person identified as a "Lender" on the signature pages hereto and its successors and permitted assigns.

"Lending Office" means, as to any Lender, the office address of such Lender and, as appropriate, account of such Lender set forth on Schedule 10.2 or such other address or account as such Lender may from time to time notify the Borrower and the Administrative Agent.

"Lien" means any security interest, mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or otherwise), charge against or interest in property, or other priority or preferential arrangement of any kind or nature whatsoever, to secure payment of a debt or performance of an obligation.

"Liquidity" means, at any time, an amount determined for Holdings and its consolidated Subsidiaries equal to the sum of unrestricted cash-on-hand and Cash Equivalent Investments of Holdings and its consolidated Subsidiaries, to the extent held in a Controlled Account; provided that, solely for purposes of the definition of "Liquidity", amounts held in any Reinvestment Account shall not be deemed to be held in a Controlled Account.

"Loan Documents" means, collectively, this Agreement, any Notes, the Security Agreements, each other agreement pursuant to which a Lien is granted to secure the Obligations (including any mortgages or other documents entered into pursuant to Section 7.8), the Guarantee, and each other agreement, certificate, document or instrument executed and delivered by any Loan Party in favor, or for the benefit, of the Administrative Agent, any Lender or any other Secured Party in connection with any Loan Document, whether or not specifically mentioned herein or therein, but excluding the Organic Documents of any Loan Party.

"Loan Parties" means, collectively, the Borrower and each Guarantor.

"Loan Request" means a Loan request and certificate duly executed by an Authorized Officer of the Borrower, substantially in the form of Exhibit B hereto or any other form approved by the Administrative Agent and the Required Lenders.

"Loans" means the Initial Loan and the Delayed Draw Loans.

"Material Adverse Effect" means a material adverse effect on (a) the business, condition (financial or otherwise), operations, performance or properties of Holdings, the Borrower and the Subsidiaries taken as a whole, (b) the rights and remedies of any Secured Party under any Loan Document or (c) the ability of Holdings, the Borrower and the other Loan Parties to perform their Obligations under any Loan Document; provided that notwithstanding the foregoing, any delay or setback (but not any liability to Holdings, the Borrower or any Subsidiary as a result thereof) in the research and development process or the approval process of any Governmental Authority with respect to any R&D Product, including any resulting or related adverse effects on the public stock price of the Capital Securities of Holdings, shall not in and of itself constitute a Material Adverse Effect hereunder so long as the effects of any such delay or setback, as applicable, do not substantially threaten the overall earnings potential of Holdings, the Borrower and the Subsidiaries from commercial Products in a durationally-significant manner.

"Material Agreements" means: (a) each contract or agreement to which Holdings, the Borrower or any Subsidiary is a party involving aggregate payments made to or from a Person that is not Holdings, the Borrower or any Subsidiary in any calendar year of more than €1,000,000; and (b) any other contract or agreement with respect to which a default or breach of the terms thereof would reasonably be expected to result in a Material Adverse Effect. The Loan Documents shall not constitute Material Agreements for purposes of this Agreement and the other Loan Documents.

"Material Subsidiary" means each Subsidiary which: (a) is organized under the laws of Austria, the United Kingdom (including Scotland), Sweden, Canada (including any province thereof), or the United States (including any state thereof or the District of Columbia); (b) holds right, title or interest in any Intellectual Property that is material to the business of the Loan Parties; (c) holds or maintains any material Regulatory Authorization, whether now in effect or hereafter issued by any Regulatory Agency, including any Key Permits received from the FDA and any CE Mark; (d) [reserved]; (e) is party to any Material Agreement, other than ordinary course contracts or agreements (including leases of real property) that are not material to the business of the Loan Parties and other than any Material Agreement between such Subsidiary and Holdings, the Borrower or another Subsidiary; (f) is party to any Key Contract; (g) has assets with a book value or fair market value exceeding €5,000,000 in the aggregate; (h) [reserved]; or (i) as of the last day of the most recent Fiscal Quarter for which financial statements have been delivered pursuant to Section 7.1(b) or 7.1(c) (or, if prior to the date of the delivery of the first financial statements to be delivered pursuant to Section 7.1(b) or 7.1(c), the most recent financial statements referred to in Section 5.6), for the period of four consecutive Fiscal Quarters then ended, contributed greater than

5% of the Revenue Base for such period; provided that, with respect to any Subsidiary that is organized under the laws of France and whose business, assets or operations solely relate to distribution, marketing and sales of Products to customers in France, the preceding clauses (b), (c), (e), (g) and (i) shall not apply and such Subsidiary shall only constitute a Material Subsidiary to the extent that such Subsidiary meets the criteria set forth in the preceding clause (f); provided, further, that from and after the Eighth Amendment Effective Date and the consummation of the VBC-3 Acquisition, VBC-3 shall be deemed not to be a Material Subsidiary unless and until such date that VBC-3 ceases to comply with the covenant in Section 8.16 (it being understood that on any date that VBC-3 becomes a Material Subsidiary pursuant to this proviso, it shall comply with all obligations of a Material Subsidiary under this Agreement, including Section 7.8).

"Maturity Date" means, (i) with respect to all Loans other than the Sixth Delayed Draw Loans and the Seventh Delayed Draw Loans, the Existing Maturity Date, and (ii) with respect to the Sixth Delayed Draw Loans and the Seventh Delayed Draw Loans, the Seventh Amendment Tranche Maturity Date.

"Monthly Report" means a monthly financial report delivered by Holdings and the Subsidiaries to the Supervisory Board of Holdings for each calendar month (other than January and July) of each Fiscal Year, which monthly financial report shall be substantially in the form of Exhibit I hereto or any other form approved by the Required Lenders.

"Moody's" means Moody's Investors Service, Inc., and any successor thereto.

"NDA" means a new drug application, as that term is defined by section 505 of the FD&C Act, and any foreign equivalent.

"Net Asset Sales Proceeds" means, with respect to a Disposition (other than any Disposition permitted by Sections 8.8(a), (b), (d), (e), (f), (g), (h), (i), (j), (l), (m), (n), (o) or (p)) after the Closing Date by Holdings, the Borrower or any Subsidiary to any Person of any assets of Holdings, the Borrower or its Subsidiaries, the excess of gross cash proceeds received by Holdings, the Borrower or any Subsidiary from such Disposition over (i) all reasonable and customary costs and expenses, and including Taxes payable or reasonably estimated to be payable in respect of such Disposition, incurred in connection with such Disposition which have not been paid to Holdings, the Borrower or any of the Subsidiaries in connection therewith, (ii) any portion of such proceeds deposited in an escrow account pursuant to the documentation relating to such Disposition and (iii) the amount of any reserves established by Holdings, the Borrower and the Subsidiaries to fund purchase price adjustments, indemnification, other contingent liabilities or any other liabilities retained by Holdings, the Borrower or the Subsidiaries associated with any asset that is subject to such Disposition (as determined by the Borrower in good faith), it being understood that Net Asset Sales Proceeds shall include (x) any amounts released from any escrow described under clause (ii) and the reversal of any reserves described in clause (iii) to the extent such release or reversal occurs without the satisfaction of any applicable liabilities in cash in a corresponding amount, and (y) the amounts described under clauses (ii) and (iii) if the applicable liabilities are satisfied or terminated other than in cash and such amounts have not been released or reversed within 90 days of such satisfaction or termination) but excluding any proceeds required to be paid to a creditor (other than the Lenders) that holds a first priority Lien permitted by Section 8.3(e) on the property that is the subject of such Disposition.

"Net Casualty Proceeds" means, with respect to any Casualty Event, the amount of any insurance proceeds (other than business interruption insurance) or condemnation awards received by Holdings, the Borrower or any of the Subsidiaries in connection with such Casualty Event, net of all reasonable and customary costs and expenses, including collection expenses and including Taxes payable or reasonably estimated to be payable in respect of such Casualty Event, incurred in connection with such Casualty Event which have not been paid to Holdings, the Borrower or any of the Subsidiaries in connection therewith, but excluding any proceeds or awards required to be paid to a creditor (other than the Lenders) that holds a first priority Lien permitted by Section 8.3(e) on the property that is the subject of such Casualty Event.

"Net Revenue" means, for any period, net revenue from Products, including license fees, royalty income and milestone payments, of Holdings, the Borrower and the Subsidiaries during such period, as determined in accordance with IFRS. Net Revenue shall be determined in a manner consistent with the methodologies, practices and procedures used in developing the Borrower's audited financial statements.

"Non-Core Assets" means the following assets of Holdings, the Borrower and the Subsidiaries (together, in each case, with any associated Intellectual Property, Material Agreements, Regulatory Authorizations, Permits or other property of Holdings, the Borrower or its Subsidiaries related thereto and not otherwise related to any assets of Holdings, the Borrower or the Subsidiaries that are not Non-Core Assets): (i) EB-66, including the EB-66 vaccine, EB-66 cell lines and other avian cell lines developed therefrom (collectively, "EB-66"), (ii) IC-31, including the IC-31 vaccine and IC-31 adjuvants, (iii) pre-clinical research stage immune-oncology assets, (iv) any assets related to vaccine-repurposing opportunities, (v) the Dukoral Patent in cancer (which, for the avoidance of doubt, shall not include any rights associated with the Dukoral vaccine product indicated for the prevention of cholera), (vi) the services and equipment related to the Clinical Trial Manufacturing business located in Sweden (except, for the avoidance of doubt, to the extent any such services or equipment is necessary or used in connection with the manufacture of Dukoral in Sweden), and (vii) the Capital Securities owned by Holdings in Blink Therapeutics SAS.

"Non-Excluded Taxes" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of the Loan Parties under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

"Note" means a promissory note of the Borrower payable to a Lender, substantially in the form of Exhibit A hereto or any other form agreed upon by the Required Lenders and the Borrower, evidencing the aggregate Indebtedness of the Borrower to such Lender resulting from the outstanding amount of such Loans, and also means all other promissory notes accepted from time to time in substitution therefor or renewal thereof.

"Obligations" means all obligations (monetary or otherwise, whether absolute or contingent, matured or unmatured) of Holdings, the Borrower and each other Loan Party arising under or in connection with a Loan Document and the principal of and premium, if any, and interest (including interest accruing during the pendency of any proceeding of the type described in Section 9.1(h), whether or not allowed in such proceeding) on the Loans.

"OFAC" means the Office of Foreign Assets Control of the United States Department of the Treasury.

"Officer's Certificate" means a certificate executed and delivered by an Authorized Officer of the Borrower in accordance with Section 5.3.

"OrbiMed" means OrbiMed Royalty & Credit Opportunities III, LP and its Affiliates.

"Organic Document" means, relative to Holdings, the Borrower or any Subsidiary, its certificate of incorporation, by-laws, certificate of partnership, partnership agreement, certificate of formation, limited liability agreement, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to Holdings, the Borrower's or any Subsidiary's Capital Securities.

"Original Jurisdiction" means, in relation to a Loan Party, the jurisdiction under whose laws such Loan Party is incorporated as of the date of this Agreement or, in the case of a Loan Party acceding to this Agreement at a later time, as of the date on which it becomes a Loan Party.

"Other Administrative Proceeding" means any administrative proceeding relating to a dispute involving a patent office or other relevant Intellectual Property registry which relates to validity, opposition, revocation, ownership or enforceability of the relevant Intellectual Property.

"Other Connection Taxes" means, with respect to any recipient, Taxes imposed as a result of a present or former connection between the applicable recipient and the jurisdiction imposing such Tax (other than connections arising from such recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

"Other Taxes" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes, or any other excise or property Taxes or similar levies that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"Outside Counsel" means, in respect of any Lender, such Lender's outside counsel as may be designated from time to time by such Lender for purposes hereof and the other Loan Documents (including, to the extent applicable, receiving notices and communications hereunder and under the other Loan Documents). The initial Outside Counsel for Deerfield shall be Katten Muchin Rosenman LLP (Attention: Mark D. Wood).

"Outstanding Amount" means, with respect to any Loans on any date, the aggregate outstanding principal amount thereof after giving effect to any borrowings and prepayments or repayments of any Loans occurring on such date.

"Party" and **"Parties"** have the meanings set forth in the preamble.

"Patent" means any patent or any type of patent application, including all divisions, continuations, continuations in-part, provisionals, continued prosecution applications, substitutions, reissues, reexaminations, *inter partes* review, post-grant review by or any other type of proceeding involving patents and patent applications before any patent office or other Governmental Authority, renewals, extensions, adjustments, restorations, supplemental protection certificates and patent rights in any form and other additions in connection therewith, whether in or related to the United States or any other country or other non-United States jurisdiction.

"Patent Security Agreement" means any Patent Security Agreement executed and delivered by the Borrower or any of the Guarantors, substantially in the form of Exhibit A to the Security Agreement or any other form approved by the Required Lenders.

"Permits" means all permits, licenses, registrations, certificates, orders, approvals, clearances, authorizations, consents, waivers, franchises, variances and similar rights issued by or obtained from any Governmental Authority, including those relating to Environmental Laws and Regulatory Authorizations.

"Permitted Acquisition" means (x) the VBC-3 Acquisition and (y) the purchase or other acquisition of all of the Capital Securities (other than qualifying directors shares) in, or all or substantially all of the property of, or all or substantially all of any business or division of, any Person (other than any joint venture owned by another Person that is purchased or acquired) that, upon the consummation thereof, will be wholly owned directly by Holdings or one or more of its Wholly-Owned Subsidiaries (including as a result of a merger or consolidation); provided that, with respect to each Permitted Acquisition under this clause (y):

- (a) any such newly-created or acquired Subsidiary shall comply with the requirements of Section 7.8;
- (b) the lines of business of the Person to be (or the property of which is to be) so purchased or otherwise acquired shall be permitted pursuant to Section 8.1;

(c) in the case of a purchase or other acquisition of the Capital Securities of another Person, the board of directors (or other comparable governing body) and, if required under applicable Law, the shareholders or equity holders of such other Person shall have duly approved such purchase or other acquisition;

(d) the total cash and non-cash consideration paid by or on behalf of Holdings, the Borrower and its Subsidiaries for any such purchase or other acquisition (excluding any such consideration that is financed with the proceeds of a sale or issuance of Capital Securities (other than Disqualified Capital Securities) that occurs no more than 30 days prior to the consummation of such purchase or acquisition and any consideration paid to the applicable seller in the form of Capital Securities (other than Disqualified Capital Securities)), when aggregated with the consideration paid by or on behalf of Holdings, the Borrower and its Subsidiaries for all other Permitted Acquisitions after the Closing Date shall not exceed an aggregate cumulative amount of €10,000,000;

(e) immediately before and after giving effect to any such purchase or other acquisition, no Default or Event of Default, shall exist or result therefrom;

(f) the Borrower shall have delivered to the Administrative Agent and each Lender that is not a Public-Side Lender, at least 10 Business Days prior to the date on which any such purchase or other acquisition is to be consummated, a written notice describing such transaction, and thereafter, if requested by any Lender for any such transaction involving consideration in excess of €3,000,000, (i) historical financial statements of or related to the Person or assets to be acquired (to the extent reasonably available to the Borrower), (ii) twelve month projections for such Person to be acquired and for the Borrower after giving effect to such transaction, and (iii) material documentation and other material information reasonably requested by any Lender and relating to such transaction; and

(g) such Person shall not have a Canadian Defined Benefit Plan where, following such acquisition, any of the Loan Parties or any of the Subsidiaries (including, for greater certainty, any Person whose Capital Securities have been acquired) shall have any obligation or liability with respect to such Canadian Defined Benefit Plan.

"Permitted Refinancing Indebtedness" means, with respect to any Person, any modification, refinancing, replacement, refunding, renewal or extension of any Indebtedness of such Person; provided that (a) the aggregate principal amount (or accreted value, if applicable) of the Indebtedness incurred pursuant to such modification, refinancing, replacement, refunding, renewal or extension does not exceed the aggregate principal amount (or accreted value, if applicable) of the Indebtedness so modified, refinanced, replaced, refunded, renewed or extended except by an amount equal to unpaid accrued interest, fees, expenses and premium thereon and any make-whole payments applicable thereto and by an amount equal to any existing commitments unutilized thereunder, (b) such modification, refinancing, replacement, refunding, renewal or extension has a final stated maturity date equal to or later than the final stated maturity date of, and has a Weighted Average Life to Maturity equal to or greater than the Weighted Average Life to Maturity of, the Indebtedness being modified, refinanced, replaced, refunded, renewed or extended (excluding the effects of nominal amortization in the amount of no greater than one percent per annum and prepayments of Indebtedness), (c) at the time thereof, no Event of Default shall have occurred and be continuing, (d) such modification, refinancing, replacement, refunding, renewal or extension does not add guarantors, change obligors or provide for security different from that which applied to the Indebtedness being modified, refinanced, replaced, refunded, renewed or extended, (e) to the extent such Indebtedness being modified, refinanced, replaced, refunded, renewed or extended is subordinated in right of payment to the Obligations, such Indebtedness incurred pursuant to such modification, refinancing, replacement, refunding, renewal or extension is subordinated in right of payment to the Obligations on terms at least as favorable to the Lenders as those contained in the documentation governing the Indebtedness being modified, refinanced, replaced, refunded, renewed or extended, and (f) to the extent such Indebtedness being modified, refinanced, replaced, refunded, renewed or extended is secured by Liens that are subordinated to the Liens securing the

Obligations, such as Indebtedness incurred pursuant to such modification, refinancing, replacement, refunding, renewal or extension is unsecured or secured by Liens that are subordinated to the Liens securing the Obligations on terms at least as favorable to the Lenders as those contained in the documentation (including any intercreditor or similar agreements) governing the Indebtedness being modified, refinanced, replaced, refunded, renewed or extended.

"Permitted Subordinated Indebtedness" means Indebtedness incurred after the Closing Date by Holdings, the Borrower or the Subsidiaries that is (a) subordinated to the Obligations pursuant to a written subordination agreement satisfactory to the Required Lenders in their sole discretion and (b) in an amount and on terms approved by the Required Lenders in their sole discretion.

"Person" means any natural person, corporation, limited liability company, partnership, joint venture, association, trust or unincorporated organization, Governmental Authority or any other legal entity, whether acting in an individual, fiduciary or other capacity.

"PHSA" means the United States Public Health Service Act (or any successor thereto), as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Platform" has the meaning set forth in **Section 10.2**.

"PPSA" means the *Personal Property Security Act* (Ontario) and the regulations thereunder, as from time to time in effect; **provided** that, if attachment, perfection or priority of the Administrative Agent's security interests in any Collateral of the Loan Parties are governed by the personal property security laws of any provincial jurisdiction in Canada other than Ontario or Quebec, then "PPSA" means those personal property security laws in such other jurisdiction for the purposes of the provisions hereof relating to such attachment, perfection or priority and for the definitions related to such provision.

"Privacy Laws" means all applicable security and privacy standards regarding protected health information under (a) the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, including the regulations promulgated thereunder and (b) any applicable state privacy Laws, and, in each case, similar laws of any non-United States jurisdiction.

"Product" means (i) Dukoral, (ii) Ixiaro and (iii) any current or future service or product researched, designed, developed, manufactured, licensed, marketed, sold, performed, distributed or otherwise commercialized by Holdings, the Borrower or any of its Subsidiaries, including any current or future R&D Product.

"Product Agreement" means each agreement, license, document, instrument, interest (equity or otherwise) or the like under which one or more parties grants or receives any right, title or interest with respect to any Product Development and Commercialization Activities in respect of one or more Products specified therein or to exclude third parties from engaging in, or otherwise restricting any right, title or interest as to any Product Development and Commercialization Activities with respect thereto, including each contract or agreement with suppliers, manufacturers, distributors, clinical research organizations, hospitals, group purchasing organizations, wholesalers, pharmacies or any other Person related to any such entity.

"Product Development and Commercialization Activities" means, with respect to any Product, any combination of research, development, manufacture, import, use, sale, importation, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to commercially exploit such Product.

"Product Reference Date" means (i) January 1, 2015 with respect to Ixiaro and (ii) January 1, 2016 with respect to Dukoral.

"Public-Side Lender" means each of Deerfield and each other Lender who, following the Closing Date, delivers written notice to the Borrower of such Lender's election to become a "Public-Side Lender" under this Agreement, in each case, until and only to the extent that such Lender delivers written notice to the Borrower of such Lender's election to no longer be a Public-Side Lender (subject to the right of such Lender to subsequently elect, by written notice to the Borrower, to elect to again be a Public-Side Lender). For the avoidance of doubt, a Public-Side Lender may elect, by written notice to the Borrower (with a copy to the Administrative Agent), to receive (or to provide that such Lender's Outside Counsel shall receive) reports, notices and/or information that would not otherwise be provided to such Public-Side Lender, in a specified case or on an ongoing basis.

"Publicly Disclose" means, in respect of any information, to publicly disclose such information through a filing under Applicable Securities Laws and/or through a widely disseminated press release, in any event, in a manner such that, after the making of such public disclosure, such information could in no event constitute or be deemed to constitute Inside Information.

"Purchase Money Indebtedness" means Indebtedness: (a) consisting of the deferred purchase price for property incurred in connection with the acquisition of such property, where the amount of such Indebtedness does not exceed the greater of (i) the cost of the property being financed and (ii) the fair market value of such property; and (b) incurred to finance such acquisition by Holdings, the Borrower or a Subsidiary of such property.

"Qualified Capital Securities" means any Capital Securities that are not Disqualified Capital Securities.

"Quebec Loan Party" means any Loan Party that is existing under the Laws of the Province of Quebec, or that has its registered office, its head office, its chief executive office, a place of business, any tangible or corporeal property or a Controlled Account in the Province of Quebec.

"R&D Product" means any service or product researched and designed by Holdings, the Borrower or any Subsidiary that is currently in development or that may be developed in the future but, in any case, excluding any Product that has been commercialized.

"Receiving Party" means the Party receiving Confidential Information.

"Recipients" is defined in [Section 10.14](#).

"Register" has the meaning specified in [Section 10.10\(c\)](#).

"Regulatory Agencies" means any Governmental Authority that is concerned with the use, control, safety, efficacy, reliability, manufacturing, testing, marketing, distribution, sale or other Product Development and Commercialization Activities relating to any Product of Holdings, the Borrower or any of the Subsidiaries, including CMS, FDA, and all similar agencies in other jurisdictions, including non-United States jurisdictions, and includes Standard Bodies.

"Regulatory Authorizations" means, with respect to the development, commercialization or sale of any Products, all approvals, clearances, notifications, authorizations, orders, exemptions, registrations, listings, certifications, licenses and Permits granted by, submitted to or filed with any Regulatory Agencies, including any IND, NDA or BLA.

"Reinvestment Account" has the meaning specified in [Section 3.2\(c\)](#).

“Related Parties” means, with respect to any Person, such Person's Affiliates and the shareholders, members, partners, managers, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person's Affiliates.

“Release” means any releasing, disposing, discharging, injecting, spilling, leaking, leaching, pumping, pouring, dumping, depositing, emitting, escaping, emptying, seeping, dispersal, migrating or placing, including movement through, into or upon the environment or any natural or man-made structure.

“Relevant Jurisdiction” means, in relation to a Loan Party, (i) its Original Jurisdiction; (ii) any jurisdiction where any Collateral or asset required to be Collateral owned by it is situated; (iii) any jurisdiction where it conducts its business; and (iv) the jurisdiction whose laws govern the perfection of any Lien created under any of the Security Agreements entered into by it.

“Repayment Premium” means a premium equal to:

(a) (i) if any prepayment or repayment is made or required to be made with respect to any Loan other than the Sixth Delayed Draw Loans or Seventh Delayed Draw Loans on or prior to December 31, 2023, a “Make-Whole Amount” in respect of the principal amount of any prepayment or repayment of the applicable Loan, determined (without duplication) by the Required Lenders, equal to the sum of (x) five percent (5.00%) of the principal amount to be repaid or prepaid and (y) the amount of all interest which would otherwise have accrued hereunder for the period from the date of such repayment or prepayment (or the date on which such repayment or prepayment was required to be made, if earlier) to December 31, 2023; provided that if the prepayment or repayment made pursuant to this clause (a)(i) is in connection with a transaction that results in a Change in Control at a time when no Default or Event of Default has occurred or is continuing, the Repayment Premium shall be 9.95% of the principal amount of such prepayment or repayment of the applicable Loan; or (ii) if any prepayment or repayment is made or required to be made with respect to any Sixth Delayed Draw Loans or Seventh Delayed Draw Loans on or prior to February 16, 2025, a “Make-Whole Amount” in respect of the principal amount of any prepayment or repayment of the applicable Loan, determined (without duplication) by the Required Lenders, equal to the sum of (x) five percent (5.00%) of the principal amount to be repaid or prepaid and (y) the amount of all interest which would otherwise have accrued hereunder for the period from the date of such repayment or prepayment (or the date on which such repayment or prepayment was required to be made, if earlier) to August 16, 2026;

(b) five percent (5.00%) of the principal amount of any prepayment or repayment of the applicable Loan, if such prepayment or repayment is not made or required to be made prior to, and is made or required to be made (i) in the case of any Loan other than Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after January 1, 2024, but on or prior to December 31, 2024, or (ii) in the case of Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after February 17, 2025, but on or prior to August 16, 2025;

(c) three percent (3.00%) of the principal amount of any prepayment or repayment of the applicable Loan, if such prepayment or repayment is not made or required to be made prior to, and is made or required to be made (i) in the case of any Loan other than Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after January 1, 2025, but on or prior to December 31, 2025, or (ii) in the case of Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after August 17, 2025, but on or prior to August 16, 2026;

(d) one percent (1.00%) of the principal amount of any prepayment or repayment of the applicable Loan, if such prepayment or repayment is not made or required to be made on or prior to, and is made or required to be made (i) in the case of any Loan other than Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after January 1, 2026, but prior to the Existing Maturity Date or (ii) in the case of Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, on or after August 17, 2026, but on or prior to August 16, 2027; or

(e) zero percent (0.00%) of the principal amount of any prepayment or repayment of any Sixth Delayed Draw Loan or Seventh Delayed Draw Loan, if such prepayment or repayment is not made or required to be made on or prior to, and is made or required to be made on or after August 17, 2027.

"Required Lenders" means Lenders having Total Credit Exposures representing more than 50% of the Total Credit Exposures of all Lenders; **provided** that so long as OrbiMed Royalty & Credit Opportunities III, LP has not assigned any Loans to a non-Affiliated Person, OrbiMed Royalty & Credit Opportunities III, LP shall be a Required Lender; **provided, further** that so long as Deerfield Partners, L.P. has not assigned any Loans to a non-Affiliated Person, Deerfield Partners, L.P. shall be a Required Lender.

"Restricted Payment" means (a) the declaration or payment of any dividend (other than dividends payable solely in Capital Securities (other than Disqualified Capital Securities)) on, or the making of any payment or distribution on account of, or setting apart assets for a sinking or other analogous fund for the purchase, redemption, defeasance, retirement or other acquisition of, any class of Capital Securities of Holdings, the Borrower or any Subsidiary, or (b) the making of any other distribution in respect of such Capital Securities, in each case either directly or indirectly, whether in cash, property or obligations of Holdings, the Borrower or any Subsidiary or otherwise.

"Revenue Base" means, with respect to any period, the Net Revenues of all Products for such period.

"ROFR Exercise Notice" has the meaning specified in Section 10.10(f)(i).

"ROFR Lender" has the meaning specified in Section 10.10(f)(i).

"ROFR Loans" has the meaning specified in Section 10.10(f)(i).

"ROFR Notice" has the meaning specified in Section 10.10(f)(i).

"ROFR Period" has the meaning specified in Section 10.10(f)(i).

"RPMRR" means the Register of Personal and Movable Real Rights for the Province of Quebec.

"S&P" means Standard & Poor's Financial Services LLC, a division of S&P Global Inc., and any successor thereto.

"Sale and Leaseback Transaction" has the meaning specified in Section 8.12.

"Sanctions" means any international economic sanction administered or enforced by the United States government (including OFAC), France or its governmental institutions, agencies or subdivisions, Canada or its governmental institutions, agencies or subdivisions (including, without limitation, the Royal Canadian Mounted Police, the Canada Border Services Agency, the Department of Foreign Affairs, Trade and Development (Canada) or the Department of Justice (Canada)), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority (including, without limitation, any Canadian sanctions administered under the *Proceeds of Crime (Money Laundering) Terrorist Financing Act* (Canada) and any other similar Canadian statute or regulation that is now or hereafter in effect).

"Scots Security Documents" means (i) a Scots law governed standard security to be granted by Valneva Scotland Limited, in favor of the Administrative Agent, in respect of its interest in ALL and WHOLE the subjects registered in the Land Register of Scotland under Title Numbers MID4303 and WLN39630, (ii) a Scots law governed bond and floating charge to be granted by Valneva Scotland Limited, in favor of the Administrative Agent, over the whole of the property (including uncalled capital)

which is or may be from time to time comprised in the Collateral owned by Valneva Scotland Limited, and (iii) a Scots law share pledge to be granted by the Borrower, in favor of the Administrative Agent, in respect of the entire issued share capital of Valneva Scotland Limited, together with all documentation required to register the shares in the name of the Administrative Agent and all evidence of such registration as the Required Lenders may reasonably request.

"Second Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the Second Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Second Delayed Draw Commitment Amount of all of the Lenders as in effect on the Closing Date is \$12,500,000.

"Second Delayed Draw Commitment Termination Date" means the earliest to occur of (a) the Second Delayed Draw Funding Date (immediately after the making of the Second Delayed Draw Loan on such date), (b) the nine-month anniversary of the Funding Date and (c) March 4, 2020, if the Initial Loan shall not have been made hereunder prior to such date.

"Second Delayed Draw Funding Date" means the date of the making of the Second Delayed Draw Loan hereunder, which in no event shall be later than December 3, 2020.

"Second Delayed Draw Loan" is defined in Section 2.1.

"Secured Parties" means the Lenders, the Administrative Agent and each Indemnified Party.

"Security Agreements" mean (a) the Pledge and Security Agreement executed and delivered by Valneva USA and the Administrative Agent, substantially in the form of Exhibit E hereto or any other form approved by the Required Lenders, (b) the Stock Pledge Agreement executed and delivered by the Borrower and the Administrative Agent, (c) the Austrian Security Documents, (d) the English Debenture, (e) the Canadian Security Documents, (f) the French Security Documents, (g) the Scots Security Documents, and (h) the Swedish Security Documents.

"Selling Lender" has the meaning specified in Section 10.10(f)(i).

"Seventh Amendment" means that Seventh Amendment, dated as of August 16, 2023, among the Borrower, Holdings, the Guarantors party thereto, the Lenders party thereto, and the Administrative Agent.

"Seventh Amendment Effective Date" shall have the meaning set forth in the Seventh Amendment.

"Seventh Amendment Tranche Maturity Date" means August 16, 2028.

"Seventh Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the Seventh Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Seventh Delayed Draw Commitment Amount of all of the Lenders as in effect on the Seventh Amendment Effective Date is \$50,000,000.

"Seventh Delayed Draw Commitment Termination Date" means the earlier to occur of (a) the Seventh Delayed Draw Funding Date (immediately after the making of the Seventh Delayed Draw Loan on such date), and (b) December 31, 2023, if the Seventh Delayed Draw Loan shall not have been made hereunder prior to such date.

"Seventh Delayed Draw Funding Date" means the date of the making of the Seventh Delayed Draw Loan hereunder, which in no event shall be later than December 31, 2023.

"Seventh Delayed Draw Loan" is defined in Section 2.1.

"Sixth Delayed Draw Commitment Amount" as to each Lender, means its obligation to make a portion of the Sixth Delayed Draw Loan to the Borrower pursuant to Section 2.1, in the principal amount set forth opposite such Lender's name on Schedule 2.1. The aggregate principal amount of the Sixth Delayed Draw Commitment Amount of all of the Lenders as in effect on the Seventh Amendment Effective Date is \$50,000,000.

"Sixth Delayed Draw Commitment Termination Date" means the Sixth Delayed Draw Funding Date (immediately after the making of the Sixth Delayed Draw Loan on such date).

"Sixth Delayed Draw Funding Date" means the date of the making of the Sixth Delayed Draw Loan hereunder, which in no event shall be later than the Seventh Amendment Effective Date.

"Sixth Delayed Draw Loan" is defined in Section 2.1.

"Solvent" means, with respect to any Person on a particular date, that on such date (a) the fair value of the property of such Person is greater than the total amount of liabilities, including contingent liabilities, of such Person, (b) the present fair saleable value of the assets of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (c) such Person has not incurred and does not intend to, and does not believe that it will, incur debts or liabilities beyond its ability to pay as such debts and liabilities mature, (d) such Person is not engaged in a business or a transaction, and is not about to engage in a business or a transaction, for which the property of such Person would constitute an unreasonably small capital, (e) such Person has not executed this Agreement or any other Loan Document, or made any transfer or incurred any obligations hereunder or thereunder, with actual intent to hinder, delay or defraud either present or future creditors, (f) solely with respect to any Person organized under the laws of the United Kingdom (including Scotland), such Person has not suspended making payments on any of its debts as they fall due, (g) solely with respect to any Person organized under the laws of the United Kingdom (including Scotland), such Person has not, by reason of actual or anticipated financial difficulties, commenced negotiations with one or more of its creditors (excluding any Secured Party in its capacity as such) with a view to rescheduling any of its indebtedness, and (h) solely with respect to any Person organized under the laws of the United Kingdom (including Scotland), no moratorium has been declared in respect of any indebtedness of such Person. The amount of Contingent Liabilities at any time shall be computed as the amount that, in light of all the facts and circumstances existing at such time, can reasonably be expected to become an actual or matured liability.

"Standard Bodies" means any of the organizations that create, sponsor or maintain safety, quality or other standards, including ISO, ANSI, CEN and SCC and the like.

"Swedish Security Documents" means (a) a Swedish law governed pledge over shares in Vaccines Holdings Sweden AB to be granted by Holdings in favor of the Administrative Agent, (b) a Swedish law governed pledge over shares in Valneva Sweden AB to be granted by Vaccines Holdings Sweden AB in favor of the Administrative Agent, (c) a Swedish law governed pledge over Swedish business mortgage certificates to be granted by Valneva Sweden AB in favor of the Administrative Agent, (d) a Swedish law governed pledge over bank accounts to be granted by Vaccines Holdings Sweden AB in favor of the Administrative Agent, (e) a Swedish law governed pledge over bank accounts to be granted by Valneva Sweden AB in favor of the Administrative Agent and (f) a Swedish law governed pledge over IP-rights in the form of trademarks to be granted by Valneva Sweden AB in favor of the Administrative Agent.

"Subsidiary" means, with respect to any Person, (a) any other Person with respect to which such first Person directly or indirectly has the right or power to direct or cause the direction of the management and policies of such other Person or (b) any other Person in respect of which more than 50% of the outstanding Voting Securities of such other Person (irrespective of whether at the time Capital Securities of any other class or classes of such other Person shall or might have voting power upon the occurrence of any contingency) is at the time directly or indirectly owned or controlled by such first Person, by such first Person and one or more other Subsidiaries of such first

Person, or by one or more other Subsidiaries of such first Person. Unless the context otherwise specifically requires, the term "Subsidiary" shall be a reference to a Subsidiary of Holdings.

"**Synthetic Lease**" means, as applied to any Person, any lease (including leases that may be terminated by the lessee at any time) of any property (whether real, personal or mixed) (a) that is not a finance lease in accordance with IFRS and (b) in respect of which the lessee retains or obtains ownership of the property so leased for federal income Tax purposes, other than any such lease under which that Person is the lessor.

"**Taxes**" means all income, stamp or other taxes, duties, levies, imposts, charges, assessments, fees, deductions or withholdings, now or hereafter imposed, levied, collected, withheld or assessed by any Governmental Authority, and all interest, additions to tax, penalties or similar liabilities with respect thereto.

"**Termination Date**" means the earlier of (a) the date on which all Obligations (other than contingent indemnification and expense reimbursement obligations for which no claim has been made) have been paid in full in cash and the Commitment has terminated and (b) March 4, 2020, if the Initial Loan shall not have been made hereunder prior to such date.

"**Third Delayed Draw Commitment Amount**" as to each Lender, means its obligation to make a portion of the Third Delayed Draw Loan to the Borrower pursuant to **Section 2.1**, in the principal amount set forth opposite such Lender's name on **Schedule 2.1**. The aggregate principal amount of the Third Delayed Draw Commitment Amount of all of the Lenders as in effect on the Closing Date is \$12,500,000.

"**Third Delayed Draw Commitment Termination Date**" means the earliest to occur of (a) the Third Delayed Draw Funding Date (immediately after the making of the Third Delayed Draw Loan on such date), (b) the first anniversary of the Funding Date and (c) March 4, 2020, if the Initial Loan shall not have been made hereunder prior to such date.

"**Third Delayed Draw Funding Date**" means the date of the making of the Third Delayed Draw Loan hereunder, which in no event shall be later than March 3, 2021.

"**Third Delayed Draw Loan**" is defined in **Section 2.1**.

"**Third Party**" means any Person other than Holdings, the Borrower or any of its Subsidiaries.

"**Total Credit Exposure**" means, as to any Lender at any time, the Outstanding Amount of the Initial Loans and the Outstanding Amount of all Delayed Draw Loans, as applicable, in each case, of such Lender at such time.

"**Trademark**" means any trademark, whether registered or not, service mark, trade name, logo, symbol, trade dress, trade style, domain name, corporate name, company name, fictitious business name, certification mark, collective mark or other business identifier or indicator of source or origin, and all applications, registrations and renewals therefor, together with all of the goodwill associated therewith.

"**Trademark Security Agreement**" means each Trademark Security Agreement executed and delivered by the Borrower or any of the Guarantors, substantially in the form of Exhibit B to any Security Agreement or any other form approved by the Required Lenders.

"**UCC**" means the Uniform Commercial Code as in effect from time to time in the State of New York; provided that, if, with respect to any financing statement or by reason of any provisions of Law, the perfection or the effect of perfection or non-perfection of the security interests granted to any Secured Party pursuant to the applicable Loan Document is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than New York, then "UCC"

means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of each Loan Document and any financing statement relating to such perfection or effect of perfection or non-perfection.

"Undrawn Fee" is defined in [Section 3.10](#).

"United States" or **"U.S."** means the United States of America, its fifty states, its territories and jurisdictions, and the District of Columbia.

"Upfront Fee" is defined in [Section 3.11](#).

"U.S. Dollar Equivalent" means with respect to any monetary amount in a currency other than U.S. Dollars (including Canadian Dollars), at any time for determination thereof, the amount of U.S. Dollars obtained by converting such foreign currency involved in such computation into U.S. Dollars at the spot rate for the purchase of U.S. Dollars with the applicable foreign currency as published by the Statistical Data Warehouse of the European Central Bank in the section entitled "ECB/Eurosystem policy and exchange rates" under the heading "Exchange rates" (<https://sdw.ecb.europa.eu/browse.do?node=9691113>) on the date that is one Business Day prior to such determination.

"Valneva Canada" means Valneva Canada Inc., a corporation existing under the *Canada Business Corporations Act* and a Wholly-Owned Subsidiary of Holdings.

"Valneva France" means Valneva France SAS, a *société par actions simplifiée* incorporated under the laws of France, whose registered office at 6 rue Alain Bombard, 44800 Saint-Herblain, France, and registered with the Trade and Companies Registry (*Registre du Commerce et des Sociétés*) of Nantes under registration number 848 509 295, and a Wholly-Owned Subsidiary of Holdings.

"Valneva USA" means Valneva USA Inc., a Delaware corporation and a Wholly-Owned Subsidiary of Holdings.

"VBC-3" means VBC-3 Errichtungs GmbH, a company organized and existing under the laws of Austria.

"VBC-3 Acquisition" means a transaction pursuant to which Borrower and Holdings shall acquire 100% of the issued and outstanding equity interests of VBC-3, following which Borrower shall own 94% of the equity interests of VBC-3 and Holdings shall own 6% of the equity interests of VBC-3.

"Voting Securities" means, with respect to any Person, Capital Securities of any class or kind ordinarily having the power to vote for the election of directors, managers or other voting members of the governing body of such Person.

"Weighted Average Life to Maturity" means, when applied to any Indebtedness, at any date, the quotient obtained by dividing (a) the sum of the products of the number of years from the date of determination to the date of each successive scheduled principal payment of such Indebtedness (including the principal payment due at maturity), multiplied by the amount of such payment; by (b) the sum of all such payments.

"Wholly-Owned Subsidiary" means any direct or indirect Subsidiaries of Holdings, all of the outstanding Capital Securities of which (other than any director's qualifying shares or investments by foreign nationals mandated by applicable Laws) are owned directly or indirectly by Holdings.

SECTION 1.2 [Use of Defined Terms](#). Unless otherwise defined or the context otherwise requires, terms for which meanings are provided in this Agreement shall have such meanings when used in each other Loan Document and the schedules attached hereto.

SECTION 1.3 Interpretation. The division of this Agreement and the other Loan Documents into Articles and Sections and the use of headings and captions is for convenience of reference only and shall not modify or affect the interpretation or construction of this Agreement or any of its provisions. The words “herein,” “hereof,” “hereunder,” “hereinafter” and “hereto” and words of similar import refer to this Agreement. The term “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or.” The term “documents” and “agreements” include any and all instruments, documents, agreements, certificates, indentures, notices and other writings, however evidenced. The use in any of the Loan Documents of the word “include” or “including,” when following any general statement, term or matter, shall not be construed to limit such statement, term or matter to the specific items or matters set forth immediately following such word or to similar items or matters, whether or not non-limiting language (such as “without limitation” or “but not limited to” or words of similar import) is used with reference thereto, but rather shall be deemed to refer to all other items or matters that fall within the broadest possible scope of such general statement, term or matter. References to a specified Article, Exhibit, Section or Schedule shall be construed as a reference to that specified Article, Exhibit, Section or Schedule of this Agreement (or other applicable Loan Document). Unless specifically stated otherwise, any reference to any of the Loan Documents means such document as the same shall be amended, restated, supplemented or otherwise modified and from time to time in effect in accordance with the terms hereof or thereof, as applicable. The references to “assets” and “properties” in the Loan Documents are meant to be mean the same and are used throughout the Loan Documents interchangeably, and such words shall be deemed to refer to any and all tangible and intangible assets and properties, including cash, securities, Capital Securities, accounts and contract rights. Terms (including uncapitalized terms) not otherwise defined herein and that are defined in the UCC shall have the meanings therein described.

SECTION 1.4 Cross-References. Unless otherwise specified, references in a Loan Document to any Article or Section are references to such Article or Section of such Loan Document, and references in any Article, Section or definition to any clause are references to such clause of such Article, Section or definition.

SECTION 1.5 Accounting and Financial Determinations. Unless otherwise specified, all accounting terms used in each Loan Document shall be interpreted, and all accounting determinations and computations thereunder (including under Section 8.4 and the definitions used in such calculations) shall be made, in accordance with IFRS, as in effect from time to time; provided that, if either the Borrower or the Required Lenders request an amendment to any provision hereof to eliminate the effect of any change occurring after the date hereof in IFRS or the application thereof on the operation of such provision, regardless of whether any such notice is given before or after such change in IFRS or the application thereof, then such provision shall be interpreted on the basis of IFRS in effect and applied immediately before such change shall have become effective until such request shall have been withdrawn or such provision amended in accordance herewith. Unless otherwise expressly provided, all financial covenants and defined financial terms shall be computed on a consolidated basis for Holdings and its Subsidiaries, in each case without duplication.

SECTION 1.6 Austrian Terms. Without prejudice to the generality of any provision of this Agreement, in this Agreement or any Loan Document, where it relates to a Person having its Centre of Main Interests in Austria, a reference to:

- (a) a “trustee”, “receiver”, “sequestrator” or “other custodian” shall include any insolvency receiver (*Insolvenzverwalter*);
- (b) a “reorganization” shall include its reorganization in the course of reorganization proceedings under the Austrian IO (*Sanierungsverfahren*) or a company reorganization (*Unternehmensreorganisation*) under the Austrian Act of Company Reorganizations (*Unternehmensreorganisationsgesetz*);
- (c) “fail to be Solvent” shall include such Person to be over-indebted (*überschuldet*) within the meaning of section 67 Austrian IO (as applicable from time to time and provided applicable to that Person), unable to pay its debts as they fall due (*zahlungsunfähig*) within the meaning of section 66 Austrian IO, presumably unable to pay its debts as they fall due (*drohend zahlungsunfähig*) within the meaning of section 167 paragraph 2 Austria IO; and
- (d) “commencement of bankruptcy” or “commencement of insolvency” shall include (i) that Person filing for the opening of insolvency proceedings (*Antrag auf Eröffnung eines Insolvenzverfahrens*) or (ii) the competent court opening insolvency proceedings (*Eröffnung eines Insolvenzverfahrens*) or rejecting (for reason of insufficiency of its funds to implement such proceedings) insolvency proceedings pursuant to Section 71b IO (*Abweisung mangels kostendeckenden Vermögens*) or (iii) the competent court approves any conservatory measure (*einstweilige Vorkehrungen*) pursuant to Section 73 Austrian IO.

SECTION 1.7 Quebec Interpretation Clause. For purposes of any assets, liabilities or entities located in the Province of Québec and for all other purposes pursuant to which the interpretation or construction of this Agreement may be subject to the laws of the Province of Québec or a court or tribunal exercising jurisdiction in the Province of Québec, (a) “personal property” shall be deemed to include “movable property”, (b) “real property” shall be deemed to include “immovable property”, (c) “tangible property” shall be deemed to include “corporeal property”, (d) “intangible property” shall be deemed to include “incorporeal property”, (e) “security interest”, “mortgage” and “lien” shall be deemed to include a “hypothec”, “prior claim”, “reservation of ownership” and a “resolutive clause”, (f) all references to filing, registering or recording under the UCC or the PPSA shall be deemed to include publication under the Civil Code of Québec, (g) all references to “perfection” of or “perfected” liens or security interest shall be deemed to include a reference to an “opposable” or “set up” hypothec as against third parties, (h) any “right of offset”, “right of setoff” or similar expression shall be deemed to include a “right of compensation”, (i) “goods” shall be deemed to include “corporeal movable property” other than chattel paper, documents of title, instruments, money and securities, (j) an “agent” shall be deemed to include a “mandatary”, (k) “construction liens” shall be deemed to include “legal hypothecs in favor of persons having taken part in the construction or renovation of an immovable”, (l) “joint and several” shall be deemed to include “solidary”, (m) “gross negligence or willful misconduct” shall be deemed to be “intentional or

gross fault”; (n) “beneficial ownership” shall be deemed to include “ownership”; (o) “legal title” shall be deemed to include “holding title on behalf of an owner as mandatary or prête-nom”; (p) “easement” shall be deemed to include “servitude”; (q) “priority” shall be deemed to include “rank” or “prior claim”, as applicable; (r) “survey” shall be deemed to include “certificate of location and plan”; (s) “state” shall be deemed to include “province”; (t) “fee simple title” shall be deemed to include “ownership” (including ownership under a right of superficies); (u) “ground lease” shall be deemed to include “emphyteusis” or a “lease with a right of superficies”, as applicable; (v) “leasehold interest” shall be deemed to include “valid rights resulting from a lease”; (w) “lease” shall be deemed to include a “contract of leasing (crédit-bail)” and (x) “deposit account” shall include a “financial account” as defined in Article 2713.6 of the Civil Code of Québec.

ARTICLE II

COMMITMENT AND BORROWING PROCEDURES

SECTION 2.1 Commitment. On the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Initial Loan”) on the Funding Date in an amount equal to (but not less than) such Lender’s Initial Commitment Amount. On the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “First Delayed Draw Loan”) on the First Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s First Delayed Draw Commitment Amount. On the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Second Delayed Draw Loan”) on the Second Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s Second Delayed Draw Commitment Amount. On the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Third Delayed Draw Loan”) on the Third Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s Third Delayed Draw Commitment Amount. Subject to the occurrence of the Fifth Amendment Effective Date, and on the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Fourth Delayed Draw Loan”) on the Fifth Amendment Effective Date in an amount equal to (but not less than) such Lender’s Fourth Delayed Draw Commitment Amount. Subject to the occurrence of the Fifth Amendment Effective Date, and on the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Fifth Delayed Draw Loan”) on the Fifth Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s Fifth Delayed Draw Commitment Amount. Subject to the occurrence of the Seventh Amendment Effective Date, and on the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Sixth Delayed Draw Loan”) on the Sixth Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s Sixth Delayed Draw Commitment Amount. Subject to the occurrence of the Seventh Amendment Effective Date, and on the terms and subject to the conditions of this Agreement, each Lender severally agrees to make its portion of a term loan (the “Seventh Delayed Draw Loan”) on the Seventh Delayed Draw Funding Date in an amount equal to (but not less than) such Lender’s Seventh Delayed Draw Commitment Amount. No amounts paid or prepaid with respect to the Loans may be reborrowed.

SECTION 2.2 Borrowing Procedure. The Borrower may request that the Initial Loan be made by delivering to the Administrative Agent an irrevocable Loan Request on or before 10:00 a.m. on a Business Day at least three Business Days prior to the proposed Funding Date (or such later date as all Lenders and the Administrative Agent may agree in their discretion). The Borrower may request that the Fourth Delayed Draw Loan be made by delivering to the Administrative Agent an irrevocable Loan Request on or before 10:00 a.m. on a Business Day at least three Business Days prior to the proposed Fifth Amendment Effective Date (or such later date as all Lenders and the Administrative Agent may agree in their discretion). The Borrower may request that the Sixth Delayed Draw Loan be made by delivering to the Administrative Agent an irrevocable Loan Request on or before 10:00 a.m. on a Business Day at least three Business Days prior to the proposed Seventh Amendment Effective Date (or such later date as all Lenders and the Administrative Agent may agree in their discretion). The Borrower shall request that the First Delayed Draw Loan be made by delivering to the Administrative Agent an irrevocable Loan Request on or before 10:00 a.m. on a Business Day at least fifteen Business Days prior to the proposed First Delayed Draw Funding Date (or such later date as all Lenders and the Administrative Agent may agree in their discretion), and may request that the Second Delayed Draw Loan, the Third Delayed Draw Loan, the Fifth Delayed Draw Loan or the Seventh Delayed Draw Loan be made by delivering to the Administrative Agent an irrevocable Loan Request on or before 10:00 a.m. on a Business Day at least fifteen Business Days prior to the proposed applicable Delayed Draw Funding Date (or such later date as all Lenders and the Administrative Agent may agree in their discretion). A Loan Request must request disbursement to a bank account of the Borrower outside Austria.

SECTION 2.3 Funding. After receipt of the Loan Request for the Initial Loan, the Administrative Agent shall promptly notify each Lender of the amount of such Lender's portion of the Initial Loan. Each Lender shall, on the Funding Date and subject to the terms and conditions hereof, make the requested proceeds of such Lender's portion of the Initial Loan available to or as instructed by the Administrative Agent. Upon satisfaction (or written waiver by each Lender) of the applicable conditions set forth in Article V, the Administrative Agent shall make all funds so received available to the Borrower by wire transfer to the account the Borrower shall have specified in its Loan Request (which account shall not be located in Austria) in an amount equal to (but not less than) the Lenders' Initial Commitment Amount. After receipt of a Loan Request for a Delayed Draw Loan, the Administrative Agent shall promptly notify each Lender of the amount of such Lender's portion of the such Delayed Draw Loan. Each Lender shall, on the applicable Delayed Draw Funding Date, and subject to the terms and conditions hereof, make the requested proceeds of such Lender's portion of such Delayed Draw Loan available to, or as instructed by, the Administrative Agent. Upon satisfaction (or written waiver by each Lender) of the applicable conditions set forth in Article V, the Administrative Agent shall make all funds so received available to the Borrower by wire transfer to the account the Borrower shall have specified in its Loan Request (which account shall not be located in Austria) in an amount equal to (but not less than) the Lenders' applicable Delayed Draw Commitment Amount.

SECTION 2.4 Reduction of the Commitment Amounts. The Initial Commitment Amount shall automatically and permanently be reduced to zero on the earlier of (a) Funding Date immediately after the funding of the Initial Loan and (b) March 4,

2020 if the Initial Loan shall not have been made hereunder prior to such date. Each Delayed Draw Commitment Amount shall automatically and permanently be reduced to zero on the applicable Delayed Draw Commitment Termination Date.

ARTICLE III

REPAYMENTS, PREPAYMENTS, INTEREST AND FEES

SECTION 3.1 Repayments and Prepayments: Application. The Borrower agrees that the Loans, and any fees or interest accrued or accruing thereon, and all other Obligations, shall be repaid and prepaid solely in U.S. dollars pursuant to the terms of this Article III.

SECTION 3.2 Repayments and Prepayments. The Borrower shall repay in full the unpaid principal amount of (i) the Loans other than the Sixth Delayed Draw Loans and the Seventh Delayed Draw Loans on the Existing Maturity Date and (ii) the Sixth Delayed Draw Loans and the Seventh Delayed Draw Loans on the Seventh Amendment Tranche Maturity Date. Prior thereto, payments and prepayments of the Loans shall be made as set forth below:

- (a) The Borrower shall have the right, upon at least three Business Days' prior notice to the Administrative Agent, at any time and from time to time to prepay any unpaid principal amount of the Loans, in whole or in part.
- (b) (i) With respect to Loans other than Sixth Delayed Draw Loans and Seventh Delayed Draw Loans, commencing on January 1, 2026, and on the first Business Day of each Fiscal Quarter thereafter until the Existing Maturity Date, the Borrower shall make a scheduled principal payment equal to 16.67% of the unpaid principal amount of such Loans outstanding on January 1, 2026 (for the avoidance of doubt, prior to giving effect to such scheduled principal payment) and (ii) with respect to Sixth Delayed Draw Loans and Seventh Delayed Draw Loans, commencing on January 1, 2027, and on the first Business Day of each Fiscal Quarter thereafter until the Seventh Amendment Tranche Maturity Date, the Borrower shall make a scheduled principal payment equal to 12.5% of the unpaid principal amount of such Loans outstanding on January 1, 2027 (for the avoidance of doubt, prior to giving effect to such scheduled principal payment).
- (c) Within three Business Days of receipt by Holdings, the Borrower or any Subsidiary of any (i) Net Casualty Proceeds or Net Asset Sales Proceeds with respect to any Disposition of Non-Core Assets (other than any Disposition of EB-66) (in one transaction or a series of related transactions) in excess of €5,000,000 or (ii) Net Casualty Proceeds or Net Asset Sales Proceeds with respect to any Disposition of assets that are not Non-Core Assets (in one transaction or a series of related transactions) in excess of €1,000,000, the Borrower shall notify the Administrative Agent and Lenders thereof. If requested by the Required Lenders, the Borrower shall within three Business Days of such request make a mandatory prepayment of the outstanding principal amount of the Loans, in an amount equal to (x) 35% of any portion of such Net Casualty Proceeds or Net Asset Sales Proceeds from a Disposition of Non-Core Assets (other than any Disposition of EB-66) that exceeds €5,000,000 or (y) 100% of

any portion of such Net Casualty Proceeds or Net Asset Sales Proceeds from a Disposition of assets that are not Non-Core Assets that exceeds €1,000,000 (or, in each case, such lesser amount as the Required Lenders may specify on the date of such request), to be applied as set forth in Section 3.3; provided that if (A) prior to the date on which any prepayment is required to be made hereunder, the Borrower notifies the Administrative Agent and the Lenders of its intention to reinvest such Net Casualty Proceeds or Net Asset Sales Proceeds, as applicable, in assets (which, for the avoidance of doubt, shall not include inventory or other current assets, unless such assets were the type subject to the applicable Net Casualty Proceeds or Net Asset Sales Proceeds) used or useful in the business of Holdings, the Borrower and the Subsidiaries, then, so long as no Event of Default then exists, the Borrower shall not be required to make a prepayment hereunder to the extent that such Net Casualty Proceeds or Net Asset Sales Proceeds, as applicable, are so reinvested (or committed to be reinvested pursuant to a binding agreement) within 180 days following receipt thereof (and, in the case of any such commitment to reinvest, (x) are actually reinvested within 180 days following the expiration of such initial 180 day period or (y) are deposited into an escrow account or other segregated deposit account which is a Controlled Account used solely to hold such proceeds (a “Reinvestment Account”), and (B) if any Net Casualty Proceeds or Net Asset Sales Proceeds, as applicable, previously designated for reinvestment have not been so reinvested (or committed to be reinvested) prior to the expiration of the applicable period described in the foregoing clause (A) or if any Net Casualty Proceeds or Net Asset Sales Proceeds that have been deposited into a Reinvestment Account cease to be subject to a binding agreement to reinvest, the Borrower shall promptly make a prepayment of the outstanding principal amount of the Loans with (i) 35% of any portion of such Net Casualty Proceeds or Net Asset Sales Proceeds from a Disposition of Non-Core Assets (other than any Disposition of EB-66) that exceeds €5,000,000 or (ii) 100% of any portion of such Net Casualty Proceeds or Net Asset Sales Proceeds from a Disposition of assets that are not Non-Core Assets that exceeds €1,000,000 (or, in each case, such lesser amount as the Required Lenders may specify at such time), in each case, that are not so reinvested (or committed to be reinvested) or that cease to be subject to a binding agreement to reinvest, as applicable. Funds held in any Reinvestment Account shall be used solely for the reinvestment purposes described in this Section 3.2(c).

- (d) The Borrower shall repay the Loans in full immediately upon any acceleration of the applicable Maturity Date thereof pursuant to Section 9.2 or Section 9.3, unless, pursuant to Section 9.3, only a portion of the Loans is so accelerated (in which case the portion so accelerated shall be so repaid).

SECTION 3.3 Application. Except as provided in Section 9.4, amounts repaid or prepaid in respect of the outstanding principal amount of the Loans pursuant to clauses (a), (b) or (c) of Section 3.2 shall be applied *pro rata* to the Initial Loan and Delayed Draw Loans.

SECTION 3.4 Interest Rate. The outstanding principal balance of the Loans shall accrue interest at the Applicable Rate.

SECTION 3.5 **Default Rate.** At all times commencing upon the date any Event of Default occurs, and continuing until such Event of Default is no longer continuing, the Applicable Rate shall be increased to (i) 14.95% *per annum* for the first fifteen days after the occurrence of such Event of Default and (ii) thereafter until such Event of Default is no longer continuing, 19.95% *per annum*.

SECTION 3.6 **Payment Dates.** Accrued but unpaid Interest (to, but not including, the date of such payment) on the Loans shall be payable in cash, without duplication:

- (a) on the applicable Maturity Date;
- (b) on the date of any payment or prepayment, in whole or in part, of principal outstanding on such Loan on the principal amount so paid or prepaid;
- (c) on the first Business Day of each Fiscal Quarter; and
- (d) on aggregate principal amount of the Loans that is accelerated pursuant to Section 9.2 or Section 9.3, immediately upon such acceleration.

Interest accrued on the outstanding principal balance of the Loans after the date such amount is due and payable (whether on the applicable Maturity Date, upon acceleration or otherwise) shall be payable upon demand.

SECTION 3.7 **Repayment Premium.** Upon the prepayment or repayment of all or any portion of any Loans (or upon the date any such prepayment or repayment is required to be paid), pursuant to Section 9.2 or Section 9.3, or otherwise (other than (i) repayments of principal made on the applicable Maturity Date and (ii) scheduled repayments of principal made pursuant to Section 3.2(b)), on the date on which such prepayment or repayment is paid or required to be paid, as the case may be, in addition to the other Obligations (including the applicable Exit Fee) so prepaid, repaid or required to be prepaid or repaid in connection with such prepayment or repayment, the Borrower shall pay to the Administrative Agent for the account of each Lender, in cash, the Repayment Premium that is applicable on such date with respect to the portion of each Loan of such Lender so prepaid, repaid or required to be prepaid or repaid. The Repayment Premium is fully earned on the date hereof.

SECTION 3.8 **Exit Fee.** Upon the prepayment or repayment of all or any portion of the Loans (or upon the date any such prepayment or repayment is required to be paid), whether on the applicable Maturity Date, pursuant to Section 3.2, Section 9.2 or Section 9.3, or otherwise, on the date on which such prepayment or repayment is paid or required to be paid, as the case may be, in addition to the other Obligations (including the Repayment Premium, if any) so prepaid, repaid or required to be prepaid or repaid in connection with such prepayment or repayment, **the Borrower shall pay to the Administrative Agent for the account of each Lender, in cash, a fee (the "Exit Fee")** in amount equal to (i) with respect to Loans other than Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, three percent (3.00%) of the principal amount of such Loans so prepaid, repaid or required to be prepaid or repaid, as the case may be, on such date and (ii) with respect to Sixth Delayed Draw Loans or Seventh Delayed Draw Loans, five percent (5.00%) of the principal amount of such Loans so prepaid, repaid or required to be prepaid or repaid, as the case may be, on such date. The Exit Fee under clause (i) of the previous sentence is fully earned on the Closing Date and

the Exit Fee under clause (ii) of the previous sentence is fully earned on the Seventh Amendment Effective Date.

SECTION 3.9 Administration Fee.

- (a) The Borrower shall pay to the Administrative Agent, for the ratable account of each Lender based on each Lender's Total Credit Exposure, in cash, a non-refundable quarterly loan administration fee in the amount of \$10,000, payable in advance, commencing on the Closing Date (which payment on the Closing Date shall be prorated for the Fiscal Quarter in which the Closing Date occurs) and continuing on the first Business Day of each Fiscal Quarter thereafter.
- (b) The Borrower shall pay to the Administrative Agent such fees in the amounts and at the times specified under the Agency Fee Letter.

SECTION 3.10 Undrawn Fee. The Borrower shall pay to the Administrative Agent for the account of each Lender (the "Undrawn Fee"), in cash, for its own account, a fee at a *per annum* rate equal to 0.75% multiplied by the average daily undrawn Delayed Draw Commitment Amounts of such Lender, payable quarterly in arrears on the first Business Day of each Fiscal Quarter with respect to the immediately preceding Fiscal Quarter, until the respective Delayed Draw Commitment Termination Date. The Undrawn Fee is fully earned and shall not be refundable under any circumstances.

SECTION 3.11 Upfront Fee. The Borrower shall pay to the Administrative Agent for the account of each Lender (the "Upfront Fee"):

- (a) on the Funding Date, a fully earned, non-refundable upfront fee in the form of original issue discount in an amount equal to one and one-half percent (1.50%) of the Initial Commitment Amount of such Lender on the Funding Date;
- (b) on each Delayed Draw Funding Date other than the Sixth Delayed Draw Funding Date and the Seventh Delayed Draw Funding Date, a fully earned, non-refundable upfront fee in the form of original issue discount in an amount equal to one and one-half percent (1.50%) of the applicable Delayed Draw Commitment Amount of such Lender; and
- (c) on each of the Sixth Delayed Draw Funding Date and the Seventh Delayed Draw Funding Date, a fully earned, non-refundable upfront fee in the form of original issue discount in an amount equal to ten percent (10.0%) of the applicable Delayed Draw Commitment Amount of such Lender.

SECTION 3.12 Payments Generally. Subject to Section 9.3, all payments of principal, interest and any Repayment Premium on the Loans and all other Obligations payable by any Loan Party under the Loan Documents shall be due, without any presentment thereof, to the Administrative Agent, at the Administrative Agent's Office. The Administrative Agent shall distribute any such payments received by it for the account of any other Person to the appropriate recipient promptly following receipt. Except as otherwise set forth herein, all repayments and prepayments under the Loan Documents shall be made to the Lenders on a *pro rata* basis in accordance with their respective Applicable Percentages. If any

payment is scheduled to be made on a day that is not a Business Day, then such payment shall be made on the next succeeding Business Day.

SECTION 3.13 Interest Act (Canada). For the purposes of the *Interest Act* (Canada) and disclosure thereunder, whenever any interest or any fee to be paid hereunder or in connection herewith is to be calculated on the basis other than a calendar year, the yearly rate of interest to which the rate used in such calculation is equivalent is the rate so used, multiplied by the actual number of days in the calendar year in which the same is to be ascertained and divided by the number of days used in the basis of such determination. The rates of interest under this Agreement are nominal rates, and not effective rates or yields. The principle of deemed reinvestment of interest does not apply to any interest calculation under this Agreement.

ARTICLE IV

OTHER PROVISIONS

SECTION 4.1 Increased Costs, Etc. The Borrower agrees to reimburse the Lenders for any increase in the cost to the Lenders of, or any reduction in the amount of any sum receivable by the Lenders in respect of, the Lenders' Commitments and the making, continuation or maintaining of the Loans hereunder that may arise in connection with any Change in Law, except for such changes with respect to increased capital costs and Taxes which are governed by Section 4.2 and Section 4.3, respectively. The Administrative Agent shall notify the Borrower in writing of the occurrence of any such event, stating the reasons therefor and the additional amount required fully to compensate the Lenders for such increased cost or reduced amount. Such additional amounts shall be payable by the Borrower directly to the Administrative Agent for the accounts of the Lenders within five days of its receipt of such notice, and such notice shall, in the absence of manifest error, be conclusive and binding on the Borrower.

SECTION 4.2 Increased Capital Costs. If any Change in Law affects or would affect the amount of capital required or expected to be maintained by any Lender or any Person controlling such Lender, and such Lender determines (in good faith but in its sole and absolute discretion) that the rate of return on its or such controlling Person's capital as a consequence of the Commitments or the Loans made by it hereunder is reduced to a level below that which such Lender or such controlling Person could have achieved but for the occurrence of any such circumstance, then upon notice from time to time by such Lender to the Borrower, the Borrower shall within five days following receipt of such notice pay directly to the Administrative Agent for the account of such Lender additional amounts sufficient to compensate such Lender or such controlling Person for such reduction in rate of return. A statement of such Lender as to any such additional amount or amounts shall, in the absence of manifest error, be conclusive and binding on the Borrower. In determining such amount, such Lender may use any method of averaging and attribution that it (in its sole and absolute discretion) shall deem applicable.

SECTION 4.3 Taxes. The Borrower covenants and agrees as follows with respect to Taxes:

- (a) Except as required by applicable Law, any and all payments by any Loan Party under each Loan Document shall be made without setoff, counterclaim or other defense, and free and clear of, and without

deduction or withholding for or on account of, any Taxes. In the event that any Taxes are imposed and required to be deducted or withheld from any payment required to be made by any Loan Party to or on behalf of the Lenders under any Loan Document, then:

- (i) if such Taxes are Non-Excluded Taxes, then the sum payable shall be increased as necessary so that after the deduction or withholding of Non-Excluded Taxes has been made (including such deductions and withholdings applicable to additional sums payable under this Section) the applicable recipient receives an amount equal to the sum it would have received had no such deduction or withholding for Non-Excluded Taxes been made; and
 - (ii) the applicable Loan Party shall deduct or withhold the full amount of Taxes required to be deducted or withheld from such payment (as increased pursuant to clause (a)(i)) and shall pay such amount to the Governmental Authority imposing such Taxes in accordance with applicable Law.
- (b) In addition, the applicable Loan Party shall pay all Other Taxes imposed to the relevant Governmental Authority imposing such Other Taxes in accordance with applicable Law.
- (c) As promptly as practicable after the payment of any Taxes or Other Taxes required to be paid by the applicable Loan Party under Section 4.3(a) or (b), the Borrower shall furnish to the Administrative Agent a copy of an official receipt (or a certified copy thereof) or other evidence of such payment reasonably satisfactory to the Administrative Agent evidencing the payment of such Taxes or Other Taxes.
- (d) The Borrower shall indemnify the Administrative Agent and each Lender for any Non-Excluded Taxes (including Non-Excluded Taxes attributable to such indemnification payments) levied, imposed or assessed on (and whether or not paid directly by) the Administrative Agent or such Lender whether or not such Non-Excluded Taxes are correctly or legally asserted by the relevant Governmental Authority, together with such Person's reasonable expenses relating thereto, within 10 Business Days of written demand therefor. In addition, the Borrower shall indemnify the Administrative Agent and each Lender for any incremental Taxes that may become payable by such Lender or the Administrative Agent as a result of any failure of the Borrower to pay any Taxes when due to the appropriate Governmental Authority or to deliver to such Lender or the Administrative Agent, pursuant to clause (c), documentation evidencing the payment of Taxes or Other Taxes. Such indemnification shall be made within 10 Business Days after the date the Administrative Agent or such Lender makes written demand therefor.
- (e) For purposes of sections 1272, 1273 and 1275 of the Code and the U.S. Department of Treasury regulations thereunder, the Loans are being made with original issue discount. Requests for information regarding the issue price, amount of original issue discount, issue date, and yield to maturity

on the Loans shall be directed to the Borrower, at the address of the Borrower specified on Schedule 10.2.

- (f) Each party's obligations under this Section 4.3 shall survive the resignation or replacement of the Administrative Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all other Obligations.

SECTION 4.4 Payments, Computations, Etc.

- (a) Unless otherwise expressly provided in a Loan Document, all payments by the Loan Parties pursuant to each Loan Document shall be made without setoff, deduction or counterclaim not later than 11:00 a.m. on the date due in same day or immediately available funds, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Administrative Agent may from time to time direct in writing. Funds received after 11:00 a.m. on any day shall be deemed to have been received on the next succeeding Business Day. All interest and fees shall be computed on the basis of the actual number of days occurring during the period for which such interest or fee is payable over a year comprised of 360 days. Payments due on other than a Business Day shall be made on the next succeeding Business Day and such extension of time shall be included in computing interest and fees in connection with that payment.
- (b) [Reserved.]
- (c) The obligations of the Lenders hereunder to make Loans and to make payments pursuant to Section 10.4(c) are several and not joint. The failure of any Lender to make any Loan or to make any payment under Section 10.4(c) on any date required hereunder shall not relieve any other Lender of its corresponding obligation to do so on such date, and no Lender shall be responsible for the failure of any other Lender to so make its Loan or to make its payment under Section 10.4(c).
- (d) Nothing herein shall be deemed to obligate any Lender to obtain the funds for any Loan in any particular place or manner or to constitute a representation by any Lender that it has obtained or will obtain the funds for any Loan in any particular place or manner.
- (e) If any Lender shall, by exercising any right of setoff or otherwise, obtain payment in respect of any principal of or interest on its portion of any of the Loans or any Repayment Premium in connection therewith resulting in such Lender's receiving payment of a proportion of the aggregate amount of the Loans and accrued interest thereon and any Repayment Premium in connection therewith greater than its Applicable Percentage thereof as provided herein, then the Lender shall (x) notify the Administrative Agent of such fact and (y) purchase (for cash at face value) participations in the portions of the Loans of the other Lenders, or make such other adjustments as shall be equitable, so that the benefit of all such payments shall be shared by the Lenders ratably in accordance with the aggregate amount of principal of, accrued interest on and any Repayment Premium

in connection with their respective portions of the Loans and other amounts owing them; provided that:

- (i) if any such participations are purchased and all or any portion of the payment giving rise thereto is recovered, such participations shall be rescinded and the purchase price restored to the extent of such recovery, without interest; and
- (ii) the provisions of this Section 4.4(e) shall not be construed to apply to (x) any payment made by or on behalf of the Borrower pursuant to and in accordance with the express terms of this Agreement or (y) any payment obtained by a Lender as consideration for the assignment of or sale of a participation in any of its portion of the Loans to any assignee or participant, other than an assignment to a Loan Party (as to which the provisions of this Section shall apply).

Each Loan Party consents to the foregoing and agrees, to the extent it may effectively do so under applicable Law, that any Lender acquiring a participation pursuant to the foregoing arrangements may exercise against such Loan Party rights of setoff and counterclaim with respect to such participation as fully as if such Lender were a direct creditor of such Loan Party in the amount of such participation.

SECTION 4.5 Setoff. Subject in all respects to Section 4.4(e), each Lender shall, upon the occurrence and during the continuance of any Event of Default described in clauses (i) through (iv) of Section 9.1(h) or, upon the occurrence and during the continuance of any other Event of Default, have the right to appropriate and apply to the payment of the Obligations owing to it (whether or not then due), and (as security for such Obligations) the Borrower hereby grants to each Lender a continuing security interest in, any and all balances, credits, deposits, accounts or moneys of the Borrower then or thereafter maintained with or on behalf of such Lender. Each Lender agrees promptly to notify the Borrower after any such appropriation and application made by it; provided that the failure to give such notice shall not affect the validity of such setoff and application. The rights of each Lender under this Section 4.5 are in addition to other rights and remedies (including other rights of setoff under applicable Law or otherwise) which each Lender may have but do not supersede the provisions of Section 4.4(e).

SECTION 4.6 Status of Lenders; Treatment of Certain Refunds.

- (a) Any Lender that is legally entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Administrative Agent, at the time or times reasonably requested by the Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Administrative Agent as will permit such payments to be made without withholding or at a reduced rate of withholding; provided that such Lender has received written notice from the Borrower or the Administrative Agent advising it of the availability of such exemption or reduction and containing all applicable documentation (together, if requested by such Lender, with a certified English translation thereof). In addition, any Lender, if reasonably requested by the Borrower or the Administrative

Agent, shall deliver such other documentation prescribed by Applicable Law or reasonably requested by the Borrower or the Administrative Agent as will enable the Borrower or the Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Each Lender agrees that, from time to time if reasonably requested by the Borrower or the Administrative Agent or as soon as practicable after becoming aware that any form or certification it previously delivered expires or becomes obsolete or has become inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Administrative Agent in writing of its legal inability to do so. Notwithstanding the foregoing, the completion, execution and submission of such documentation shall not be required if, in such Lender's reasonable judgment, such completion, execution or submission would subject such Lender or the Administrative Agent to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

- (b) Each Lender shall deliver to the Administrative Agent at the time or times prescribed by applicable Law and at such time or times reasonably requested by the Borrower or the Administrative Agent such documentation prescribed by applicable Law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by the Borrower or the Administrative Agent as may be necessary for the Borrower and the Administrative Agent to comply with their obligations under FATCA, to determine that such Lender has complied with such Lender's obligations under FATCA, or to determine the amount, if any, to deduct and withhold from payment, in each case only if FATCA is applicable.
- (c) If any Lender determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Article (including by the payment of additional amounts pursuant to this Section), it shall pay to the Borrower an amount equal to such refund (but only to the extent of indemnity payments made under this Article with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including any Taxes) of such Lender and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). The Borrower, upon the request of such Lender, shall repay to such Lender the amount paid over pursuant to this paragraph (c) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such Lender is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this paragraph (c), in no event will the Lender be required to pay any amount to the Borrower pursuant to this paragraph (c) the payment of which would place such Lender in a less favorable net after-Tax position than such Lender would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This paragraph shall not be construed to require any Lender to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the Borrower or any other Person.

ARTICLE V
CONDITIONS TO EFFECTIVENESS AND FUNDING

SECTION 5.1 Credit Extensions. This Agreement shall become effective on the Closing Date subject to the satisfaction (or written waiver by each Lender) of each of the conditions precedent set forth below that are specifically stated to be applicable to the Closing Date, subject to Section 7.17. The obligation of each Lender to make its portion of the Initial Loan shall be subject to the delivery of a Loan Request pursuant to Section 2.3 and the satisfaction (or written waiver by each Lender) of each of the conditions precedent set forth below that are specifically stated to be applicable to the Funding Date, subject to Section 7.17. The obligation of each Lender to make its portion of a Delayed Draw Loan shall be subject to the prior funding of the Initial Loan, the delivery of a Loan Request pursuant to Section 2.3 and the satisfaction (or written waiver by each Lender) of each of the conditions precedent set forth below that are specifically stated to be applicable to a Delayed Draw Funding Date.

SECTION 5.2 Secretary's Certificate, Etc. With respect to the Closing Date, the Administrative Agent and each Lender shall have received from Holdings, the Borrower and each other Loan Party, (i) a copy of a good standing certificate, certificate of registration or similar certificate from the applicable Governmental Authority of each Loan Party's jurisdiction of incorporation, formation or organization to the extent that such certificate is obtainable in such jurisdiction, dated a date reasonably close to the Closing Date, for each such Person (or, as regards Holdings (a) an original copy of an extrait K-bis not more than 30 days old), (b) a copy (certified by its authorized representative) of its updated by-laws (*statuts*), and (c) an original copy of its *état des inscriptions et privilèges* not more than 30 days old and an original copy of its non-bankruptcy certificate (*certificat de recherches négatives*) not more than 30 days old) and (ii) a certificate, dated as of the Closing Date, duly executed and delivered by such Person's Secretary or Assistant Secretary, managing member or general partner, as applicable, as to:

- (a) resolutions of such Person's board of directors (or other managing body, in the case of other than a corporation) and any other corporate resolutions required by applicable Law or pursuant to such Person's Organic Documents, each of which shall be then in full force and effect, authorizing the execution, delivery and performance of each Loan Document to be executed by such Person and the transactions contemplated hereby and thereby and, in the case of Holdings, resolutions of its Supervisory Board (*conseil de surveillance*) then in full force and effect approving, in accordance with Article L.225-68 and Article L.225-86 of the French *Code de commerce* and with Article 19 and Article 22 of Holdings by-laws, the terms of and the transactions contemplated by the Loan Documents (in particular regarding the Guarantee and the French Security Documents)), authorizing the execution by Holdings' board of directors (*directoire*), delivery and performance of each Loan Document to be executed by Holdings and the transactions contemplated hereby and thereby and authorizing all documents and notices to be signed by Holdings' board of directors (*directoire*) and/or dispatched by it under or in connection with the Loan Documents;
- (b) the incumbency and signatures of such Person's officers, managers, managing member or general partner, as applicable, authorized to act with

respect to each Loan Document to be executed by such Person and, as regards Holdings, certified copies of any powers of attorney and copies of the passports or IDs of the authorized signatories; and

(c) each Organic Document of such Person being in full force and effect, and attaching copies thereof;

upon which certificates the Administrative Agent and each Lender may conclusively rely until it shall have received a further certificate of the Secretary, Assistant Secretary, managing member or general partner, as applicable, of any such Person canceling or amending the prior certificate of such Person.

SECTION 5.3 Officer's Certificate. With respect to the Closing Date, the Funding Date and each Delayed Draw Funding Date, the Administrative Agent and each Lender shall have received an Officer's Certificate, dated as of the Closing Date, the Funding Date or such Delayed Draw Funding Date, as the case may be, and duly executed and delivered by an Authorized Officer of the Borrower, in which certificate the Borrower shall certify that (a) the representations and warranties set forth in each Loan Document shall, in each case, be true and correct in all material respects (except with respect to any representations and warranties that are qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects) as of such date (except to the extent that such representations and warranties specifically relate to an earlier date, in which case, each shall be true and correct in all material respects (except with respect to any representations and warranties that are qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects) as of such earlier date), (b) no Default shall have then occurred and be continuing, or, if applicable, would result from the Loan to be advanced on the Funding Date or such Delayed Draw Funding Date, as the case may be, and (c) all of the applicable conditions set forth in this Article V for the Closing Date, the Funding Date or such Delayed Draw Funding Date, as the case may be, shall have been satisfied.

SECTION 5.4 Payment of Outstanding Indebtedness, Etc. With respect to the Funding Date, all Indebtedness identified in Schedule 8.2(b), together with all interest, all prepayment premiums and all other amounts due and payable with respect thereto, shall be paid in full from the proceeds of the Initial Loan and the commitments in respect of such Indebtedness shall be terminated, and all Liens securing payment of any such Indebtedness shall be released, pursuant to a customary payoff letter executed by the holder of such Indebtedness.

SECTION 5.5 Delivery of Note. With respect to the Funding Date, each Lender shall have received a Note duly executed and delivered by an Authorized Officer of the Borrower.

SECTION 5.6 Financial Information, Etc. With respect to the Closing Date and the Funding Date, the Administrative Agent and the Lenders shall have received:

- (a) audited consolidated financial statements of Holdings and its Subsidiaries for each of the fiscal years ended December 31, 2016, December 31, 2017, and December 31, 2018, as Publicly Disclosed by Holdings;

- (b) unaudited consolidated balance sheets and related income statements of Holdings and its Subsidiaries for each Fiscal Quarter ended after December 31, 2018 to the extent such financial statements have been Publicly Disclosed by Holdings; and
- (c) such other financial information as to Holdings, the Borrower and the Subsidiaries and their respective businesses, assets and liabilities as any Lender or the Administrative Agent may reasonably request no later than five (5) Business Days prior to the Closing Date.

SECTION 5.7 Compliance Certificate. With respect to the Funding Date, the Lenders and the Administrative Agent shall have received an initial Compliance Certificate on a *pro forma* basis as if the Initial Loan had been made as of December 31, 2019 and as to such items therein as any Lender reasonably requests, dated as of the Funding Date, duly executed (and with all schedules thereto duly completed) and delivered by the chief financial or accounting Authorized Officer of the Borrower.

SECTION 5.8 Solvency, Etc. With respect to the Funding Date and each Delayed Draw Funding Date, the Lenders and the Administrative Agent shall have received a solvency certificate, duly executed and delivered by the chief financial or accounting Authorized Officer of the Borrower, dated as of the Funding Date or such Delayed Draw Funding Date, as the case may be, substantially in the form of Exhibit H hereto or any other form approved by the Administrative Agent and the Required Lenders, certifying solely in such Authorized Officer's official capacity and not in any personal capacity or with any personal liability therefor that, as of such date, Holdings, the Borrower and the Subsidiaries, taken as a whole on a consolidated basis, both immediately before and immediately after giving effect to the borrowing of the Loan to be advanced on such date, are Solvent.

SECTION 5.9 Guarantee. With respect to the Funding Date, the Lenders and the Administrative Agent shall have received executed counterparts of the Guarantee, duly executed and delivered by Holdings and each other Loan Party (other than the Borrower).

SECTION 5.10 Security Agreements. The Administrative Agent and the Lenders shall have received:

- (a) with respect to the Funding Date, (i) the Pledge and Security Agreement executed by Valneva USA in favor of the Administrative Agent and (ii) the Stock Pledge Agreement executed by the Borrower in favor of the Administrative Agent with respect to the Capital Securities of Valneva USA;
- (b) with respect to the Funding Date, (i) the English Debenture executed by Valneva UK Limited and Holdings in favor of the Administrative Agent, (ii) a copy of each notice required to be sent under the English Debenture, executed by the relevant Loan Party, duly acknowledged by the addressee and (iii) all documents of title to be provided under the English Debenture;
- (c) with respect to the Funding Date, evidence that the English Debenture has been registered with the Companies House of England and Wales against the name of Valneva UK Limited;

- (d) with respect to the Funding Date, (i) the Deed of Hypothec granted by Valneva Canada and an application for registration (Form RH) in respect thereof shall have been registered at the RPMRR and (ii) the Security Agreement executed by Valneva Canada in favor of the Administrative Agent and PPSA financing statements in respect thereof shall have been registered with the Personal Property Registry of Ontario;
- (e) with respect to the Funding Date, the Stock Pledge Agreement executed by Holdings in favor of the Administrative Agent with respect to the Capital Securities of Valneva Canada;
- (f) with respect to the Funding Date, a Scots law governed standard security to be granted by Valneva Scotland Limited in favor of the Administrative Agent in respect of its interest in ALL and WHOLE the subjects registered in the Land Register of Scotland under Title Numbers MID4303 and WLN39630;
- (g) with respect to the Funding Date, a Scots law governed bond and floating charge to be granted by Valneva Scotland Limited in favor of the Administrative Agent over the whole of the property (including uncalled capital) which is or may be from time to time comprised in the Collateral;
- (h) with respect to the Funding Date, a Scots law share pledge to be granted by the Borrower in favor of the Administrative Agent in respect of the Capital Securities of Valneva Scotland Limited, together with all documentation required to register such Capital Securities in the name of the Administrative Agent and all evidence of such registration as the Required Lenders may reasonably request;
- (i) with respect to the Funding Date, in respect of each parcel of real property owned by the Borrower or any other Loan Party in Scotland:
 - (i) copies of all title documents relating to the relevant Loan Party's interest in such property;
 - (ii) copies of any lease documents relating to such property;
 - (iii) a clear search in the Property and Personal Registers for the relevant prescriptive periods or clear Land Register reports, as the case may be, together with clear searches in the Register of Inhibitions against the relevant Loan Parties showing (x) no adverse entries, (y) an advance notice as defined in the Land Registration etc. (Scotland) Act 2012 for each Standard Security giving not less than 20 protected Business Days beyond the Funding Date, and (z) no other advance notices as defined in the Land Registration etc. (Scotland) Act 2012;
 - (iv) a copy of each advance notice referred to in clause (iii) above; and

- (v) a certificate of title to such property, prepared by the Borrower's Scottish solicitors and addressed to the Administrative Agent and the Lenders;
- (j) with respect to the Funding Date, a French law governed pledge over shares to be granted by Holdings in favor of the Administrative Agent with respect to the Capital Securities of Valneva France;
 - (k) with respect to the Funding Date, a French law governed pledge over bank accounts to be granted by Holdings in favor of the Administrative Agent with respect to the bank accounts of Holdings (other than any Excluded Account) located in France;
 - (l) with respect to the Funding Date, a French law governed pledge over the *fonds de commerce* to be granted by Holdings in favor of the Administrative Agent which shall include the Trademarks and Patents of Holdings registered with INPI, EUIPO and WIPO and as listed therein to the extent constituting Collateral;
 - (m) with respect to the Funding Date, a French law governed pledge to be granted by Holdings in favor of the Administrative Agent with respect to the intercompany loans owing to Holdings by the Borrower, Valneva UK Limited and Valneva Canada and (if any) Valneva France;
 - (n) with respect to the Funding Date, an Austrian law governed pledge over shares to be granted by Holdings in favor of the Administrative Agent with respect to the Capital Securities in the Borrower, together with the notice (executed by Holdings and acknowledged by the Borrower), proxy and power of attorney required to be delivered thereunder;
 - (o) with respect to the Funding Date, an Austrian law governed pledge over bank accounts to be granted by the Borrower in favor of the Administrative Agent with respect to the bank accounts of the Borrower (other than any Excluded Account) located in Austria, together with the notices required to be sent (including evidence of dispatch) and evidence of the book annotations required to be made thereunder;
 - (p) with respect to the Funding Date, an Austrian law governed pledge over all existing and future receivables to be granted by the Borrower in favor of the Administrative Agent with respect to receivables of the Borrower, together with the notices required to be sent (including evidence of dispatch) and evidence of the book annotations required to be made thereunder;
 - (q) with respect to the Funding Date, an Austrian law governed pledge over Intellectual Property to be granted by the Borrower in favor of the Administrative Agent with respect to Intellectual Property of the Borrower to the extent constituting Collateral, together with the registrations, notifications, book annotations and power of attorney required to be delivered thereunder;
 - (r) with respect to the Funding Date, a Swedish law governed pledge over shares in (i) Vaccines Holdings Sweden AB to be granted by Holdings and

- (ii) Valneva Sweden AB to be granted by Vaccines Holdings Sweden AB, in each case in favor of the Administrative Agent together with the perfection requirements and deliverables specified therein;
- (s) with respect to the Funding Date, a Swedish law governed pledge over the existing Swedish business mortgage certificates to be granted by Valneva Sweden AB in favor of the Administrative Agent together with the perfection requirements and deliverables specified therein;
 - (t) with respect to the Funding Date, a Swedish law governed pledge over bank accounts to be granted by Vaccines Holdings Sweden AB in favor of the Administrative Agent together with the perfection requirements and deliverables specified therein;
 - (u) with respect to the Funding Date, a Swedish law governed pledge over bank accounts to be granted by Valneva Sweden AB in favor of the Administrative Agent together with the perfection requirements specified and deliverables therein;
 - (v) with respect to the Funding Date, a Swedish law governed pledge over IP-rights in the form of trademarks to be granted by Valneva Sweden AB in favor of the Administrative Agent together with the perfection requirements and deliverables specified therein;
 - (w) with respect to the Funding Date, subject to Section 7.17, certificates (in the case of Capital Securities that are securities (as defined in the UCC)) evidencing all of the issued and outstanding Capital Securities owned by Holdings, the Borrower or any Guarantor in its direct Subsidiaries to the extent such Capital Securities constitute Collateral, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank, or, in the case of such Capital Securities that are uncertificated securities (as defined in the UCC), to the extent such Capital Securities constitute Collateral, confirmation and evidence reasonably satisfactory to the Administrative Agent and the Lenders that a security interest therein has been granted to and perfected in favor of the Administrative Agent for the benefit of the Secured Parties in accordance with Articles 8 and 9 of the UCC, if applicable, and all laws otherwise applicable to the perfection of the pledge of such Capital Securities;
 - (x) with respect to the Funding Date, subject to Section 7.17, financing statements suitable in form for naming Holdings, the Borrower and each other Loan Party as a debtor and the Administrative Agent as the secured party, or other similar instruments or documents to be filed under the UCC of all jurisdictions as may be necessary or, in the opinion of the Administrative Agent or any Lender, desirable to perfect the security interests of the Administrative Agent and the other Secured Parties pursuant to the Security Agreements;
 - (y) with respect to the Funding Date, perfection certificates executed by each Loan Party in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders;

- (z) with respect to the Funding Date, subject to Section 7.17, UCC Form UCC-3 termination statements, applications for voluntary cancellation (RV forms - Quebec) or similar release letters, notices, or terminations, if any, necessary to release all Liens (other than Liens permitted by Section 8.3) of any Person (i) in any assets of Holdings, the Borrower or any Subsidiary or (ii) securing any of the Indebtedness identified in Schedule 8.2(b), together with such other UCC Form UCC-3 termination statements, applications for voluntary cancellation (RV forms - Quebec) or similar release letters, notices, or terminations as the Administrative Agent or any Lender may reasonably request from Holdings, the Borrower or any Subsidiary;
- (aa) with respect to the Funding Date, subject to Section 7.17, landlord access agreements and bailee letters in form and substance satisfactory to the Administrative Agent and the Required Lenders from each landlord to Holdings, the Borrower or any Guarantor and each other Person that has possession of any Collateral;
- (bb) with respect to the Funding Date, subject to Section 7.17, evidence that all deposit accounts, disbursement accounts, investment accounts or other similar accounts of Holdings, the Borrower and each other Loan Party (other than Excluded Accounts) are Controlled Accounts; and
- (cc) with respect to the Funding Date, any such other documentation requested by the Secured Parties, in form and substance satisfactory to the Secured Parties, in order to provide a perfected security interest in favor of the Secured Parties over the Collateral.

SECTION 5.11 Intellectual Property Security Agreements. With respect to the Funding Date, in case the Collateral includes any Patents, any Copyrights or any Trademarks, the Administrative Agent and the Lenders shall have received, respectively, a Patent Security Agreement, a Copyright Security Agreement and a Trademark Security Agreement, as applicable, duly executed and delivered by Holdings, the Borrower or any other Loan Party that, pursuant to the Security Agreements, is required to provide such intellectual property security agreements to the Administrative Agent for the benefit of the Secured Parties.

SECTION 5.12 Opinions of Counsel. With respect to the Closing Date and/or the Funding Date, subject to Section 7.17, the Administrative Agent and the Lenders shall have received the following customary legal opinions, dated as of the Closing Date or the Funding Date, as applicable, and addressed to the Secured Parties, in each case in form and substance acceptable to the Secured Parties in their reasonable discretion:

- (a) a customary secured transactions opinion, to be provided by Dechert LLP, U.S. counsel to Holdings, the Borrower and the Subsidiaries, with respect to New York, Delaware and federal law;
- (b) a customary legal opinion to be provided by DORDA Rechtsanwälte GmbH, Austrian counsel to the Administrative Agent and the Lenders, with respect to Austrian law matters;

- (c) a customary capacity opinion to be provided by bpv Hugel Rechtsanwälte GmbH, Austrian counsel to the Borrower, with respect to (i) due registration, (ii) non-insolvency and (iii) power and capacity of the Borrower to enter into the Loan Documents to which it is a party and to perform its obligations thereunder;
- (d) a customary legal opinion to be provided by Lette & Associs S.E.N.C.R.L., Canadian counsel to the Borrower, with respect to Quebec law matters and an opinion to be provided by Lette LLP with respect to the Security Agreement executed by Valneva Canada in favor of the Administrative Agent for Ontario and PPSA financing statements in respect thereof registered with the Personal Property Registry of Ontario;
- (e) a customary validity opinion to be provided by Bryan Cave Leighton Paisner, French local counsel to the Administrative Agent and the Lenders;
- (f) a customary capacity opinion to be provided by Hogan Lovells (Paris) LLP, French local counsel to Holdings, with respect to (i) due registration, (ii) non-insolvency and (iii) power and capacity of Holdings to enter into the Loan Documents to which it is a party and to perform its obligations thereunder;
- (g) a customary legal opinion to be provided by Covington & Burling LLP, English counsel to the Administrative Agent and the Lenders, with respect to English law matters;
- (h) a customary legal opinion to be provided by Burness Paull, Scots counsel to the Administrative Agent and the Lenders, with respect to Scottish law matters; and
- (i) a customary legal opinion to be provided by Cirio Advokatbyr AB, Swedish counsel to the Administrative Agent and the Lenders, with respect to Swedish law matters.

SECTION 5.13 Insurance. With respect to the Funding Date, subject to Section 7.17, the Administrative Agent and the Lenders shall have received certified copies of the insurance policies (or binders in respect thereof) of Holdings, the Borrower and the Subsidiaries evidencing coverage required to be maintained pursuant to Section 7.4 hereof, with the Administrative Agent named as loss payee or additional insured, as applicable, to the extent required pursuant to Section 7.4.

SECTION 5.14 Closing Fees, Expenses, Etc. With respect to the Closing Date, each Lender and the Administrative Agent shall have received for its own account all fees due and payable pursuant to Section 3.9 prior to the Closing Date. With respect to the Funding Date, each Lender shall have received for its own account the Upfront Fee due and payable pursuant to Sections 3.11(a). With respect to each Delayed Draw Funding Date, each Lender shall have received for its own account the applicable Upfront Fee due and payable pursuant to Sections 3.11(b) or 3.11(c). With respect to the Closing Date, the Funding Date and each Delayed Draw Funding Date, each Lender and the Administrative Agent shall have received for its own account reimbursement of all costs and expenses due and payable pursuant to Section 10.4 (to the extent invoiced at least two Business

Days (or such shorter period as the Borrower may agree) prior to the Closing Date, the Funding Date or such Delayed Draw Funding Date, as applicable).

SECTION 5.15 Anti-Terrorism Laws. With respect to the Closing Date, each Lender and the Administrative Agent shall have received, as applicable, all documentation and other information required by bank regulatory authorities under applicable “know your customer” and anti-money laundering rules and regulations, including the U.S. Patriot Act.

SECTION 5.16 Reserved.

SECTION 5.17 Disclosure Schedules. With respect to the Funding Date and each Delayed Draw Funding Date, the Administrative Agent and the Lenders shall have received updates to Schedules 6.15(a), 6.16(a), 6.19 and 6.22, if necessary, which updated Schedules shall reflect the information required by the corresponding Section of this Agreement as of the Funding Date or such Delayed Draw Funding Date.

SECTION 5.18 Loan Documents. With respect to the Closing Date, (i) the Administrative Agent shall have received executed counterparts (or, in the case of the French Security Documents, an executed copy which may not be executed in counterparts) of each other Loan Document required to be executed and delivered on the Closing Date, in each case, properly executed by an Authorized Officer of the applicable Loan Party and each other party to each such Loan Document, and (ii) each other Loan Document required to be executed on or after the Funding Date shall either be in agreed form on the Closing Date or otherwise in form satisfactory to the Lenders and the Administrative Agent in their sole discretion. With respect to the Funding Date, subject to Section 7.17, the Administrative Agent shall have received executed counterparts (or, in the case of the French Security Documents, an executed copy which may not be executed in counterparts) of each other Loan Document required to be executed and delivered on the Funding Date, in each case, properly executed by an Authorized Officer of the applicable Loan Party and each other party to each such Loan Document. Notwithstanding the above, to the extent that any assets of any Loan Party are disclosed after the Closing Date that were not previously disclosed (or the disclosed Loan Party that owns such assets is updated after the Closing Date), the Parties will enter into such Security Agreements and take such actions as the Administrative Agent and the Required Lenders shall determine, in their sole discretion, are necessary to take a perfected security interest in such assets to the extent that such assets are included (or intended to be included) in the Collateral.

SECTION 5.19 Fifth Delayed Draw Loan. With respect to the Fifth Delayed Draw Funding Date, the Administrative Agent and each Lender shall have received evidence reasonably satisfactory to the Administrative Agent and such Lenders that the Borrower’s inactivated COVID-19 vaccine candidate, VLA2001, shall have been granted marketing authorization from the European Commission for primary vaccination in people 18-50 years of age.

For **purposes** of determining compliance with the conditions specified in this Article V, each Lender that has signed this Agreement shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender on the Closing Date, the Funding Date or any Delayed Draw Funding Date, as the case may be, unless the Administrative Agent shall have received

notice from such Lender prior to the Closing Date, the Funding Date or each Delayed Draw Funding Date, as the case may be, specifying its objection thereto.

ARTICLE VI REPRESENTATIONS AND WARRANTIES

In order to induce the Lenders and the Administrative Agent to enter into this Agreement and to make the Loans hereunder, the Borrower represents and warrants to the Lenders and the Administrative Agent on the Closing Date, the Funding Date, each Delayed Draw Funding Date and each other date that such representations and warranties are required to be made under the Loan Documents that:

SECTION 6.1 Organization, Etc. Each of Holdings, the Borrower and each Subsidiary (a) is validly organized and existing and in good standing under the Laws of the jurisdiction of its incorporation or organization (to the extent that such concept is applicable in such jurisdiction), is duly qualified to do business and is in good standing as a foreign entity in each jurisdiction where the nature of its business requires such qualification (to the extent that such concept is applicable in such jurisdiction) (unless the failure to so qualify as a foreign entity could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect), (b) has full power and authority (i) to enter into and perform its Obligations under each Loan Document to which it is a party (if applicable), and (ii) to own and hold under lease its property and to conduct its business substantially as currently conducted by it, and (c) holds all material governmental Permits required to enter into and perform its Obligations under each Loan Document to which it is a party (if applicable).

SECTION 6.2 Due Authorization, Non-Contravention, Etc. The execution, delivery and performance by Holdings, the Borrower and each other Loan Party of each Loan Document executed or to be executed by it are in each case within such Person's corporate or organizational powers, have been duly authorized by all necessary corporate or organizational action, and do not:

- (a) contravene (i) the Organic Documents of such Loan Party, (ii) any material court decree or order binding on or directly affecting such Loan Party or (iii) any material Law or regulation binding on or directly affecting such Loan Party; or
- (b) (i) result in or require the creation or imposition of any Lien on such Loan Party's properties (except as permitted by this Agreement) or (ii) result in a material breach or a material default under any material contract, agreement, or instrument (including any Material Agreement or Key Contract) binding on or affecting such Loan Party.

SECTION 6.3 Government Approval, Regulation, Etc. No material authorization, approval, clearance or other action by, and no material notice to or filing with, any Governmental Authority or other Person (other than those that have been, or on the Closing Date will be, duly obtained or made and which are, or on the Closing Date will be, in full force and effect and other than those which will be made after the Closing Date pursuant to the terms hereof (including Article V and Section

7.17) or in accordance with UK statutory requirements) is required for the due execution, delivery or performance by Holdings, the Borrower or any other Loan Party of any Loan Document to which it is a party.

SECTION 6.4 Validity, Etc. Each Loan Document to which Holdings, the Borrower or any other Loan Party is a party constitutes the legal, valid and binding obligations of such Loan Party enforceable against such Loan Party in accordance with its respective terms (except, in any case, as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar Laws affecting creditors' rights generally and by principles of equity (including the Austrian IO, Canadian Insolvency Laws, the Quebec Civil Code and the French *Code de commerce* and *Code civil*)).

SECTION 6.5 Financial Information; Accounting Controls.

- (a) The financial statements of Holdings and its Subsidiaries furnished to the Administrative Agent and the Lenders pursuant to Sections 5.6 and 7.1 have been prepared in all material respects in accordance with IFRS, consistently applied, and present fairly in all material respects the consolidated financial condition of the Persons covered thereby as at the dates thereof and the results of their operations for the periods then ended, subject, in the case of interim statements, to the absence of footnote disclosures and customary year-end audit adjustments.
- (b) The Loan Parties and their Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS as required by this Agreement.

SECTION 6.6 No Material Adverse Effect. Since December 31, 2018, no Material Adverse Effect has occurred.

SECTION 6.7 Litigation, Labor Matters and Environmental Matters.

- (a) Except as described on Schedule 6.7(a), there are no actions, suits or proceedings by or before any arbitrator or Governmental Authority pending against or, to the knowledge of Holdings, threatened in writing, against or directly affecting Holdings, the Borrower or any Subsidiary (i) that would reasonably be expected, individually or in the aggregate, to result in liabilities in excess of €3,000,000 or (ii) that would reasonably be likely to adversely affect this Agreement or any other Loan Document or the transactions contemplated hereby and thereby.
- (b) There are no labor strikes, lockouts or work stoppages pending against or, to the knowledge of Holdings, threatened in writing, against or directly affecting Holdings, the Borrower or any Subsidiary (i) that would reasonably be expected, individually or in the aggregate, to result in liabilities in excess of €3,000,000 or (ii) that would reasonably be likely to adversely affect this Agreement or any other Loan Document or the transactions contemplated hereby or thereby.
- (c) None of Holdings, the Borrower or any Subsidiary (i) has failed to comply with any Environmental Law or to obtain, maintain or comply with any

Permit required under or in connection with any Environmental Law (“Environmental Permit”), (ii) is or has been subject to any Environmental Liability, (iii) has received written notice of any Environmental Liability, or (iv) knows of any basis for any Environmental Liability, in each case of clauses (i) through (iv) above, which would reasonably be expected to result in a Material Adverse Effect.

SECTION 6.8 Subsidiaries. As of the Closing Date, Holdings has no direct or indirect Subsidiaries except those Subsidiaries that are identified in Schedule 6.8 (which Schedule also identifies the direct owners of the Capital Securities of such Subsidiaries).

SECTION 6.9 Ownership of Properties. Holdings, the Borrower and each Subsidiary owns (a) in the case of owned real property, good and marketable fee title to or is heritable proprietor of, and (b) in the case of owned personal property, good and valid title to, or, in the case of leased real or personal property, valid and enforceable leasehold interests (as the case may be) in, all of its material properties and assets, tangible and intangible, of any nature whatsoever, free and clear in each case of all Liens, except for Liens permitted pursuant to Section 8.3.

SECTION 6.10 Taxes. Holdings, the Borrower and each Subsidiary has filed all income and other material Tax returns and reports required by Law to have been filed by it and has paid all Taxes due and owing (other than any amounts not in excess of €1,000,000), except any such Taxes which are being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with IFRS have been set aside on its books.

SECTION 6.11 Benefit Plans, Etc. None of Holdings or any of the Borrower’s Subsidiaries sponsors, maintains, contributes to, is required to contribute to, or has any actual or potential liability with respect to, any Canadian Defined Benefit Plan, and except as would not reasonably be expected to result in a Material Adverse Effect, (i) none of Holdings or any of the Borrower’s Subsidiaries or any of their respective ERISA Affiliates, sponsors, maintains, contributes to, is required to contribute to, or has any actual or potential liability with respect to, any other Benefit Plan, (ii) none of Holdings or any of the Borrower’s Subsidiaries is a party to any collective bargaining agreement, and none of the employees of Holdings or any of the Borrower’s Subsidiaries are subject to any collective bargaining agreement with any labor union or labor organization with respect to their employment with Holdings or any of the Borrower’s Subsidiaries, (iii) no “employee benefit plan,” as defined in section 3(3) of ERISA, that provides retirement benefits, is sponsored by Holdings or any of its ERISA Affiliates, and is intended to be Tax qualified under section 401(a) of the Code (or equivalent provisions of non-U.S. law) has failed to receive a determination letter or opinion letter from the U.S. Internal Revenue Service (or comparable approval from a non-U.S. tax authority) on which it remains entitled to rely, and no assets of any such plan are invested in Capital Securities of Holdings, and (iv) no “employee benefit plan,” as defined in section 3(3) of ERISA, that is sponsored, maintained, contributed to or required to be contributed to by Holdings or any of the Borrower’s Subsidiaries has failed to comply, both in form and in operation, in all material respects with its terms and applicable Law.

SECTION 6.12 Accuracy of Information. None of the written information heretofore or contemporaneously furnished in writing to the Administrative Agent or any

Lender by or on behalf of Holdings, the Borrower or any Subsidiary in connection with any Loan Document or any transaction contemplated hereby (excluding financial projections, other forward-looking information, other pro forma information, budgets, forecasts, estimates and information of a general economic or industry specific nature), taken as a whole and giving effect to all supplements and updates thereto that have been furnished to the Administrative Agent or any Lender, contains any untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not materially misleading. Any written financial projections or written budgets furnished to the Administrative Agent or any Lender by or on behalf of Holdings, the Borrower or any Subsidiary in connection with any Loan Document or any transaction contemplated hereby were prepared in good faith based upon assumptions that were believed by Holdings to be reasonable at the time made (it being understood that financial projections, other forward-looking information, other pro forma information, budgets, forecasts and/or estimates are not to be viewed as facts, are subject to significant uncertainties and contingencies, many of which are beyond the control of Holdings and its Subsidiaries, and are not a guarantee of financial performance, and no assurance can be given that such financial projections, other forward-looking information, other pro forma information, budgets, forecasts and/or estimates will be realized, and actual results during such period or periods may differ significantly from projected results, and such differences may be material).

SECTION 6.13 **Regulations U and X.** None of Holdings, the Borrower or any Subsidiary is engaged in the business of extending credit for the purpose of buying or carrying margin stock, and no proceeds of the Loans will be used to purchase or carry margin stock or otherwise for a purpose which violates, or would be inconsistent with, Regulation U or Regulation X of the F.R.S. Board. Terms for which meanings are provided in Regulation U and Regulation X of the F.R.S. Board, or any regulations substituted therefor, as from time to time in effect, are used in this **Section 6.13** with such meanings.

SECTION 6.14 **Solvency.** As of the Funding Date and each Delayed Draw Funding Date, Holdings, the Borrower and its Subsidiaries, taken as a whole on a consolidated basis, both immediately before and immediately after giving effect to the borrowing of the Loan to be advanced on such date, are Solvent.

SECTION 6.15 **Intellectual Property.**

- (a) **Schedule 6.15(a)**, sets forth a complete and accurate list as of the Closing Date, the Funding Date or any Delayed Draw Funding Date, as the case may be, of all of the foregoing with respect to Holdings and its Subsidiaries: (i) Patents, including any Patent applications and other items so defined as Patents, (ii) registered Trademarks (including domain names) and any pending registrations for Trademarks, and (iii) any other registered Intellectual Property, in each case of **clauses (i) through (iii)** that are owned by or, to the knowledge of Holdings, exclusively licensed to Holdings, the Borrower or any of the Subsidiaries. For each item of Intellectual Property listed on **Schedule 6.15(a)**, the Borrower has, where relevant, indicated (A) the countries in each case in which such item is registered, (B) the application numbers, (C) the registration or patent numbers, (D) the owner of such item of Intellectual Property and (E) with

respect to Intellectual Property owned by any Third Party, the agreement pursuant to which the Intellectual Property is licensed to Holdings, the Borrower or any Subsidiary.

(b) With respect to all material Intellectual Property listed, or required to be listed, on Schedule 6.15(a), in each case, except as set forth on Schedule 6.15(b):

- (i) Holdings, the Borrower or a Subsidiary owns or has a valid and enforceable right to use such Intellectual Property free and clear of any and all Liens, other than Liens permitted pursuant to Section 8.3, and (x) all such Intellectual Property owned by Holdings, the Borrower or a Subsidiary are in full force and effect and have not expired, lapsed or been forfeited, cancelled or abandoned unless permitted hereunder, and (y) all such Intellectual Property exclusively licensed to Holdings, the Borrower or a Subsidiary are, to the knowledge of Holdings, in full force and effect and have not expired, lapsed or been forfeited, cancelled or abandoned unless permitted hereunder;
- (ii) each of Holdings, the Borrower and the Subsidiaries, as applicable, has taken commercially reasonable actions to maintain and protect such Intellectual Property that is owned by it or exclusively licensed to it and for which that it has the right to take such actions, and there are no unpaid maintenance or renewal fees payable by Holdings, the Borrower or any of the Subsidiaries that are currently overdue for any of such registered Intellectual Property;
- (iii) there is no actual or threatened (in writing or, to the knowledge of Holdings, orally) proceeding in any court, patent office, Governmental Authority, arbitral body or elsewhere challenging the validity or enforceability of any such Intellectual Property owned by Holdings, the Borrower or the Subsidiaries or, to the knowledge of Holdings, any such Intellectual Property exclusively licensed to Holdings, the Borrower or the Subsidiaries, and none of such Intellectual Property is, to the knowledge of Holdings, the subject of any Other Administrative Proceeding;
- (iv) to the knowledge of Holdings, (A) such Intellectual Property is valid, enforceable and subsisting and (B) no event has occurred, and nothing has been done or omitted to have been done by Holdings, the Borrower or the Subsidiaries, that would affect the validity or enforceability of such Intellectual Property; and
- (v) each of Holdings, the Borrower and each Subsidiary, as applicable, is the sole and exclusive owner of all right, title and interest (other than the interest of any holder of any Lien permitted by Section 8.3) in and to all such Intellectual Property that is owned by it.

- (c) To the knowledge of Holdings, no Third Party is committing any act of Infringement of any Intellectual Property listed, or required to be listed, on Schedule 6.15(a), except as disclosed on Schedule 6.15(c).
- (d) With respect to each material license agreement listed on Schedule 6.15(a), such license agreement (i) is in full force and effect and is binding upon and enforceable against Holdings, the Borrower and the Subsidiaries party thereto and, to the knowledge of Holdings, all other parties thereto in accordance with its terms (except, in any case, as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar Laws affecting creditors' rights generally and by principles of equity), and (ii) to the knowledge of Holdings, has not suffered a default or breach thereunder. To the knowledge of Holdings, none of Holdings, the Borrower or any of the Subsidiaries has taken or omitted to take any action that would permit any other Person party to any such license agreement to have, and no such Person otherwise has, any defenses, counterclaims, termination rights or rights of setoff thereunder.
- (e) Except as set forth on Schedule 6.15(e), during the three years prior to the Closing Date, none of Holdings, the Borrower or any of the Subsidiaries has received written notice from any Third Party alleging that the conduct of its business (including the development, manufacture, use, sale or other commercialization of any Product) Infringes any Intellectual Property of any Third Party and, to the knowledge of Holdings, the conduct of its business and the business of the Subsidiaries (including the development, manufacture, use, sale or other commercialization of any Product) does not Infringe any Intellectual Property of any Third Party.
- (f) Holdings, the Borrower and the Subsidiaries have used commercially reasonable efforts and precautions to protect their respective commercially significant unregistered Intellectual Property.

SECTION 6.16 Material Agreements and Key Contracts.

- (a) Set forth on Schedule 6.16(a) is a complete and accurate list as of the Closing Date, the Funding Date or any Delayed Draw Funding Date, as the case may be, of all Material Agreements and Key Contracts, in each case of Holdings, the Borrower or any of the Subsidiaries, with an adequate description of the parties thereto, subject matter thereof and amendments and modifications thereto. As of such dates, respectively, each such Material Agreement and each such Key Contract (i) is in full force and effect and is the legal, valid and binding obligation of Holdings, the Borrower or the applicable Subsidiary party thereto and, to the knowledge of Holdings, each other Person party thereto, enforceable against such Person in accordance with its terms (except, in any case, as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar Laws affecting creditors' rights generally and by principles of equity (including the Austrian IO, Canadian Insolvency Laws, the Quebec Civil Code and the French *Code de commerce* and *Code civil*)) and (ii) has not been amended or otherwise modified except as has been disclosed to the Administrative Agent and the Lenders in accordance with the terms of this Agreement. As of such dates, respectively, (A) none of Holdings, the Borrower or any of the Subsidiaries is in breach or in

default under any Material Agreement or Key Contract and (B) to the knowledge of Holdings, no other Person party to such Material Agreement or Key Contract is in breach or in default thereunder.

- (b) As of the Closing Date, the Borrower has provided to the Administrative Agent and the Lenders full, complete and correct copies of each of the Key Contracts (including all exhibits and schedules thereto).

SECTION 6.17 **Permits.** Holdings, the Borrower and the Subsidiaries have all Permits (excluding Environmental Permits (which shall be subject to [Section 6.7\(c\)](#)) and excluding Key Permits and other Permits with respect to the Products (to the extent subject to [Section 6.18](#))) that are necessary or required for the proper conduct of their business, except as would not reasonably be expected to have a Material Adverse Effect.

SECTION 6.18 **Regulatory Matters.**

- (a) The conduct of the business of Holdings, the Borrower and its Subsidiaries since the applicable Product Reference Date has been, and currently is being, conducted in compliance in all material respects with all applicable Laws, including the FD&C Act, the PHSA and Privacy Laws and other similar state Laws and Laws of non-United States jurisdictions. The Products were researched, developed, designed, manufactured, distributed and validated by Holdings, the Borrower and its Subsidiaries in compliance in all material respects with all applicable Laws, including the FD&C Act, the PHSA, FTC Act, Privacy Laws and other similar state Laws and Laws of non-United States jurisdictions, and have been and continue to be performed, marketed, advertised, promoted, labeled, assembled, imported, exported, stored, packaged and conducted in compliance with all applicable Laws, including the FD&C Act, the PHSA, FTC Act, Privacy Laws and other similar state Laws and Laws of non-United States jurisdictions. All material required notices, material registrations and listings, supplemental applications or notifications, material reports (including reports of adverse experiences) and other material required filings and material Regulatory Authorizations with respect to the Products have been filed with the FDA and all other applicable Governmental Authorities.
- (b) To the knowledge of Holdings, no investigation or prosecution by any Governmental Authority with respect to the research, development, manufacturing, commercialization or sale of Products by Holdings, the Borrower or any Subsidiary has occurred, nor is any such action pending or threatened in writing. None of the Borrower or any of the Subsidiaries has received any written communication from any Person (including any Governmental Authority) alleging any noncompliance in any material respect with any applicable Laws or any written communication from any Governmental Authority of any material issues regarding the quality, compliance or performance of any Product, and, to the knowledge of Holdings, there is no basis for any material adverse regulatory action against Holdings, the Borrower or any of the Subsidiaries with respect to any Product. To the knowledge of Holdings, (i) since the applicable Product Reference Date, there have been no product recalls, safety alerts, corrections, withdrawals, clinical holds, marketing suspensions, removals

or the like conducted, undertaken or issued by any Person, whether or not at the request, demand or order of any Governmental Authority or otherwise, with respect to any Product, in each case, that have had or would reasonably be expected to have an adverse impact on the business of Holdings, the Borrower and the Subsidiaries in any material respect, and (ii) there is no basis for the issuance of any such product recalls, safety alerts, corrections, withdrawals, clinical holds, marketing suspensions, removals, or the like by any Person with respect to any Products, in each case, that would reasonably be expected to have an adverse impact on the business of Holdings, the Borrower and the Subsidiaries in any material respect. None of Holdings, the Borrower or any of the Subsidiaries has received any written notice of, and does not otherwise have knowledge of, any criminal, injunctive, seizure, detention or civil penalty actions that have at any time been commenced or threatened in writing by any Governmental Authority with respect to or in connection with any Product, or any consent decrees (including plea agreements) which relate to any Product or the business of Holdings, the Borrower and its Subsidiaries, and, to the knowledge of Holdings, there is no basis for the commencement for any criminal injunctive, seizure, detention or civil penalty actions by any Governmental Authority relating to any Product or for the issuance of any consent decrees relating to any Product, or the business of Holdings, the Borrower or its Subsidiaries.

- (c) Holdings, the Borrower or the applicable Subsidiary, as the case may be, owns, free and clear of all Liens, except those permitted pursuant to Section 8.3, all Key Permits (including all authorizations under the FD&C Act, the PHSA and other similar state Laws and Laws of non-United States jurisdictions) necessary for the research and development and commercialization of the Products and to carry on the business of Holdings, the Borrower and each such Subsidiary. All such Key Permits are valid and in full force and effect, and Holdings, the Borrower and each such Subsidiary is in compliance in all material respects with all terms and conditions of such Key Permits and with all filing and maintenance requirements (including any fee requirements) thereof. None of Holdings, the Borrower or any of the Subsidiaries has received any written notice that any Key Permits have been or are being revoked, withdrawn, suspended, modified, limited or challenged.
- (d) The Borrower has made available to the Administrative Agent and each Lender, to the extent requested by any such Person, copies of all Key Permits and material correspondence submitted to or received from FDA, CMS or other Governmental Authority (including minutes and official contact reports relating to any material communications with any Governmental Authority) in the Borrower's possession or control. The Borrower has made available to the Administrative Agent and the Lenders, to the extent requested by any such Person, all material adverse event reports and communications to or from the FDA (if any) and other relevant Governmental Authorities, including inspection reports, warning letters, untitled letters, and material reports, studies and other correspondence, other than opinions of counsel that are attorney-client privileged, with respect to regulatory matters relating to Holdings, the Borrower and any Subsidiaries, the conduct of their business, the operation of any manufacturing facilities owned, leased or operated by the

Borrower or any of the Subsidiaries, and the Products. No written statement made to the FDA, CMS or any other Governmental Authority by Holdings, the Borrower or any of the Subsidiaries, nor any written statement authorized or knowingly permitted by Holdings, the Borrower or any of the Subsidiaries to be made to the FDA, CMS or any other Governmental Authority by any of their respective agents or representatives, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not materially misleading, taken as a whole, in each case as of the date any such written statement was made.

- (e) With respect to the Products, (i) all design, manufacturing, storage, distribution, packaging, labeling, sale, recordkeeping and other activities by Holdings, the Borrower or any of its Subsidiaries or, to the knowledge of Holdings, their respective suppliers relating to the Products have been conducted since the applicable Product Reference Date, and are currently being conducted, in compliance in all material respects with the applicable requirements of the FD&C Act and other requirements of the FDA and all other Governmental Authorities, including adverse event reporting requirements, and (ii) none of Holdings, the Borrower or any of its Subsidiaries, or, to the knowledge of Holdings, any of their respective suppliers, has received written notice or written threat of commencement of action by any Governmental Authority to withdraw its approval of or to enjoin production of any Product at any facility. No Product in the inventory of Holdings, the Borrower or any of its Subsidiaries is adulterated or misbranded.
- (f) All manufacturing facilities owned, leased or operated by Holdings, the Borrower or any of the Subsidiaries, or used by Holdings, the Borrower or any of the Subsidiaries in the production of any Product, are and since the applicable Product Reference Date have been operated in material compliance with all applicable GMPs and all other applicable Laws. Except as disclosed on Schedule 6.18, as of the Closing Date, FDA has not issued any Form 483, warning letter, or untitled letter with respect to any such facility, or otherwise alleged in writing any material non-compliance with GMPs or other requirements or applicable Laws, nor has any other Governmental Authority issued any similar written notices or warning letters.
- (g) No right of Holdings, the Borrower or any Subsidiary to receive reimbursements pursuant to any government program or private program has ever been terminated or otherwise adversely affected as a result of any investigation, enforcement action or allegation in writing of non-compliance in any material respect by Holdings, the Borrower or any Subsidiary with applicable Laws, whether by any Governmental Authority or other Third Party, and none of Holdings, the Borrower or any Subsidiary has been the subject of any inspection, investigation or audit by any Governmental Authority for the purpose of any alleged material non-compliance by Holdings, the Borrower or any Subsidiary with any applicable Laws regarding reimbursement for any Products.

- (h) Holdings, the Borrower and the Subsidiaries have not entered into any arrangement providing for any rebates, kickbacks or other forms of compensation to be paid to any Person in return for the referral of business or for the arrangement of such referrals, in each case, in violation in any material respect of any applicable Law. All billings by Holdings, the Borrower and the Subsidiaries for their respective services have been made in compliance in all material respects with all applicable Laws, including the Federal False Claims Act or any applicable state false claims or fraud Law, or any non-U.S. equivalent.
- (i) None of Holdings, the Borrower or any of its Subsidiaries or, to the knowledge of Holdings, any individual who is an officer, director, manager, employee, shareholder, agent or managing agent of Holdings, the Borrower or of any of its Subsidiaries has been convicted of, charged with or, to the knowledge of Holdings, investigated for any federal or state health program-related offense or any other offense related to healthcare or been excluded, disqualified or suspended from participation in any such program or, to the knowledge of Holdings, within the past five years, has been convicted of, charged with or, to the knowledge of Holdings, investigated for a violation of Laws related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, or obstruction of an investigation, or has been subject to any judgment, stipulation, order or decree of, or criminal or civil fine or penalty imposed by, any Governmental Authority related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, or obstruction of an investigation. None of Holdings, the Borrower or any of its Subsidiaries or, to the knowledge of Holdings, any individual who is an officer, director, manager, employee, shareholder, agent or managing agent of Holdings, the Borrower or of any of its Subsidiaries has been convicted of any crime or engaged in any conduct that has resulted or would reasonably be expected to result in a debarment or exclusion under (i) 21 U.S.C. Section 335a, (ii) Section 1128 of the Social Security Act or (iii) any similar applicable Law. No debarment proceedings or investigations in respect of the business of Holdings, the Borrower or any of its Subsidiaries are pending or, to the knowledge of Holdings, threatened in writing against the Borrower or any of its Subsidiaries or, to the knowledge of Holdings, any individual who is an officer, director, manager, employee, shareholder, agent or managing agent of Holdings, the Borrower or of any of its Subsidiaries.
- (j) All preclinical studies, tests and clinical trials relating to each Product conducted by or on behalf of Holdings, the Borrower and the Subsidiaries, and, to the knowledge of Holdings, their respective licensees, licensors and Third Party services providers and consultants, have been conducted, and are currently being conducted, in compliance in all material respects with all applicable Laws, including the FD&C Act, the PHSA, GLPs, GCPs and other similar state Laws and Laws of non-United States jurisdictions. All results of such preclinical studies, tests and clinical trials, and all other material information related to such preclinical studies, tests and clinical trials, have been made available to each Lender as requested by it. To the extent required by applicable Law, Holdings, the Borrower or the applicable Subsidiary has obtained all material Regulatory

Authorizations, including an IND, for any clinical trials conducted by Holdings, the Borrower or such Subsidiary for any Product.

- (k) To the knowledge of Holdings, none of the clinical investigators in any clinical trial conducted by Holdings, the Borrower or any of the Subsidiaries for any Product has been or is disqualified or otherwise sanctioned by the FDA (e.g., pursuant to 21 C.F.R. 312.70), the U.S. Department of Health and Human Services, or any other Governmental Authority and, to the knowledge of Holdings, no such disqualification, or other sanction of any such clinical investigator is pending or threatened in writing. None of Holdings, the Borrower or any of the Subsidiaries has received any written communication from the FDA or any other Governmental Authority requiring or threatening the termination or suspension (in whole or in part) of any study, test or clinical trial conducted by Holdings, the Borrower or any of the Subsidiaries for any Product.
- (l) The transactions contemplated by the Loan Documents (or contemplated by the conditions to effectiveness of any Loan Document) will not materially impair the rights of Holdings, the Borrower or any of the Subsidiaries under any material Regulatory Authorizations relating to any Product.

SECTION 6.19 **Transactions with Affiliates.** Except as set forth on Schedule 6.19, as of the Closing Date, the Funding Date or any Delayed Draw Funding Date, as the case may be, none of Holdings, the Borrower or any Subsidiary is a party to, any transaction (including the purchase, sale, lease, transfer or exchange of property or assets of any kind or the rendering of services of any kind) with any of its Affiliates, except to the extent permitted by Section 8.10 (other than transactions permitted by Section 8.10(a)) involving payments in excess of €250,000).

SECTION 6.20 **Investment Company Act.** None of Holdings, the Borrower or any Subsidiary is an “investment company” or is “controlled” by an “investment company,” as such terms are defined in, or subject to regulation under, the Investment Company Act of 1940, as amended.

SECTION 6.21 **OFAC.** None of Holdings, the Borrower, any Subsidiary or, to the knowledge of Holdings, any Related Party (a) is currently the subject of any Sanctions, (b) is located, organized or residing in any Designated Jurisdiction, or (c) is or has been (within the previous five years) engaged in any transaction with any Person who is now or was then the subject of Sanctions or who is located, organized or residing in any Designated Jurisdiction in violation of any Sanctions. No Loan, nor the proceeds from any Loan, has been or will be used, directly or indirectly, in violation of any Sanctions to lend, contribute or provide to, or has been or will be otherwise made available to fund, any activity or business in any Designated Jurisdiction or to fund any activity or business of any Person located, organized or residing in any Designated Jurisdiction or who is the subject of any Sanctions, or in any other manner that will result in any violation by any Person (including the Administrative Agent, any Lender and any of their respective Affiliates) of Sanctions.

SECTION 6.22 **Deposit and Disbursement Accounts.** Set forth on Schedule 6.22 is a complete and accurate list as of the Closing Date, the Funding Date or any

Delayed Draw Funding Date, as the case may be, of all banks and other financial institutions at which Holdings, the Borrower or any Subsidiary maintains lockbox arrangements, deposit accounts, disbursement accounts, investment accounts or other similar accounts. Schedule 6.22 correctly identifies the name, address and telephone number of each bank or financial institution, the name in which each such account is held, the type of each such account, and the complete account number for each such account, and whether such account (to the extent held in the name of a Loan Party) is a Controlled Account or an Excluded Account, if applicable.

SECTION 6.23 Centre of Main Interests and Establishments. For the purposes of Regulation (EU) 2015/848 of 20 May 2015 on insolvency proceedings (recast) (the "Regulation"), its centre of main interest (as that term is used in Article 3(1) of the Regulation) is situated in its Original Jurisdiction and it has no "establishment" (as that term is used in Article 2(10) of the Regulation) in any other jurisdiction.

ARTICLE VII

AFFIRMATIVE COVENANTS

The Borrower covenants and agrees with the Administrative Agent and the Lenders that until the Termination Date has occurred, Holdings and the Borrower will, and will cause the Subsidiaries to, perform or cause to be performed the obligations set forth below.

SECTION 7.1 Financial Information, Reports, Notices, Etc. The Borrower will furnish the Administrative Agent and the Lenders with copies of the following financial statements, reports, notices and information:

- (a) (i) within five Business Days after submission to the Supervisory Board of Holdings, a copy of each Monthly Report, and (ii) as soon as available and in any event within 30 days after the end of each calendar month, an unaudited report, certified as complete and correct in all material respects by the chief financial or accounting Authorized Officer of the Borrower (solely in such Authorized Officer's official capacity and not in any personal capacity or with any personal liability therefor), of (A) the Revenue Base for such calendar month and (B) Liquidity as of the end of such calendar month;
- (b) as soon as available and in any event within 60 days after the end of each Fiscal Quarter, an unaudited consolidated balance sheet of Holdings and the Subsidiaries as of the end of such Fiscal Quarter and the related consolidated statements of income and cash flow of Holdings and the Subsidiaries for the period commencing at the end of the previous Fiscal Year and ending with the end of such Fiscal Quarter, setting forth in comparative form the figures for the year-to-date portion of the immediately preceding Fiscal Year, certified as complete and correct in all material respects by the chief financial or accounting Authorized Officer of the Borrower (solely in such Authorized Officer's official capacity and not in any personal capacity or with any personal liability therefor) (subject to the absence of footnote disclosures and customary normal year-end audit adjustments); provided that Holdings shall Publicly Disclose

such financial statements no later than the date provided to the Administrative Agent and the Lenders;

- (c) as soon as available and in any event within 120 days after the end of each Fiscal Year, a copy of the consolidated balance sheet of Holdings and the Subsidiaries as of the end of such Fiscal Year, and the related consolidated statements of income and cash flow of Holdings and the Subsidiaries for such Fiscal Year, setting forth in comparative form the figures for the immediately preceding Fiscal Year, audited (without any Impermissible Qualification) by independent public accountants reasonably acceptable to the Required Lenders (it being agreed that Holdings' auditors as of the Closing Date are reasonably acceptable to the Required Lenders); provided that Holdings shall Publicly Disclose such financial statements no later than the date provided to the Administrative Agent and the Lenders;
- (d) concurrently with the delivery of the financial information pursuant to clauses (b) and (c), a Compliance Certificate, executed by the chief financial or accounting Authorized Officer of the Borrower (solely in such Authorized Officer's official capacity and not in any personal capacity or with any personal liability therefor), (i) showing compliance with the covenant set forth in Section 8.4, (ii) stating that no Default has occurred and is continuing (or, if a Default has occurred, specifying the details of such Default and the action (if any) that Holdings, the Borrower or any of the Subsidiaries has taken or proposes to take with respect thereto), (iii) stating that no Subsidiary has been formed or acquired since the delivery of the last Compliance Certificate (or, if a Subsidiary has been formed or acquired since the delivery of the last Compliance Certificate, a statement that such Subsidiary has complied with Section 7.8 to the extent required by the terms thereof) and (iv) stating that no real property has been acquired by Holdings, the Borrower or any of the Subsidiaries since the delivery of the last Compliance Certificate (or, if any real property has been acquired since the delivery of the last Compliance Certificate, a statement that the Borrower has complied with Section 7.8 with respect to such real property to the extent required by the terms thereof);
- (e) as soon as possible and in any event within five Business Days after Holdings obtains knowledge of the occurrence of a Default, a statement of an Authorized Officer of the Borrower (solely in such Authorized Officer's official capacity and not in any personal capacity or with any personal liability therefor) setting forth details of such Default and the action (if any) which Holdings, the Borrower or any of the Subsidiaries has taken or proposes to take with respect thereto;
- (f) as soon as possible and in any event within five Business Days after Holdings obtains knowledge thereof, notice of (i) the occurrence of any material adverse development with respect to any litigation, action, proceeding or labor strike, lockout, or work stoppage described in Schedule 6.7(a) or (ii) the commencement of any litigation, action, proceeding or labor strike, lockout, or work stoppage of the type and materiality described in Section 6.7; and, in each case of clause (i), or (ii), to the extent any Lender reasonably requests, copies of all documentation relating thereto;

- (g) as soon as possible and in any event within five Business Days after Holdings obtains knowledge thereof, notice of any return, recovery, dispute or claim related to any Product that involves more than €1,000,000;
- (h) as soon as possible and in any event within five Business Days after Holdings obtains knowledge thereof, notice (i) that Holdings, the Borrower or any of the Subsidiaries or any of their ERISA Affiliates has actual or potential liability under a Benefit Plan other than in the ordinary course of business, or (ii) of correspondence with the Internal Revenue Service (or applicable non-U.S. tax authority) asserting that the qualification of a retirement plan under section 401(a) of the Code (or equivalent provisions of non-U.S. law) is not so qualified;
- (i) [reserved];
- (j) promptly upon receipt thereof, copies of all final “management letters” (or equivalent) submitted to Holdings, the Borrower or any of the Subsidiaries by the independent public accountants referred to in clause (c), in connection with each audit made by such accountants (provided that in the event that Holdings or the Borrower engages such auditors to perform a specific review, test, valuation or other analysis of all or any portion of the financial condition or financial performance of Holdings, the Borrower or the Subsidiaries, the results of such engagement shall not be required to be delivered to the Administrative Agent or the Lenders to the extent that such results are not otherwise required to be delivered pursuant to another provision of this Agreement);
- (k) (i) within 60 days after the end of each Fiscal Quarter, a report listing (A) all Material Agreements and Key Contracts entered into during such Fiscal Quarter and (B) all existing Material Agreements or Key Contracts amended or terminated during such Fiscal Quarter; and (ii) as soon as possible, and in any event within five Business Days, after the Administrative Agent or any Lender so requests, copies of any such Material Agreement, Key Contract, amendment or termination instrument, in each case, as are listed in such report;
- (l) as soon as possible and in any event within five Business Days after receipt by, or delivery by, Holdings or the Borrower, as the case may be, copies of any written notice alleging breach or default under any Key Contract by any party thereto;
- (m) as soon as available, but in any event not later than January 31 of each calendar year, a copy of the financial and business projections and budget of Holdings and the Subsidiaries approved by the Supervisory Board of Holdings for such calendar year;
- (n) as soon as possible and in any event within five Business Days after Holdings obtains knowledge thereof, notice of any changes to the Japanese encephalitis vaccine recommendation guidelines published by the Advisory Committee on Immunization Practices (ACIP) which could reasonably be expected to have a material adverse impact on Ixiaro sales by Holdings and the Subsidiaries;

- (o) copies of any reports, statements, documents or other information publicly filed under Applicable Securities Laws or otherwise Publicly Disclosed, contemporaneously therewith; and
- (p) such other financial and other information as any Lender or the Administrative Agent may from time to time reasonably request (including information and reports in such detail as such Lender or the Administrative Agent may request with respect to the terms of and information provided pursuant to the Compliance Certificate).

Notwithstanding the foregoing, (X) the Borrower shall not provide to any Public-Side Lender (or any of its attorneys, agents or representatives (other than the Administrative Agent and its Outside Counsel)) any reports, notices or information referenced in subsection (a), (f), (g), (h), (j), (k), (m), (n) or, except to the extent provided in response to a request by such Public-Side Lender, (p) of this Section 7.1, in each case, unless (and only to the extent) such Public-Side Lender has provided written notice to the Borrower of such Public-Side Lender's election (i) to receive such reports, notices and/or information in a specified case or on an ongoing basis (subject in any case to such Public-Side Lender's right to change such election in a subsequent written notice to the Borrower (with a copy to the Administrative Agent)) or (ii) to direct the Borrower to provide such reports, notices and/or information in a specified case or on an ongoing basis (subject in any case to such Public-Side Lender's right to change such election in a subsequent written notice to the Borrower (with a copy to the Administrative Agent)) to Outside Counsel to such Public-Side Lender; provided that no such election shall affect the Borrower's obligations, and such Public-Side Lender's rights, under Section 7.15 with respect to any such report, notice or other information (which obligations and rights shall apply in all cases); and (Y) with respect to any report, notice or information referenced in subsection (d) or (e) of this Section 7.1 that includes Inside Information, the Borrower shall provide such report, notice or information to each Public-Side Lender in accordance with and subject to the terms of Section 7.15(d).

Notwithstanding anything to the contrary set forth herein, the Borrower shall not be required to provide or disclose any information (i) that constitutes non-financial trade secrets of Holdings, the Borrower and/or the Subsidiaries or any of their respective customers and/or suppliers, (ii) in respect of which disclosure to the Administrative Agent or any Lender (or any of their respective representatives or contractors) is prohibited by applicable Law; provided that, with respect to this clause (ii), the Borrower shall (A) notify the Administrative Agent in writing that information is being withheld (to the extent permitted by applicable Law) and (B) use commercially reasonable efforts to communicate the relevant information in a way that does not violate such applicable Law, (iii) that is subject to attorney-client privilege (or other legally recognized privilege) or constitutes attorney work product; provided that, with respect to this clause (iii), the Borrower shall (A) notify the Administrative Agent in writing that information is being withheld and (B) use commercially reasonable efforts to communicate the relevant information in a way that does not violate such attorney-client privilege (or other legally recognized privilege) or (iv) in respect of which Holdings, the Borrower or any Subsidiary owes confidentiality obligations (to the extent not created in contemplation of such party's obligations hereunder) to any third party; provided that, with respect to this clause (iv), the Borrower shall (A) make the Administrative Agent aware of such confidentiality obligations (to the extent permitted under the applicable confidentiality obligation) and (B) use commercially reasonable efforts to communicate the relevant information in a way that does not violate such confidentiality obligations.

SECTION 7.2 Maintenance of Existence; Compliance with Contracts, Laws, Etc. Each of Holdings, the Borrower and each Subsidiary will (a) preserve and maintain its legal existence (except as otherwise permitted by Section 8.7), (b) perform in all material respects its obligations under all Material Agreements and Key Contracts, in each case to which Holdings, the Borrower or any of the Subsidiaries is a party, and (c) comply in all material respects with all applicable Laws, rules, regulations and orders, including the payment (before the same become delinquent), of all material Taxes, imposed upon Holdings, the Borrower or any of the Subsidiaries or upon their property except to the extent being

diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with IFRS have been set aside on the books of Holdings, the Borrower or any of the Subsidiaries, as applicable.

SECTION 7.3 Maintenance of Properties. Each of Holdings, the Borrower and the Subsidiaries will maintain, preserve, protect and keep its and their respective material properties in good repair, working order and condition (ordinary wear and tear, casualty and condemnation excepted), and make necessary repairs, renewals and replacements so that the business carried on by Holdings, the Borrower or any of the Subsidiaries may be properly conducted at all times, unless Holdings, the Borrower or any of the Subsidiaries determines in good faith that the continued maintenance of such property is no longer economically desirable, necessary or useful to the business of Holdings, the Borrower or any of the Subsidiaries or the Disposition of such property is otherwise permitted by Section 8.7 or Section 8.8.

SECTION 7.4 Insurance. Each of Holdings, the Borrower and each of the Subsidiaries will maintain:

- (a) insurance on its property with financially sound and reputable insurance companies against loss and damage in at least the amounts (and with only those deductibles) customarily maintained, and against such risks as are typically insured against in the same general area, by Persons of comparable size engaged in the same or similar business as Holdings, the Borrower and the Subsidiaries; and
- (b) to the extent required under the Laws of any state or jurisdiction in which it is engaged in business, worker's compensation insurance, employer's liability insurance or similar insurance.

Without limiting the foregoing, all insurance policies required pursuant to this Section 7.4 (other than any pollution legal liability policy, representation and warranty policy, directors and officers policies and workers' compensation policies or any property insurance policy that provides coverage exclusively for property that is not Collateral) shall (i) to the extent obtainable from the applicable insurer, name the Administrative Agent as mortgagee and loss payee (in the case of property insurance) and additional insured (in the case of liability insurance), as applicable, and provide that no cancellation or modification as to the amount or scope of coverage of the policies will be made without prior written notice to the Administrative Agent and (ii) be in addition to any requirements to maintain specific types of insurance contained in the other Loan Documents.

SECTION 7.5 Books and Records. Each of Holdings, the Borrower and each of the Subsidiaries will keep books and records in accordance with IFRS which accurately reflect in all material respects all of its business affairs and transactions and will permit the Administrative Agent, any Lender or any of their respective representatives, at reasonable times and intervals upon reasonable prior notice to the Borrower, to visit the offices of Holdings, the Borrower or any of the Subsidiaries, to discuss financial and other matters regarding Holdings, the Borrower or any of the Subsidiaries with its officers and its independent public accountants (and the Borrower hereby authorizes such independent public accountant to discuss financial and other matters regarding Holdings, the Borrower and any of the Subsidiaries with the Lender or its representatives, whether or not any representative of Holdings, the Borrower or any of the

Subsidiaries is present) and to examine (and photocopy extracts from) any of its books and records; provided that when no Event of Default exists, only the Administrative Agent (or an authorized representative designated by the Administrative Agent) on behalf of the Lenders may exercise any rights under this Section 7.5 and the Administrative Agent shall not exercise such rights more often than one time during any calendar year and such time shall be at the Borrower's expense; provided, further; that prior to any visit or inspection, any representative of the Administrative Agent or any Lender shall have agreed in writing to comply with confidentiality provisions substantially similar to those set forth in this Agreement or shall otherwise be bound by professional ethics rules or regulations or agreements that require such representative to maintain confidentiality generally. The Borrower shall pay any fees of such independent public accountant incurred in connection with the exercise of rights by the Administrative Agent or any Lender pursuant to this Section 7.5.

SECTION 7.6 Environmental Law Covenant. Each of Holdings, the Borrower and each of the Subsidiaries will (a) except as would not reasonably be expected to result in a Material Adverse Effect, use and operate all of its and their businesses, facilities and properties in compliance with all Environmental Laws, and keep and maintain all Environmental Permits and remain in compliance therewith, and (b) promptly notify the Administrative Agent of, and provide the Administrative Agent with copies of all material claims, complaints, written notices or written inquiries relating to, any actual or alleged non-compliance by Holdings, the Borrower or any of the Subsidiaries, or their businesses, facilities or properties with any Environmental Laws or Environmental Permits or any actual or alleged Environmental Liabilities, in either case, as would reasonably be expected to result in a Material Adverse Effect. Holdings, the Borrower and each of the Subsidiaries will promptly resolve, remedy and mitigate any such non-compliance or Environmental Liabilities, and shall keep the Lenders reasonably informed as to the progress of same.

SECTION 7.7 Use of Proceeds. The Borrower will use the proceeds of the Initial Loan to repay the Indebtedness identified on Schedule 8.2(b), to pay fees, costs and expenses incurred in connection with the transactions contemplated by this Agreement and for working capital and other general corporate purposes. The Borrower will use the proceeds of any Delayed Draw Loan for working capital and other general corporate purposes.

SECTION 7.8 Future Guarantors, Security, Etc. Holdings, the Borrower and each other Loan Party will execute any documents, financing statements, agreements and instruments, and will take all further action that may be required under applicable Law, or that the Administrative Agent or the Required Lenders may reasonably request, in order to effectuate the transactions contemplated by the Loan Documents and in order to grant, preserve, protect and perfect the validity and first priority (subject to Liens permitted by Section 8.3) of the Liens created or intended to be created by the Loan Documents, subject in all respects to any exclusions, limitations or other requirements set forth in any other provision of this Agreement or any other Loan Document (including any such other provision that requires periodic compliance with the terms hereof). If, after the Closing Date, any Loan Party becomes a Canadian PPSA Loan Party or a Quebec Loan Party, it shall execute as promptly as practicable but in no event later than 30 days (or such later date as may be agreed upon by the Required Lenders) after it becomes a Canadian PPSA Loan Party or a Quebec Loan Party all relevant

Canadian Security Documents and make or cause to be made all applicable PPSA and/or RPMRR filings and registrations. Holdings will (a) upon its acquisition or organization, cause any subsequently acquired or organized Subsidiary that qualifies as a Material Subsidiary to, and (b) as promptly as practicable but in no event later than 30 days (or such later date as may be agreed upon by the Required Lenders) after any Subsidiary qualifies independently as, or is designated by the Borrower or the Required Lenders as, a Material Subsidiary, provide the Administrative Agent and each Lender that is not a Public-Side Lender with written notice thereof and cause each such Material Subsidiary to, in each case of clauses (a) or (b), become a Guarantor and execute a supplement (in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders) to the Guarantee (which, in the case of a Guarantee (or supplement thereto) executed by any Material Subsidiary located in Austria or France that becomes a Guarantor hereunder, shall contain customary guarantee limitation wording) and each other applicable Loan Document in favor of the Secured Parties (and, if such Subsidiary becomes a Canadian PPSA Loan Party or a Quebec Loan Party, it shall execute all relevant Canadian Security Documents and make or cause to be made all applicable PPSA and/or RPMRR filings and registrations) and take such other actions as may be required or reasonably requested for the Secured Parties to have a valid Lien with the priority intended to be created on and security interest in all of the assets of such Material Subsidiary constituting Collateral, subject to no other Liens (other than Liens permitted by Section 8.3). The Borrower will promptly notify the Administrative Agent of any subsequently acquired ownership interest in real property by the Borrower or by any other Loan Party and will provide the Administrative Agent with a description of such real property, the acquisition date thereof and the purchase price therefor. In addition, from time to time, each of Holdings, the Borrower and each of the other Loan Parties will, at its cost and expense, promptly secure the Obligations by pledging or creating, or causing to be pledged or created, perfected Liens with respect to such of its assets and properties as the Administrative Agent or the Required Lenders shall designate, it being agreed that it is the intent of the Parties that the Obligations shall be secured by, among other things, substantially all the assets of Holdings, the Borrower and the other Loan Parties (including real property and personal property acquired subsequent to the Closing Date), except to the extent excluded or otherwise not required to be Collateral hereunder or under the other Loan Documents. Such Liens will be created under the Loan Documents in form and substance reasonably satisfactory to the Administrative Agent and the Required Lenders, and Holdings, the Borrower and each of the other Loan Parties shall deliver or cause to be delivered to the Administrative Agent all such instruments and documents (including mortgages, legal opinions, title insurance policies and lien searches) as the Administrative Agent or the Required Lenders shall reasonably request to evidence compliance with this Section 7.8. Holdings shall not permit any Subsidiary that is organized in France or Austria to be a Material Subsidiary, unless consented to by the Required Lenders, taking into account the effect of customary guarantee limitation language on the Guarantee by any such Subsidiary.

SECTION 7.9 Obtaining of Permits, Etc. Each of Holdings, the Borrower and each of the Subsidiaries will obtain, maintain and preserve, and take all necessary action to timely renew, all Permits (excluding Environmental Permits (which shall be subject to Section 7.6) and excluding Key Permits and other Permits with respect to the Products (which shall be subject to Section 7.11)) that are necessary or

required for the proper conduct of their business, except as would not reasonably be expected to have a Material Adverse Effect.

SECTION 7.10 [Reserved].

SECTION 7.11 Maintenance of Regulatory Authorizations, Contracts, Intellectual Property, Etc.

- (a) With respect to the Products, each of Holdings, the Borrower and each of the Subsidiaries will: (i) maintain in full force and effect all material Regulatory Authorizations necessary for the operations of its business; (ii) notify the Administrative Agent, promptly after Holdings obtains knowledge thereof, of any product recalls, safety alerts, clinical holds, corrections, withdrawals, marketing suspensions, removals or the like conducted, undertaken or issued, whether or not at the request, demand or order of any Governmental Authority or otherwise, with respect to any Product, in each case, that would reasonably be expected to have an adverse impact on the business of Holdings, the Borrower and the Subsidiaries in any material respect; (iii) develop, test, store, label, sell, promote, import, export, distribute and manufacture all Products in compliance in all material respects with GMPs, the FD&C Act, the PHSA and other applicable Laws; (iv) conduct all preclinical studies, tests and clinical trials relating to the Products in accordance in all material respects with all GLPs, GCPs and other applicable Laws; (v) operate all manufacturing facilities in material compliance with GMPs and all other applicable Laws; (vi) maintain in full force and effect all Material Agreements (except in the event that the Borrower determines in its reasonable commercial judgment not to do so) and all Key Contracts; (vii) notify the Administrative Agent, promptly after Holdings obtains knowledge thereof, of any material Infringement or other violation by any Person of its Intellectual Property; (viii) use commercially reasonable efforts to pursue and maintain in full force and effect legal protection for, and protect against Infringement with respect to, all Intellectual Property, including Patents, developed or controlled by Holdings, the Borrower or any of the Subsidiaries, except in the event that the Borrower determines in its reasonable commercial judgment that failure to so pursue such action will not be adverse to the interests of Holdings, the Borrower and the Subsidiaries in any material respects; and (ix) notify the Administrative Agent, promptly after Holdings obtains knowledge thereof, of any claim by any Person that the conduct of business of Holdings, the Borrower or any of the Subsidiaries (including the development, manufacture, use, sale or other commercialization of any Product) materially Infringes any Intellectual Property of that Person and use commercially reasonable efforts to resolve such claim, except where the Borrower determines in its reasonable commercial judgment not to do so.
- (b) Each of Holdings, the Borrower and its Subsidiaries will furnish to the Administrative Agent prompt written notice of the following, and, with respect to clause (ii) below, copies of any written notices from, or responses to, the FDA or other Governmental Authority:
- (i) [reserved];
 - (ii) with respect to any Product, (w) Holdings, the Borrower or any of its Subsidiaries becoming subject to any administrative or regulatory action, any inspection by the FDA or any other Governmental Authority or any non-routine inspection by any other Person, (x) receipt by Holdings, the Borrower or any of its Subsidiaries of

inspectional observations (e.g., on FDA Form 483), any warning letter, untitled letter or notice of violation letter, (y) any Product being seized, detained or subject to a suspension of manufacturing or import alert, or the commencement of any proceedings in the United States or any other jurisdiction seeking the seizure, detention or suspension of any Product, or if any of the foregoing are pending or threatened in writing against Holdings, the Borrower, any of its Subsidiaries or, to the knowledge of Holdings, any of its or their suppliers, or (z) Holdings, the Borrower or any of its Subsidiaries becoming subject to a consent decree; or

- (iii) with respect to any Product, copies of any written recommendation from any Governmental Authority that Holdings, the Borrower or any of its Subsidiaries should have its licensure, clearances, provider or supplier number, or accreditation suspended, revoked, or limited in any way, or any penalties or sanctions imposed.

SECTION 7.12 Inbound Licenses. Each of Holdings, the Borrower and the other Loan Parties will, promptly after entering into or becoming bound by any inbound license or agreement (other than for generally commercially available software or "open-source" software) in respect of any Intellectual Property material to the business of Holdings, the Borrower and the Subsidiaries, taken as a whole: (a) provide written notice to the Administrative Agent of the material terms of such license or agreement with a description of its anticipated and projected impact on the business and financial condition of Holdings, the Borrower and the Subsidiaries; and (b) take such commercially reasonable actions as the Administrative Agent or the Required Lenders may reasonably request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for the Secured Parties to be granted and perfect a valid security interest in such license or agreement and to fully exercise its rights under any of the Loan Documents in the event of a disposition or liquidation of the rights, assets or property that is the subject of such license or agreement.

SECTION 7.13 Cash Management. Each of Holdings, the Borrower and the other Loan Parties will maintain a current and complete list of all accounts (of the type initially set forth on Schedule 6.22) and, subject to Section 7.17 (or, with respect to any accounts opened or established after the Funding Date, upon such opening or establishment), enter into such documentation (including, if applicable, a Control Agreement) or take such other actions as may be necessary to cause such accounts (other than (i) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit programs for the benefit of the employees of Holdings, the Borrower or a Subsidiary in the ordinary course of business, (ii) any deposit account the funds in which are in trust for any third parties or any other trust accounts, escrow accounts, defeasance and redemption accounts and other fiduciary accounts, (iii) tax accounts, including without limitation, sales tax accounts, and (iv) any other accounts the aggregate balance held on deposit in all such accounts at any time shall not exceed €5,000,000 (collectively, the "Excluded Accounts")) to become Controlled Accounts, and thereafter maintain each such Controlled Account as a cash collateral account (which may be an interest-bearing account), with all cash, checks and other similar items of payment in such account securing payment of the Obligations (and in which Holdings, the

Borrower and the other Loan Parties shall have granted a Lien to the Secured Parties).

SECTION 7.14 Board Observation Rights.

- (a) Each of OrbiMed and Deerfield shall have the option (exercisable or terminable at any time), but not the obligation, to appoint, and Holdings shall permit the appointment of, one person representing OrbiMed and one person representing Deerfield (collectively, the "Observers") to attend and observe (but not vote) at all meetings of the Supervisory Board of Holdings, whether in person, by telephone or otherwise. Holdings shall notify the Observers in writing at the same time and in the same manner as notice is provided to the members of the Supervisory Board in advance of (i) the date and time for each general or special meeting of the Supervisory Board and (ii) the adoption of any resolutions or actions by written consent, in each case, which notice may exclude information as to the agenda for such meeting or the nature of such resolution or action to the extent necessary to avoid disclosing Inside Information to any Observer that has not elected to receive Inside Information. Following such notice, each Observer will notify Holdings at least five (5) Business Days in advance of such event if such Observer will attend, whether in person, by telephone or otherwise and, to the extent requested by Holdings, will execute and deliver to Holdings a customary acknowledgment of such Observer's election to receive Inside Information. The general meetings of the Supervisory Board shall take place on no less than a quarterly basis. Holdings shall concurrently deliver to the Observers all notices and any materials delivered to the Supervisory Board in connection with any such meeting or action to be taken by written consent, including a draft of any material resolutions or actions proposed to be adopted by written consent, except to the extent that such Observer elects not to attend any such meeting (or receive any such resolutions, actions by written consent or other materials related thereto) in order to avoid receiving Inside Information. The Observers shall be free prior to such meeting or adoption by consent to contact the Supervisory Board and discuss the pending actions to be taken.
- (b) Each Observer shall pay its own out-of-pocket expenses (including the cost of travel, meals and lodging) in connection with the attendance of such meetings.
- (c) If an issue is to be discussed or otherwise arises at any meeting of the Supervisory Board (or any materials are to be distributed at any such meeting) which, in the reasonable good faith judgment of the Supervisory Board, is not appropriate to be discussed in the presence of any Observer in order to avoid an actual or potential conflict of interest on the part of such Observer or would result in disclosure of trade secrets, or to the extent that attendance by such Observer at any such meeting (or receipt of any such materials) would violate, jeopardize, impair or otherwise adversely affect an attorney-client privilege (or other legally recognized privilege), or to the extent that attendance by such Observer at such meeting (or receipt of any such materials) would cause the Borrower to provide Inside Information to any Observer that has not elected to receive Inside Information, then such issue may be discussed without such Observer being present, and any materials delivered to the Supervisory Board pertaining to such issue need not be delivered to such Observer, so long as such Observer is given notice of the occurrence of such judgment by the Supervisory Board, that such Observer is being excused, and that certain materials will not be delivered to such Observer.

SECTION 7.15 Securities Laws; Disclosure; Inside Information.

- (a) Holdings (i) shall timely (A) file all reports, statements and other documents required to be publicly filed by Holdings under Applicable Securities Laws, and (B) Publicly Disclose all financial and other information required to be Publicly Disclosed under Applicable Securities Laws, and (ii) shall not terminate the registration of its Capital Securities under Applicable Securities Laws or otherwise terminate its status as an issuer required to publicly file reports under Applicable Securities Laws, even if the Applicable Securities Laws would otherwise permit any such termination. None of the reports, statements, documents or information publicly filed by Holdings under Applicable Securities Laws or Publicly Disclosed by Holdings, when filed or Publicly Disclosed, shall contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not materially misleading, taken as a whole and giving effect to all supplements and updates thereto.
- (b) Not later than the first Business Day following the Closing Date, Holdings shall Publicly Disclose in a broadly distributed press release the terms of the transactions contemplated by this Agreement and the other Loan Documents and any other Inside Information provided to any Public-Side Lender on or prior to the Closing Date (the "Announcing Report"). Not later than the first Business Day following the Funding Date and any Delayed Draw Funding Date, Holdings shall Publicly Disclose the terms of the transactions occurring hereunder on the Funding Date or such Delayed Draw Funding Date, as applicable, and any other material transactions occurring in connection therewith. Subject to the foregoing, no Loan Party shall (and no Loan Party shall permit any of its Affiliates to) issue any press releases or any other public statements with respect to the transactions contemplated by any Loan Document or disclosing the name of any Secured Party or any of its Affiliates; provided, however, that Holdings shall be entitled, without the prior approval of any Secured Party, to make any press release or other public disclosure with respect to such transactions (i) in substantial conformity with the Announcing Report and substantially contemporaneously therewith and (ii) as is required by Applicable Securities Laws (provided that each Secured Party shall be consulted by Holdings and the Borrower in connection with any such press release or other public disclosure prior to its release and shall be provided with a copy thereof).
- (c) Upon the issuance of the Announcing Report, Holdings shall have Publicly Disclosed all Inside Information (if any) provided to any Public-Side Lender on or prior to the Closing Date. Each Loan Party and the Administrative Agent shall not, and shall cause each of its employees, officers, directors (or equivalent persons), Affiliates, attorneys, agents and representatives to not, provide any Public-Side Lender or any of its attorneys, agents or representatives (other than the Administrative Agent and its Outside Counsel) with any Inside Information from and after the Closing Date without the express prior written consent of such Public-Side Lender (which consent may be provided by written notice to the Borrower in a specified case or on an ongoing basis (subject in any case to such Public-Side Lender's right to withdraw such consent in a subsequent written notice to the Borrower)).
- (d) Notwithstanding anything to the contrary herein, in the event that any Loan Party believes that any notice, report, information or communication required to be provided hereunder or under any other Loan Document to any Public-Side Lender contains Inside Information, the Borrower shall (i) so indicate to such Public-Side Lender prior to delivery of such notice, report, information or communication (without otherwise disclosing or describing the nature of such Inside Information), which indication shall provide such Public-Side Lender the means to refuse to receive such notice, report, information or communication (and in the absence of any such indication, such Public-

Side Lender shall be allowed to presume that such notice, report, information or communication does not contain Inside Information), and (ii) provide such notice, report, information or communication to Outside Counsel to such Public-Side Lender. Notwithstanding anything to the contrary contained herein or in any other Loan Document, in the event of a breach of any of the foregoing covenants by any Loan Party, any of its Affiliates, or any of its or their respective officers, directors (or equivalent persons), employees, attorneys, agents or representatives, in addition to any other remedies provided in the Loan Documents or otherwise available at law or in equity, any Public-Side Lender shall have the right to Publicly Disclose in the form of a press release or otherwise, of the applicable Inside Information without the prior approval by any Loan Party or any of its Affiliates, officers, directors (or equivalent persons), employees, stockholders, attorneys, agents or representatives, and such Public-Side Lender shall not have any liability to any Loan Party, any of its Affiliates or any of its or their respective officers, directors (or equivalent persons), employees, shareholders, attorneys, agents or representatives for any such disclosure.

- (e) Each of the parties hereto acknowledges and agrees that (i) the Administrative Agent shall not provide any Inside Information to any Public-Side Lender without complying with the process set forth in clause (i) of the first sentence of Section 7.15(d), as if the Administrative Agent were the Borrower for purposes thereof, and (ii) no Lender or any Affiliate of any Lender shall be deemed to be in possession of any Inside Information because such Inside Information was provided to the Administrative Agent, any other Lender or any attorney or agent of any Lender (including Outside Counsel to any Lender), and the Borrower agrees not to (and the Borrower agrees to cause its Affiliates not to) assert any contrary position.

SECTION 7.16 Material Subsidiaries. If at any time (a) the aggregate book value or the aggregate fair market value of the assets attributable to all Subsidiaries that are not Material Subsidiaries (other than, for purposes of this Section 7.16, the assets owned by or attributable to VBC-3) exceeds €5,000,000, the Borrower shall designate sufficient Subsidiaries as “Material Subsidiaries” to eliminate such excess, and such designated Subsidiaries shall for all purposes of this Agreement constitute “Material Subsidiaries,” or (b) the aggregate portion of the Revenue Base attributable to all Subsidiaries that are not Material Subsidiaries exceeds 5% of the Revenue Base for any period of four consecutive Fiscal Quarters (determined as of the last day of the most recent Fiscal Quarter for which financial statements have been delivered pursuant to Section 7.1(b) or 7.1(c) (or, if prior to the date of the delivery of the first financial statements to be delivered pursuant to Section 7.1(b) or 7.1(c), the most recent financial statements referred to in Section 5.6)), the Borrower shall designate sufficient Subsidiaries as “Material Subsidiaries” to eliminate such excess, and such designated Subsidiaries shall for all purposes of this Agreement constitute “Material Subsidiaries”, provided that any Subsidiary that is organized under the laws of France and whose business, assets and operations solely relate to distributions, marketing and sales of Products to customers in France shall be disregarded for purposes of this Section 7.16.

SECTION 7.17 Post-Closing Obligations.

- (a) Holdings and the Borrower will, and will cause each other Loan Party to, take each of the actions described on Schedule 7.17, notwithstanding anything to the contrary contained herein or in any other Loan Document with respect to any such action, in each case, in the form or manner

specified thereon, and no later than the dates specified thereon (or such later dates as may be agreed by the Required Lenders in their reasonable discretion). All representations and warranties contained in this Agreement and the other Loan Documents shall be deemed modified (or waived on a limited basis) to the extent necessary to give effect to the foregoing (and to permit the taking of the actions described on Schedule 7.17 within the time periods specified thereon), and, to the extent any provision of this Agreement or any other Loan Document would be violated or breached (or any non-compliance with any such provision would result in a Default or Event of Default hereunder) as a result of any such extended deadline, such provision shall be deemed modified (or waived on a limited basis) to the extent necessary to give effect to this Section 7.17.

(b) Following the Eighth Amendment Effective Date:

- (i) On or prior to November 6, 2023 (or such later date as may be agreed by the Required Lenders in their reasonable discretion (which agreement may be via email), Borrower and Holdings shall deliver to the Administrative Agent (x) a fully executed copy of the stock purchase agreement with respect to the VBC-3 Acquisition and (y) a PDF scan of the duly executed notarial deed on the VBC-3 Acquisition; and
- (ii) Within 30 days following the Eighth Amendment Effective Date (or such later date as may be agreed by the Required Lenders in their reasonable discretion (which agreement may be via email), Borrower and Holdings shall (x) enter into an Austrian law governed pledge over the Capital Securities of VBC-3 owned by each of Borrower and Holdings and (y) take any such other actions as the Required Lenders may reasonably request to grant the Collateral Agent a perfected security interest and pledge over all of the equity interests of VBC-3 under applicable Law.

ARTICLE VIII NEGATIVE COVENANTS

The Borrower covenants and agrees with the Administrative Agent and the Lenders that, until the Termination Date has occurred, Holdings, the Borrower and the Subsidiaries will, and will cause the Subsidiaries to, perform or cause to be performed the obligations set forth below.

SECTION 8.1 Business Activities. None of Holdings, the Borrower or any of the Subsidiaries will engage in any business activity except those business activities engaged in on the date of this Agreement and activities reasonably related, complementary, ancillary or incidental thereto or a reasonable extension, expansion or development thereto or otherwise expressly permitted hereunder.

SECTION 8.2 Indebtedness. None of Holdings, the Borrower or any of the Subsidiaries will create, incur, assume or permit to exist any Indebtedness, other than:

- (a) Indebtedness in respect of the Obligations;
- (b) until the Funding Date, the Indebtedness identified on Schedule 8.2(b);

- (c) Indebtedness existing as of the Closing Date which is identified in Schedule 8.2(c), and Permitted Refinancing Indebtedness in respect of such Indebtedness;
- (d) unsecured Indebtedness in respect of performance, surety or appeal bonds provided in the ordinary course of business;
- (e) Purchase Money Indebtedness and Capitalized Lease Liabilities incurred after the Closing Date in a principal amount not to exceed €10,000,000 in the aggregate outstanding at any time;
- (f) Permitted Subordinated Indebtedness;
- (g) Indebtedness of any Guarantor or the Borrower owing to the Borrower or any Guarantor;
- (h) other Indebtedness of Holdings, the Borrower and the Subsidiaries in an aggregate principal amount at any time outstanding not to exceed €5,000,000;
- (i) Indebtedness of (i) any Loan Party owing to a Subsidiary that is not a Guarantor; provided that all of such Indebtedness shall be subordinated to the Obligations pursuant to an intercompany debt subordination agreement in substantially the form of Exhibit G hereto (or any other form approved by the Required Lenders), (ii) any Subsidiaries that are not Guarantors owing to the Borrower or any Guarantor in an aggregate principal amount at any time outstanding not to exceed, when combined with outstanding Investments by any Loan Party in or to any Subsidiary that is not a Guarantor pursuant to Section 8.5(h)(1) and any Disposition by any Loan Party to any Subsidiary that is not a Guarantor pursuant to Section 8.8(p), €5,000,000, and (iii) any Subsidiaries that are not Guarantors owing to any other Subsidiary that is not a Guarantor;
- (j) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;
- (k) Indebtedness in respect of commercial credit cards, employee credit card programs, purchasing cards, treasury management services, netting services, overdraft protection, check drawing services, automated payment services (including controlled disbursement, ACH transactions and return items services) and any other similar arrangements or services in connection with cash management and deposit accounts;
- (l) Indebtedness consisting of reimbursement obligations pursuant to letter of credit arrangements that are repaid within five Business Days of becoming due;
- (m) Indebtedness consisting of the financing of insurance premiums and other obligations in respect of workers' compensation insurance, unemployment insurance (including premiums related thereto), property, casualty or liability insurance and similar obligations, and other types of social security, pension obligations, vacation pay, health, disability or other

employee benefits in the ordinary course of business consistent with past practice;

(n) Indebtedness in respect of hedging, derivative or swap agreements incurred in the ordinary course of business and not for speculative purposes; and

(o) Indebtedness consisting of accrued obligations in respect of payroll and other similar compensation liabilities incurred or arising in the ordinary course of business.

provided that no Indebtedness otherwise permitted by clauses (c), (f) or (h) shall be assumed, created or otherwise incurred if a Default has occurred and is then continuing or would result therefrom; provided, further, that no Indebtedness otherwise permitted by clause (e) shall be assumed, created or otherwise incurred if an Event of Default under Section 9.1(a) or Section 9.1(h) has occurred and is then continuing or would result therefrom.

SECTION 8.3 **Liens.** None of Holdings, the Borrower or any of the Subsidiaries will create, incur, assume or permit to exist any Lien upon any of its property (including Capital Securities of any Person), revenues or assets, whether now owned or hereafter acquired, except:

- (a) Liens securing payment of the Obligations;
- (b) Liens securing the Indebtedness identified on Schedule 8.2(b) so long as such Indebtedness is permitted to remain outstanding hereunder, subject to Section 7.17 for the filing and/or recordation of any applicable termination or release documentation;
- (c) Liens existing as of the Closing Date and disclosed in Schedule 8.3(c) securing Indebtedness described in Section 8.2(c), and Permitted Refinancing Indebtedness in respect of such Indebtedness; provided that no such Lien shall encumber any additional property and, except as permitted by the definition of "Permitted Refinancing Indebtedness", the amount of Indebtedness secured by such Lien is not increased from that existing on the Closing Date (as such Indebtedness may have been reduced following the Closing Date);
- (d) Liens securing payment of Permitted Subordinated Indebtedness that are (i) subordinate to the Liens securing payment of the Obligations and (ii) subject to a written subordination agreement satisfactory to the Secured Parties in their sole discretion;
- (e) Liens securing Indebtedness of Holdings, the Borrower or the Subsidiaries permitted pursuant to Section 8.2(e); provided that (i) such Liens shall be created within 180 days of the acquisition of the assets financed with such Indebtedness and (ii) such Liens do not at any time encumber any property other than the property so financed;
- (f) Liens in favor of carriers, warehousemen, mechanics, materialmen and landlords granted in the ordinary course of business for amounts not overdue or being diligently contested in good faith by appropriate

proceedings and for which adequate reserves in accordance with IFRS shall have been set aside on its books;

- (g) Liens incurred or deposits made in the ordinary course of business in connection with worker's compensation, unemployment insurance or other forms of governmental insurance or benefits, or to secure performance of tenders, statutory obligations, bids, leases or other similar obligations (other than for borrowed money) entered into in the ordinary course of business or to secure obligations on surety and appeal bonds or performance bonds;
- (h) judgment Liens which do not result in an Event of Default under Section 9.1(f);
- (i) easements, servitudes, rights-of-way, zoning restrictions, minor defects or irregularities in title and other similar encumbrances not interfering in any material respect with the value or use of the property to which such Lien is attached;
- (j) Liens for Taxes not at the time delinquent or thereafter payable without penalty or being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with IFRS shall have been set aside on its books;
- (k) licenses or sublicenses of Intellectual Property otherwise permitted under this Agreement or the other Loan Documents, and restrictions under licenses of Intellectual Property entered into in the ordinary course of business;
- (l) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with the deposit accounts or securities accounts of Holdings, the Borrower or any Subsidiary held at such institutions;
- (m) Liens on insurance policies and the proceeds thereof securing the financing of the premiums with respect thereto;
- (n) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of any assets or property in the ordinary course of business or by operation of law under Article 2 of the UCC (or similar law of any jurisdiction);
- (o) the interest of lessors under leases (other than Capitalized Lease Liabilities) or licensors under license agreements;
- (p) Liens securing Indebtedness or other obligations expressly permitted by Sections 8.2(k); and
- (q) other Liens of Holdings, the Borrower and the Subsidiaries securing Indebtedness or other obligations in an aggregate principal amount at any time outstanding not to exceed €2,000,000.

Each Secured Party agrees to execute and deliver such collateral subordination agreements and related documents as reasonably requested of it to confirm the priority of the Liens permitted pursuant to Section 8.3(e).

SECTION 8.4 Financial Covenants.

(a) *Liquidity*. The Liquidity of Holdings, the Borrower and the Subsidiaries, on a consolidated basis, shall not at any time be less than €35,000,000.

(b) *Revenue Base*.

(i) At all times (x) on or prior to June 30, 2020 and (y) after January 1, 2023, the Revenue Base of Holdings, the Borrower and its Subsidiaries, on a consolidated basis, for the most recently ended period of twelve consecutive months, shall not be less than €115,000,000.

(ii) At all times from January 1, 2021 through and including December 31, 2022 (except with respect to the Fiscal Quarters ending March 31, 2022 and June 30, 2022, for each of which there shall be no separate quarterly Revenue Base requirement, subject to subclauses (i) above and (iii) below), the Revenue Base of Holdings, the Borrower and its Subsidiaries, on a consolidated basis, for the most recently ended quarterly period, shall not be less than the amount set forth below opposite the period during which such quarterly period ends:

Date of Fiscal Quarter End	Quarterly Revenue Base
March 31, 2021	€14,000,000
June 30, 2021	€13,500,000
September 30, 2021	€16,000,000
December 31, 2021	€20,500,000
March 31, 2022	Not applicable
June 30, 2022	Not applicable
September 30, 2022	€27,500,000
December 31, 2022	€28,750,000

(iii) The Revenue Base of Holdings, the Borrower and its Subsidiaries, on a consolidated basis, for the six-month period ending June 30, 2022, shall not be less than €47,500,000.

SECTION 8.5 Investments. None of Holdings, the Borrower or any of the Subsidiaries will purchase, make, incur, assume or permit to exist any Investment in or to any other Person, except:

- (a) Investments existing on the Closing Date and identified in Schedule 8.5(a);
- (b) Investments consisting of cash and Cash Equivalent Investments;
- (c) Investments received in connection with the bankruptcy or reorganization of, or settlement of delinquent accounts and disputes with, customers and suppliers, in each case in the ordinary course of business;
- (d) Investments consisting of any deferred portion of the sales price received by Holdings, the Borrower or any of the Subsidiaries in connection with any Disposition permitted under Section 8.8;
- (e) Investments constituting (i) accounts receivable arising, (ii) trade debt granted or trade credit extended, (iii) deposits or prepayments made or (iv) advances made to distributors, suppliers, licensors and licensees, in each case of clauses (i) through (iv), in the ordinary course of business;
- (f) Permitted Acquisitions;
- (g) Investments by the Borrower or any Guarantor in or to the Borrower or any Guarantor;
- (h) Investments (i) by Holdings, the Borrower or any Guarantor in or to any Subsidiary that is not a Guarantor, in an aggregate amount at any time outstanding not to exceed, when combined with any outstanding Indebtedness of any Subsidiary that is not a Guarantor owing to the Borrower or any Guarantor pursuant to Section 8.2(i)(ii) and any Disposition by any Loan Party to any Subsidiary that is not a Guarantor pursuant to Section 8.8(p), €5,000,000, (ii) by any Subsidiary that is not a Loan Party in or to any other Subsidiary that is not a Loan Party and (iii) by any Subsidiary that is not a Loan Party in or to Holdings, the Borrower or any Guarantor;
- (i) Investments in the ordinary course of business consisting of endorsements of negotiable instruments for collection or deposit;
- (j) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business in an aggregate amount not to exceed €250,000 outstanding at any time, and (ii) loans to employees, officers or directors relating to the purchase of Capital Securities of the Holdings or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by the board of directors of Holdings;
- (k) Investments in hedging, derivative or swap agreements incurred in the ordinary course of business and not for speculative purposes;
- (l) [reserved]; and

(m) other Investments in an aggregate amount not to exceed €3,000,000 over the term of this Agreement.

SECTION 8.6 Restricted Payments, Etc. None of Holdings, the Borrower or any of the Subsidiaries will declare or make a Restricted Payment, or make any deposit for any Restricted Payment, other than (i) Restricted Payments made by the Borrower or any Subsidiary to the Borrower or any Guarantor or by any Subsidiary to any other Subsidiary, (ii) Restricted Payments made by Holdings to repurchase Capital Securities of Holdings held by employees, officers, directors, consultants or managers (or any of their respective heirs, administrators, executors, estates or other similar transferees) to the extent that such Capital Securities were issued or awarded pursuant to any management equity plan, profits interest or stock option plan or any other management or employee benefit plan or agreement, pension plan, any stock subscription or shareholder agreement or any distributor equity plan or agreement, or any similar equity plan or agreement, in an aggregate annual amount not to exceed €1,000,000, (iii) Restricted Payments in the form of Capital Securities (other than Disqualified Capital Securities), (iv) Restricted Payments payable in cash in lieu of the issuance of fractional shares in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Capital Securities of Holdings in an aggregate amount not to exceed €500,000, and (v) Restricted Payments made by Holdings from existing cash reserves to repurchase Capital Securities of Holdings in accordance with the requirements of its Organic Documents, in an aggregate amount not to exceed €200,000.

SECTION 8.7 Consolidation, Merger, Permitted Acquisitions, Etc. None of the Borrower or any of the Subsidiaries will liquidate or dissolve, consolidate or amalgamate with, or merge into or with, any other Person, or purchase or otherwise acquire all or substantially all of the assets of any Person (or any division thereof), other than in connection with a Permitted Acquisition, except that, so long as no Event of Default has occurred and is continuing (or would occur), any Subsidiary may liquidate or dissolve voluntarily into, and may merge with and into, the Borrower or any Subsidiary; and provided that, in connection with any Permitted Acquisition, the Borrower or any Subsidiary may merge into or consolidate with any other Person or permit any other Person to merge into or consolidate with it, so long as (a) the Person surviving such merger with any Subsidiary shall be a direct or indirect Wholly-Owned Subsidiary of the Borrower and, if qualifying as a Material Subsidiary, it shall be a Guarantor, and (b) in the case of any such merger to which the Borrower is a party, the Borrower is the surviving Person.

SECTION 8.8 Permitted Dispositions. None of Holdings, the Borrower or any of the Subsidiaries will Dispose of any of its assets (including accounts receivable and Capital Securities of the Borrower or Subsidiaries) to any Person in one transaction or series of related transactions, other than: (a) Dispositions of inventory or of obsolete, damaged, worn out or surplus property Disposed of in the ordinary course of business; (b) Dispositions pursuant to a transaction permitted by Section 8.7; (c) other Dispositions not to exceed €5,000,000 in the aggregate over the term of this Agreement so long as (x) at least 75% of the consideration received from such Disposition is in the form of cash or Cash Equivalent Investments and (y) no Default or Event of Default shall have occurred and be continuing at the time of, or would result from, such Disposition; provided that no sale or other transfer of any Intellectual Property that is material to the business of any Loan Party shall be permitted pursuant to this clause (c); (d) Dispositions of property to the extent that such property is exchanged for credit

against the purchase price of similar replacement property; (e) Dispositions of property as a result of a Casualty Event; (f) the leasing or subleasing of real property in the ordinary course of business and which do not, in the reasonable judgment of the Borrower, materially interfere with the business of Holdings, the Borrower and the Subsidiaries, taken as a whole; (g) Dispositions of accounts receivable in the ordinary course of business in connection with the settlement of any dispute related thereto or otherwise in connection with customary early payment programs, rebate programs or volume incentive programs conducted by Holdings, the Borrower and the Subsidiaries in the ordinary course of business and consistent with past practice; (h) licensing, co-licensing and cross-licensing arrangements with respect to any Products and/or any Intellectual Property of Holdings, the Borrower or the Subsidiaries (i) set forth in Schedule 8.8 (provided that any exclusive licensing arrangement shall be a bona fide, customary license arrangement and shall be approved by the Supervisory Board of Holdings), (ii) constituting Non-Core Assets or (iii) otherwise entered into in the ordinary course of business on a non-exclusive basis; (i) abandonments, cancellations or lapses of Intellectual Property, or issuances or registrations or applications for issuances or registrations of Intellectual Property, which, in the reasonable good faith determination of the Borrower are no longer economical to maintain in light of its use; (j) terminations or unwinds of any hedging, derivative or swap agreement permitted hereunder; (k) sales, transfers, contributions or other conveyances of any Non-Core Assets; (l) issuances of Capital Securities in the form of directors' qualifying shares as required by applicable Laws; (m) Dispositions between or among Loan Parties, so long as such Disposition does not adversely affect the Liens in favor of the Secured Parties in the property that is subject to any such Disposition; (n) Dispositions between or among Subsidiaries that are not Loan Parties; (o) a sale or other Disposition of any priority review voucher received by Holdings or any of its Subsidiaries with respect to its Chikungunya Disease vaccine; and (p) Dispositions from any Loan Party to any Subsidiary that is not a Loan Party in an aggregate amount over the term of this Agreement not to exceed, when combined with any outstanding Indebtedness of any Subsidiary that is not a Guarantor owing to the Borrower or any Guarantor pursuant to Section 8.2(i)(ii) and any outstanding Investments by any Loan Party in or to any Subsidiary that is not a Guarantor pursuant to Section 8.5(h)(i), €5,000,000, provided that no sale or other transfer of any Intellectual Property that is material to the business of any Loan Party shall be permitted pursuant to this clause (q); provided further that Holdings, the Borrower and the Subsidiaries may not consummate any Disposition of any assets necessary to satisfy in all material respects the obligations of Holdings, the Borrower and the Subsidiaries under any Key Contract (other than any Disposition permitted pursuant to clause (m)). To the extent that any Collateral is sold in a transaction that is permitted by this Section 8.8 to any Person that is not a Loan Party, such Collateral shall be sold free and clear of the Liens in favor of the Secured Parties, which Liens shall be automatically released upon the consummation of such sale, and the Administrative Agent shall take any actions and execute any consent, release or termination documentation reasonably requested by the Borrower in order to evidence or effect the foregoing. To the extent that any Collateral is Disposed of to a Person that is not a Loan Party, which Disposition consists of a license, co-license, cross-license, sublicense, lease, sublease or other similar arrangement with respect to any Product (including any R&D Product and/or any Non-Core Asset) or any related Intellectual Property or other property, in each case, to the extent constituting Collateral, the Administrative Agent shall enter into any subordination agreement, non-disturbance agreement or consent documentation

reasonably requested by the Borrower and in form reasonably acceptable to the Required Lenders in connection with the consummation of, or in order to consummate, such Disposition.

SECTION 8.9 Modification of Certain Agreements. None of Holdings, the Borrower or any of the Subsidiaries will consent to any amendment, supplement, waiver or other modification of, or enter into any forbearance from exercising any rights with respect to, the terms or provisions contained in (a) any Organic Documents, if the result would have an adverse effect in any material respect on the rights or remedies of the Administrative Agent or the Lenders under this Agreement or any Loan Document, (b) any agreement governing any Permitted Subordinated Indebtedness, if the result would shorten the maturity date thereof or advance the date on which any cash payment is required to be made thereon or would otherwise change any terms thereof in a manner adverse to the Administrative Agent or the Lenders in any material respect, or (c) any Key Contract, if the result could reasonably be expected to have an adverse effect in any material respect on the Administrative Agent or the Lenders. None of Holdings, the Borrower or any of the Subsidiaries will (i) terminate or agree to the termination, expiration or non-renewal of any Key Contract for any reason (other than the expiration or non-renewal of any Key Contract in accordance with its terms, to the extent that such expiration or non-renewal of such Key Contract would not reasonably be expected to cause Holdings, the Borrower and the Subsidiaries to fail to satisfy the financial covenants set forth in Section 8.4 for the twelve month period immediately succeeding such expiration or non-renewal), (ii) fail to enforce any of its material rights under any Key Contract or (iii) agree to any assignment or transfer of any Key Contract, or any rights or obligations thereunder, by Holdings, the Borrower or any Subsidiary.

SECTION 8.10 Transactions with Affiliates. None of Holdings, the Borrower or any of the Subsidiaries will enter into or cause or permit to exist any arrangement, transaction or contract (including for the purchase, lease or exchange of property or the rendering of services) with any of its Affiliates, other than: (a) any such arrangement, transaction or contract that (i) is in the ordinary course of business, (ii) is on fair and reasonable terms no less favorable to Holdings, the Borrower or any Subsidiary than it could obtain in an arm's-length transaction with a Person that is not one of its Affiliates and (iii) is of the kind which would be entered into by a prudent Person in its position with a Person that is not one of its Affiliates; (b) arrangements, transactions and contracts (i) between or among Loan Parties, (ii) between or among Subsidiaries that are not Loan Parties or (iii) between any Loan Parties, on the one hand, and any Subsidiaries that are not Loan Parties, on the other hand, in each case, to the extent otherwise not prohibited by the terms of this Agreement and subject in all respects to any applicable conditions or restrictions set forth herein; (c) transactions involving the provision of services and payment of consideration therefor between and among Holdings, the Borrower and the Subsidiaries in the ordinary course of business and consistent with past practices; (d) any issuance of Capital Securities of Holdings to the extent not resulting in a Change in Control; (e) transactions in respect of compensation, including the performance of any obligations under any employment or service contract or other similar contract entered into in the ordinary course of business, the payment of compensation (including bonuses and commissions) and severance, and indemnification payments and reimbursement of expenses to employees, officers, directors, consultants and managers, and the establishment and maintenance of benefit plans, programs or arrangements for

employees, officers, directors and managers, including, without limitation, vacation plans, health and life insurance plans, deferred compensation plans, retirement or savings plans and similar plans or equity incentive or equity option plans (including any subscription or similar agreement pertaining to the issuance, purchase or repurchase of Capital Securities), in each case, in the ordinary course of business (to the extent applicable); and (f) transactions existing on the Closing Date and identified in Schedule 8.10.

SECTION 8.11 Restrictive Agreements, Etc. None of Holdings, the Borrower or any of the Subsidiaries will enter into any agreement prohibiting (a) the creation or assumption of any Lien upon its properties, revenues or assets, whether now owned or hereafter acquired, (b) the ability of Holdings, the Borrower or any Subsidiary to amend or otherwise modify any Loan Document, or (c) the ability of Holdings, the Borrower or any Subsidiary to make any payments, directly or indirectly, to the Borrower, including by way of dividends, advances, repayments of loans, reimbursements of management and other intercompany charges, expenses and accruals or other returns on investments. The foregoing prohibitions shall not apply to restrictions contained (i) in any Loan Document, (ii) in the case of clause (a), in any agreement governing any Indebtedness permitted by Section 8.2(e) as to the assets financed with the proceeds of such Indebtedness, (iii) in any agreement governing any Investment permitted by Section 8.5 or any Disposition permitted by Section 8.8 to the extent such restrictions apply to the asset or property subject to such Investment or Disposition, as applicable, (iv) in leases, subleases, licenses or asset sale agreements otherwise permitted hereby so long as such restrictions relate only to the assets subject thereto, or (v) in any Permit (including any Key Permit) or any Regulatory Authorization.

SECTION 8.12 Sale and Leaseback. None of Holdings, the Borrower or any of the Subsidiaries will directly or indirectly enter into any agreement or arrangement providing for the sale or transfer by it of any property (now owned or hereafter acquired) to a Person and the subsequent lease or rental of such property or other similar property from such Person (a "Sale and Leaseback Transaction").

SECTION 8.13 Product Agreements. None of Holdings, the Borrower or any of the Subsidiaries will enter into any amendment with respect to any existing Product Agreement or enter into any new Product Agreement that contains (a) any provision that permits any counterparty other than Holdings, the Borrower or any of the Subsidiaries to terminate such Product Agreement for any reason related to the insolvency or change of control of the Borrower or any of the Subsidiaries or assignment of such Product Agreement by Holdings, the Borrower or any of the Subsidiaries, (b) any provision which restricts or penalizes a security interest in, or the assignment of, any Product Agreements, upon the sale, merger or other Disposition of all or a material portion of a Product to which such Product Agreement relates, or (c) any other provision that has affected or is reasonably likely to adversely affect, in any material respect, any Product to which such agreement relates or any Secured Party's rights hereunder.

SECTION 8.14 Change in Name, Location or Executive Office or Executive Management; Change in Fiscal Year. None of Holdings, the Borrower or any of the Subsidiaries will (a) change its legal name or any trade name used to identify it in the conduct of its business or ownership of its properties without 30 days' prior written notice to the Administrative Agent, (b) change its jurisdiction of organization or legal structure, (c) relocate its chief executive office, principal place of business or any

office in which it maintains current books or records relating to its business (including the establishment of any new office or facility serving any such purpose) without 30 days' prior written notice to the Administrative Agent or, with respect to the chief executive office or principal place of business of Holdings or the Borrower, to the extent any relocation would be materially adverse to the interests of the Lenders, (d) change its federal taxpayer identification number or organizational number (or equivalent) without 30 days' prior written notice to the Administrative Agent, (e) replace the chief executive officer or chief financial officer (or other senior officer or executive officer performing the duties and functions customarily performed by an officer serving in the role of chief executive officer or chief financial officer) of Holdings or the Borrower without written notification to the Administrative Agent within 30 days thereafter, (f) change its Fiscal Year or any of its Fiscal Quarters, or (g) enter into any Division/Series Transaction, or permit any of its Subsidiaries to enter into, any Division/Series Transaction (it being understood that none of the provisions in this Agreement nor any other Loan Document shall be deemed to permit any Division/Series Transaction).

SECTION 8.15 Benefit Plans and Agreements. None of Holdings or any of the Borrower's Subsidiaries will become the sponsor of, incur any responsibility to contribute to or otherwise incur actual or potential liability with respect to, any Canadian Defined Benefit Plan, and except as would not reasonably be expected to result in a Material Adverse Effect, none of Holdings or any of the Borrower's Subsidiaries will (a) become the sponsor of, incur any responsibility to contribute to or otherwise incur actual or potential liability with respect to, any other Benefit Plan, (b) allow any "employee benefit plan" as defined in section 3(3) of ERISA that provides retirement benefits, is sponsored by Holdings, any of the Borrower's Subsidiaries or any of their ERISA Affiliates, and is intended to be Tax qualified under section 401(a) of the Code (or equivalent provisions of non-U.S. law) to cease to be Tax qualified, or (c) allow any employee benefit plan, program or arrangement sponsored, maintained, contributed to or required to be contributed to by Holdings or any of the Borrower's Subsidiaries to fail to comply in all material respects with its terms and applicable Laws.

SECTION 8.16 Activity of VBC-3. From and after the Eighth Amendment Effective Date and the consummation of the VBC-3 Acquisition, Holdings and Borrower shall cause VBC-3 to not, have any operations, own any assets or have any liabilities, except for (a) ownership of the office building located at Campus-Vienna-Biocenter 3, 1030 Vienna, Austria (the "Vienna Office Building") and leasing all or any portion thereof, (b) preserving and keeping in full force and effect its legal existence and (c) any activities related to any of the foregoing. Holdings and Borrower shall not permit VBC-3 to Dispose (including, for the avoidance of doubt, pursuant to any sale-leaseback transaction) of the Vienna Office Building to any Person (other than a Loan Party) without the consent of the Required Lenders (which consent may be via email).

ARTICLE IX

EVENTS OF DEFAULT

SECTION 9.1 Listing of Events of Default. Each of the following events or occurrences described in this Article IX shall constitute an "Event of Default":

- (a) Non-Payment of Obligations. The Borrower shall default in the payment or prepayment when due of (i) any principal of any Loan, or (ii) any interest in respect of any Loan, any fee described in Article III or any other monetary Obligation, and in the case of clause (ii) such default shall continue unremedied for a period of three Business Days after such amount was due.
- (b) Breach of Warranty. Any representation or warranty made or deemed to be made by Holdings, the Borrower or any other Loan Party in any Loan Document (including any certificates delivered pursuant to Article V) is or shall be incorrect in any material respect when made or deemed to have been made.
- (c) Non-Performance of Certain Covenants and Obligations. Holdings, the Borrower or any other Loan Party shall default in the due performance or observance of any of its obligations under Sections 7.1(a), (b), (c), (d), (e), (k), or (m), Section 7.7, Section 7.17, or Article VIII.
- (d) Non-Performance of Other Covenants and Obligations. Holdings, the Borrower or any other Loan Party shall default in the due performance and observance of any other covenant, obligation or agreement contained in any Loan Document executed by it (other than any covenant, obligation or agreement referred to in Section 9.1(c)), and such default shall continue unremedied for a period of 30 days after the earlier to occur of (i) notice thereof given to the Borrower by the Lenders or (ii) the date on which Holdings, the Borrower or any other Loan Party has knowledge of such default.
- (e) Default on Other Indebtedness. A default shall occur in the payment of any amount when due (subject to any applicable grace period), whether by acceleration or otherwise, of any principal or stated amount of, or interest or fees on, any Indebtedness (other than the Obligations hereunder) of Holdings, the Borrower or any of the Subsidiaries having a principal or stated amount, individually or in the aggregate, in excess of €4,000,000, or a default shall occur (subject to any applicable grace period) in the performance or observance of any obligation or condition with respect to such Indebtedness if the effect of such default is to accelerate the maturity of any such Indebtedness or such default shall continue unremedied for any applicable period of time sufficient to permit the holder or holders of such Indebtedness, or any trustee or agent for such holders, to cause or declare such Indebtedness to become due and payable or to require such Indebtedness to be prepaid, redeemed, purchased or defeased, or require an offer to purchase or defease such Indebtedness to be made, prior to its expressed maturity.
- (f) Judgments. Any judgment or order for the payment of money individually or in the aggregate in excess of €4,000,000 (exclusive of any amounts paid or covered by insurance or indemnity as to which the insurer or indemnifying party, as applicable, has been notified of such judgment and has not disputed or otherwise contested in writing such insurance coverage or indemnification obligation, as applicable) shall be rendered against Holdings, the Borrower or any of the Subsidiaries and such judgment shall not have been vacated, discharged, stayed or bonded pending appeal

within 45 days after the entry thereof (except to the extent that the terms of such judgment specifically provide for a longer payment term and Holdings, the Borrower or such Subsidiary, as applicable, timely discharges or satisfies such obligations during such specified longer term) or enforcement proceedings shall have been validly commenced by any creditor upon such judgment or order.

(g) Change in Control. Any Change in Control shall occur.

(h) Bankruptcy, Insolvency, Etc. Holdings, the Borrower or (except as permitted pursuant to Section 8.7) any of the Subsidiaries shall:

- (i) fail to be Solvent or generally fail to pay, or admit in writing its inability or unwillingness generally to pay, debts as they become due;
- (ii) apply for, consent to, or acquiesce in the appointment of a trustee, receiver, sequestrator or other custodian for any substantial part of the property of any thereof, or make a general assignment for the benefit of creditors;
- (iii) in the absence of such application, consent or acquiescence, permit or suffer to exist the appointment of a trustee, receiver, sequestrator or other custodian for a substantial part of the property of any thereof, and such trustee, receiver, sequestrator or other custodian shall not be discharged within 60 days; provided that Holdings, the Borrower and each Subsidiary hereby expressly authorizes the Administrative Agent and the Lenders to appear in any court conducting any relevant proceeding during such 60-day period to preserve, protect and defend its rights under the Loan Documents;
- (iv) permit or suffer to exist the commencement of any bankruptcy, insolvency, reorganization, debt arrangement, arrangement (including any plan of compromise or arrangement or other corporate proceeding involving or affecting its creditors), composition or other case or proceeding under any bankruptcy or insolvency law (including, without limitation, any Canadian Insolvency Laws) or any dissolution, winding up or liquidation proceeding, in respect thereof (each, an "Insolvency Event"), and, if any such case or proceeding is not commenced by Holdings, the Borrower or any Subsidiary, such case or proceeding shall be consented to or acquiesced in by Holdings, the Borrower or such Subsidiary, as the case may be, or shall result in the entry of an order for relief or shall remain for 60 days (or, in the case of Valneva UK Limited, 15 days) undismissed; provided that Holdings, the Borrower and each Subsidiary hereby expressly authorizes the Administrative Agent and the Lenders to appear in any court conducting any such case or proceeding during such 60-day period (or, in the case of Valneva UK Limited, 15-day

period) to preserve, protect and defend its rights under the Loan Documents; or

- (v) take any corporate or other organizational action authorizing, or in furtherance of, any of the foregoing.
- (i) Impairment of Security, Etc. Any Loan Document or any Lien granted thereunder shall (except in accordance with its terms), in whole or in part, terminate, cease to be effective or cease to be the legally valid, binding and enforceable obligation of Holdings, the Borrower or any other Loan Party subject thereto; Holdings, the Borrower or any other Loan Party shall, directly or indirectly, contest in any manner such effectiveness, validity, binding nature or enforceability; or, except as permitted under any Loan Document, any Lien securing any Obligation shall, in whole or in part, cease to be a perfected first priority Lien (subject to Liens permitted by Section 8.3).
- (j) [Reserved].
- (k) Material Adverse Change. Any circumstance occurs that has had or could reasonably be expected to have a Material Adverse Effect.
- (l) Key Person Event. If (i) Thomas Lingelbach ceases to be employed full time by, and actively working in the position of President and Chief Executive Officer of, Holdings, the Borrower and the Subsidiaries (taken as a whole), unless within 180 days after such Person ceases to be employed full time and actively working, Holdings, the Borrower and the Subsidiaries hire a replacement for such individual reasonably acceptable to the Required Lenders or (ii) any replacement hired pursuant to the foregoing clause (i) ceases to be employed full time by, and actively working in the position of President and Chief Executive Officer of, Holdings, the Borrower and the Subsidiaries (taken as a whole), unless within 180 days after such Person ceases to be employed full time and actively working, Holdings, the Borrower and the Subsidiaries hire a replacement for such individual reasonably acceptable to the Required Lenders.
- (m) Regulatory Matters. Any of the following occurs: (i) the FDA, CMS or any other Governmental Authority (A) issues a letter or other communication asserting that any Product lacks a required Regulatory Authorization or (B) initiates enforcement action against, or issues a warning letter with respect to, Holdings, the Borrower or any of the Subsidiaries, or any Product or the manufacturing facilities therefor, that in the case of either clause (A) or (B) causes Holdings, the Borrower or such Subsidiary to discontinue marketing of or withdraw any Product, or causes a delay in the manufacture or offering of any Product (other than any R&D Product), which discontinuance, withdrawal or delay could reasonably be expected to last for more than six months; (ii) there occurs a recall with respect to any Product which could reasonably be expected to result in (A) aggregate liability to Holdings, the Borrower and the Subsidiaries in excess of €4,000,000 (exclusive of any amounts paid or covered by insurance or indemnity as to which the insurer or indemnifying party, as applicable, has been notified of the underlying claim and has not

disputed or otherwise contested in writing such insurance coverage or indemnification obligation, as applicable, and exclusive of the value of such Product) or (B) a Material Adverse Effect; or (iii) Holdings, the Borrower or any of the Subsidiaries enters into a settlement agreement with the FDA, CMS or any other Governmental Authority with respect to any Product that results in aggregate liability as to any single or related series of transactions, incidents or conditions in excess of €4,000,000 (exclusive of any amounts paid or covered by insurance or indemnity as to which the insurer or indemnifying party, as applicable, has been notified of the underlying claim and has not disputed or otherwise contested in writing such insurance coverage or indemnification obligation, as applicable).

- (n) **Key Contracts.** Any Key Contract is terminated by a counterparty to such Key Contract or terminates automatically by the terms of such Key Contract due to a default or breach by Holdings, the Borrower or any of the Subsidiaries.

SECTION 9.2 Action if Bankruptcy. If any Event of Default described in clauses (i) through (iv) of Section 9.1(h) with respect to Holdings, the Borrower shall occur, the Commitments (if not theretofore terminated) shall automatically terminate and the outstanding principal amount of the Loans and all other Obligations shall automatically be and become immediately due and payable, without notice or demand to any Person.

SECTION 9.3 Action if Other Event of Default. If any Event of Default (other than any Event of Default described in clauses (i) through (iv) of Section 9.1(h)) shall occur for any reason, whether voluntary or involuntary, and be continuing, the Administrative Agent may, and, at the direction of the Required Lenders by notice to the Borrower, shall declare all or any portion of the outstanding principal amount of the Loans and other Obligations to be due and payable and the Commitments (if not theretofore terminated) to be terminated, whereupon the full unpaid amount of the Loans and other Obligations which shall be so declared due and payable shall be and become immediately due and payable, without further notice, demand or presentment, and the Commitments shall terminate.

SECTION 9.4 Application of Funds. After the exercise of remedies provided for in Section 9.3 (or after the Loans have automatically become immediately due and payable as set forth in Section 9.2), any amounts received by any Lender or the Administrative Agent on account of the Obligations shall be applied in the following order:

First, to payment of that portion of the Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Administrative Agent and amounts payable under Article III) payable to the Administrative Agent in its capacity as such;

Second, to payment of that portion of the Obligations constituting fees, indemnities and other amounts (other than principal and interest) payable to the Lenders (including fees, charges and disbursements of counsel to the respective Lenders) arising under the Loan Documents and amounts payable under Section 4.3, ratably among them in accordance with their Applicable Percentages of the amounts described in this clause Second payable to them;

Third, to payment of that portion of the Obligations constituting accrued and unpaid interest on the Loans and amounts payable under **Sections 3.7, 3.8, 3.10 and 3.11**, ratably among the Lenders in accordance with their respective Applicable Percentages of the amounts described in this clause **Third** held by them;

Fourth, to payment of that portion of the Obligations constituting accrued and unpaid principal of the Loans, ratably among the Lenders in accordance with their respective Applicable Percentages of the amounts described in this clause **Fourth** held by them;

Fifth, to payment of all other outstanding Obligations, ratably among the Lenders in accordance with their respective Applicable Percentages of the amounts described in this clause **Fifth** held by them; and

Last, the balance, if any, after all of the Obligations have been indefeasibly paid in full, to the Borrower or as otherwise required by law.

ARTICLE X
MISCELLANEOUS PROVISIONS

SECTION 10.1 **Waivers, Amendments, Etc.** No amendment or waiver of any provision of this Agreement or any other Loan Document, and no consent to any departure by Holdings, the Borrower or any other Subsidiary therefrom, shall be effective unless in writing signed by the Required Lenders and the Borrower and acknowledged by the Administrative Agent, and each such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; **provided, further,** that

(a) no such amendment, waiver or consent shall:

- (i) extend or increase the Commitment of a Lender (or reinstate any Commitment terminated pursuant to **Section 9.2**) without the written consent of such Lender whose Commitment is being extended or increased (it being understood and agreed that a waiver of any condition precedent set forth in **Article V** or a waiver of any Default or Event of Default or a mandatory reduction in Commitments pursuant to the terms of this Agreement is not considered an extension or increase in Commitments of any Lender);
- (ii) postpone any date fixed by this Agreement or any other Loan Document for any payment of principal (excluding mandatory prepayments), interest, Repayment Premiums, fees or other amounts due to the Lenders (or any of them) without the written consent of each Lender entitled to receive such payment (it being understood that a waiver of any Default or Event of Default shall not constitute such a postponement);
- (iii) reduce the principal of, the rate of interest specified herein on, or any Repayment Premium or applicable Exit Fee specified herein on any Loan, or any other fees or other amounts payable hereunder or under any other Loan

Document without the written consent of each Lender entitled to receive such payment of principal, interest, fees or other amounts;

- (iv) (x) amend or waive any provision of Section 9.4, or (y) amend or waive Section 4.4(e) or any other provision providing for the *pro rata* treatment of the Lenders, in each case without the written consent of Lender directly affected thereby;
- (v) change any provision of this Section 10.1(a), the definition of "Required Lenders" without the written consent of all the Lenders or any provision of this Agreement or any other Loan Documents providing for consent or other action by all Lenders;
- (vi) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by the Borrower of any of their rights and obligations under this Agreement and the other Loan Documents, or release all or substantially all of the Collateral or release all or substantially all of the Guarantors from their obligations under the Guarantee, in each case without the written consent of all the Lenders;
- (vii) release or subordinate any Lien granted in favor of the Administrative Agent with respect to all or substantially all of the Collateral or release all or substantially all of the value of the guarantees of the Obligations provided by the Guarantors, in each case, other than in accordance with the terms of the Loan Documents;
- (viii) amend, waive or modify the penultimate paragraph of Section 7.1, Section 7.15, or Section 10.14, in each case, without the consent of each Public-Side Lender; or
- (ix) amend, waive or modify Section 11.6 hereof, without the consent of the Required Lenders; and

- (b) unless also signed by the Administrative Agent, no amendment, waiver or consent shall affect the rights or duties of the Administrative Agent under this Agreement or any other Loan Document;

provided, however, that notwithstanding anything to the contrary herein, (i) each Lender is entitled to vote as such Lender sees fit on any bankruptcy reorganization plan that affects the Loans, and each Lender acknowledges that the provisions of Section 1126(c) of the Bankruptcy Code of the United States supersedes the unanimous consent provisions set forth herein and (ii) the Required Lenders shall determine whether or not to allow a Loan Party to use cash collateral in the context of a bankruptcy or insolvency proceeding and such determination shall be binding on all of the Lenders.

Any payments, fees or other consideration (other than reimbursements for out-of-pocket expenses) received by or on behalf of the Administrative Agent or any of the

Lenders in respect of any amendment, waiver or consent under the Loan Documents shall be distributed to the Lenders on a *pro rata* basis.

SECTION 10.2 Notices; Time.

- (a) All notices and other communications provided under any Loan Document shall be in writing or by facsimile and addressed, delivered or transmitted, if to the Administrative Agent, the Borrower or the Lenders, to the applicable Person at its address, email address or fax number set forth on Schedule 10.2, or at such other address, email address or fax number as may be designated by such Party in a notice to the other Parties. Any notice, if mailed and properly addressed with postage prepaid or if properly addressed and sent by pre-paid courier service, shall be deemed given when received; any notice, if transmitted by email or fax, shall be deemed given when received by the addressee. Unless otherwise indicated, all references to the time of a day in a Loan Document shall refer to New York City time.
- (b) The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic loan notices) purportedly given by or on behalf of Holdings, the Borrower or any Subsidiary even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. Holdings, the Borrower and the Subsidiaries shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of Holdings, the Borrower or any Subsidiary; provided that such indemnity shall not, as to any Person be available to the extent that such losses, costs, expenses or liabilities are determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from the gross negligence or willful misconduct of such Person. All telephonic notices to and other telephonic communications with the Administrative Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.
- (c) Borrower Materials may be delivered pursuant to procedures approved by the Administrative Agent, including electronic delivery (if possible) upon request by the Administrative Agent to an electronic system maintained by the Administrative Agent (the "Platform"). The Borrower shall notify the Administrative Agent of each posting of Borrower Materials on the Platform and the materials shall be deemed received by the Administrative Agent only upon its receipt of such notice. Borrower Materials and other information relating to this credit facility may be made available to Lenders on the Platform. The Platform is provided "as is" and "as available." The Administrative Agent does not warrant the accuracy or completeness of any information on the Platform nor the adequacy or functioning of the Platform, and expressly disclaims liability for any errors or omissions in the Borrower Materials or any issues involving the Platform, except to the extent resulting from the Administrative Agent's own gross negligence or willful misconduct as determined by a final non-

appealable judgment by a court of competent jurisdiction. NO WARRANTY OF ANY KIND, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THIRD PARTY RIGHTS, OR FREEDOM FROM VIRUSES OR OTHER CODE DEFECTS, IS MADE BY ADMINISTRATIVE AGENT WITH RESPECT TO BORROWER MATERIALS OR THE PLATFORM. None of the Administrative Agent nor any of its Affiliates, partners, directors, officers, employees, agents, trustees, administrators, managers or advisors, nor any of the partners, directors, officers, employees, agents, trustees, administrators, managers or advisors of its Affiliates shall have any liability to the Loan Parties, Lenders or any other Person for losses, claims, damages, liabilities or expenses of any kind (whether in tort, contract or otherwise) relating to use by any Person of the Platform or delivery of Borrower Materials and other information through the Platform except to the extent any thereof result from the applicable Person's own gross negligence or willful misconduct as determined by a final non-appealable judgment by a court of competent jurisdiction.

SECTION 10.3 [Reserved].

SECTION 10.4 Indemnification; Expenses; and Damage Waiver.

- (a) In consideration of the execution and delivery of this Agreement by the Lenders and the Administrative Agent, the Borrower hereby indemnifies, agrees to defend, exonerates and holds each Lender and the Administrative Agent (and any sub-agent thereof) and each Related Party of any of the foregoing Persons (collectively, the "Indemnified Parties") free and harmless from and against any and all actions, causes of action, suits, losses, costs, liabilities, obligations and damages, claims and expenses incurred in connection therewith (irrespective of whether any such Indemnified Party is a party to the action for which indemnification hereunder is sought), including reasonable and documented out-of-pocket attorneys' and professionals' fees and disbursements, whether incurred in connection with actions between the Parties or the Parties and third parties (collectively, the "Indemnified Liabilities"), including Indemnified Liabilities arising out of or relating to (a) the entering into, administration, performance and enforcement of any Loan Document by any of the Indemnified Parties (including any action brought by or on behalf of the Borrower as the result of any determination by any Lender pursuant to Article V not to fund any Loan), (b) any disclosure pursuant to Section 7.15 or (c) any Environmental Liability relating to Holdings, the Borrower or the Subsidiaries; provided that the foregoing indemnity will not, as to any Indemnified Party, apply to losses, claims, damages, liabilities or related expenses to the extent that they have resulted from (i) the willful misconduct or gross negligence of such Indemnified Party (or any of its Related Parties) (as determined by a court of competent jurisdiction in a final and non-appealable decision), (ii) (x) other than with respect to the Administrative Agent (and its Related Parties), a material breach of the obligations of such Indemnified Party (or any of its Related Parties) under the Loan Documents or (y) with respect to the Administrative Agent, a material breach by it or any of its Related Parties under Section 7.15, in each case as determined by a court of competent jurisdiction in a final and

non-appealable decision, or (iii) disputes solely between and among Indemnified Parties not arising from any act or omission of Holdings, the Borrower or any Subsidiary or any of their Affiliates. If and to the extent that the foregoing indemnification may be unenforceable for any reason, the Borrower agrees to make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable Law.

- (b) Costs and Expenses. The Loan Parties shall pay (i) all reasonable and documented out-of-pocket fees and expenses incurred by OrbiMed, Deerfield and the Administrative Agent (including the fees, charges and disbursements of counsel for OrbiMed, Deerfield and the Administrative Agent and due diligence expenses incurred by OrbiMed and Deerfield), in connection with (x) the preparation, negotiation, execution, delivery and administration of this Agreement and the other Loan Documents, including schedules and exhibits, or any amendments, supplements, modifications or waivers of the provisions hereof or thereof (whether or not the transactions contemplated hereby or thereby shall be consummated) (provided that such expenses incurred by OrbiMed and Deerfield and to be reimbursed hereunder, through and including the Closing Date, shall not exceed \$600,000), (y) the filing or recording of any Loan Document (including any financing statements) and all amendments, supplements, amendment and restatements and other modifications to any thereof, searches made following the Closing Date in jurisdictions where financing statements (or other documents evidencing Liens in favor of the Secured Parties) have been recorded and any and all other documents or instruments of further assurance required to be filed or recorded by the terms of any Loan Document and (z) the preparation and review of the form of any document or instrument relevant to any Loan Document, and (ii) all documented out-of-pocket expenses incurred by the Administrative Agent or any Lender (including the fees, charges and disbursements of any counsel for the Administrative Agent or any Lender) in connection with the enforcement or protection of its rights (A) in connection with this Agreement and the other Loan Documents, including its rights under this Section, or (B) in connection with the Loans made hereunder, including all such documented out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Loans or in connection with any enforcement of any Obligations but, in each case under this Section 10.4(b), excluding any expenses to the extent that they have resulted from (1) the willful misconduct or gross negligence of the Administrative Agent or any Lender (or any of their respective Related Parties) (as determined by a court of competent jurisdiction in a final and non-appealable decision), (2) (x) a material breach of the obligations of any Lender (or any of its respective Related Parties) under the Loan Documents or (y) a material breach of the obligations of the Administrative Agent (or any of its Related Parties) under Section 7.15 (in each case, as determined by a court of competent jurisdiction in a final and non-appealable decision), or (3) disputes solely between and among the Administrative Agent and/or the Lenders not arising from any act or omission of Holdings, the Borrower or any Subsidiary or any of their Affiliates.

- (c) Reimbursement by Lenders. To the extent that Holdings, the Borrower or any Subsidiary for any reason fails to indefeasibly pay any amount required under subsection (a) or (b) of this Section to be paid by them to the Administrative Agent (or any sub-agent thereof) or any Related Party thereof, each Lender severally agrees to pay to the Administrative Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's *pro rata* share (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought based on each Lender's share of the Total Credit Exposure at such time) of such unpaid amount (including any such unpaid amount in respect of a claim asserted by such Lender), such payment to be made severally among them based on such Lenders' Applicable Percentages (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought); provided that, to the extent that Holdings, the Borrower or any Subsidiary is not required to indemnify or reimburse the Administrative Agent (or any of its Related Parties) for losses, claims, damages, liabilities or expenses pursuant to Section 10.4(a)(ii), (y) or Section 10.4(b)(2)(y), upon a determination by a court of competent jurisdiction in a final and non-appealable decision that such losses, claims, damages, liabilities or expenses resulted from a material breach by the Administrative Agent or any of its Related Parties under Section 7.15, each Public-Side Lender agrees to indemnify or reimburse the Administrative Agent for losses, claims, damages, liabilities or expenses relating to such material breaches by the Administrative Agent or any of its Related Parties of Section 7.15 involving, related to, in connection with or arising out of the disclosure of information to such Public-Side Lender, excluding any losses, claims, damages, liabilities or expenses to the extent they have resulted from the willful misconduct or gross negligence of the Administrative Agent (or any of its Related Parties) (as determined by a court of competent jurisdiction in a final and non-appealable decision); provided, further, that the unreimbursed expense or indemnified loss, claim, damage, liability or related expense, as the case may be, was incurred by or asserted against the Administrative Agent (or any such sub-agent), or against any Related Party thereof acting for the Administrative Agent (or any such sub-agent) in connection with such capacity. The obligations of the Lenders under this subsection (c) are subject to the provisions of Section 2.09(b).
- (d) Waiver of Consequential Damages, Etc. To the fullest extent permitted by applicable Law, no Party hereto shall assert, and the Parties hereto hereby waive, and acknowledge that no other Party shall have any claim against any other Party, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) arising out of, in connection with, or as a result of, this Agreement, any other Loan Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Loan or the use of the proceeds thereof. No Indemnified Party referred to in subsection (a) above shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby, except to the extent resulting from the willful misconduct or gross negligence of such Indemnified Party (or any of its Related Parties) (as

determined by a court of competent jurisdiction in a final and non-appealable decision).

(e) Payments. All amounts due under this Section shall be payable not later than thirty days after the Borrower's receipt of a reasonably detailed invoice therefor.

SECTION 10.5 Survival. The obligations of the Borrower under Section 4.1, Section 4.2, Section 4.3 and Section 10.4, shall in each case survive any assignment by any Lender and the occurrence of the Termination Date. The representations and warranties made by Holdings, the Borrower and any other Loan Party in each Loan Document shall survive the execution and delivery of such Loan Document. Such representations and warranties have been or will be relied upon by the Administrative Agent and each Lender, regardless of any investigation made by the Administrative Agent or any Lender or on their behalf and notwithstanding that the Administrative Agent or any Lender may have had notice or knowledge of any Default at the time of the borrowing of any Loan, and shall continue in full force and effect as long as any Loan or any other Obligation hereunder shall remain unpaid or unsatisfied. The agreements in this Section and the indemnity provisions of Section 10.2(b) shall survive the resignation of the Administrative Agent, the replacement of any Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all the other Obligations.

SECTION 10.6 Severability. Any provision of any Loan Document which is prohibited or unenforceable in any jurisdiction shall, as to such provision and such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of such Loan Document affecting the validity or enforceability of such provision in any other jurisdiction.

SECTION 10.7 Headings. The various headings of each Loan Document are inserted for convenience only and shall not affect the meaning or interpretation of such Loan Document or any provisions thereof.

SECTION 10.8 Execution in Counterparts, Effectiveness, Etc.. This Agreement may be executed by the Parties in several counterparts, each of which shall be an original and all of which shall constitute together but one and the same agreement. This Agreement shall become effective when counterparts hereof executed on behalf of the Borrower and the Lenders, shall have been received by the Lenders. Delivery of an executed counterpart of a signature page to this Agreement by email (in "pdf," "tiff" or similar format) or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

SECTION 10.9 Governing Law; Entire Agreement. EACH LOAN DOCUMENT (OTHER THAN ANY LOAN DOCUMENT THAT IS, ACCORDING TO ITS TERMS, GOVERNED BY LAWS OTHER THAN THE INTERNAL LAWS OF THE STATE OF NEW YORK) AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT CONTEMPLATED HEREBY AND THEREBY (OTHER THAN ANY LOAN DOCUMENT THAT IS, ACCORDING TO ITS TERMS, GOVERNED BY OTHER LAWS) SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW

YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK) WITHOUT REGARD TO ANY CHOICE OR CONFLICT OF LAWS PROVISIONS OR RULES THAT WOULD REQUIRE THE APPLICATION OF THE LAWS OF ANY OTHER JURISDICTION. The Loan Documents constitute the entire understanding among the Parties with respect to the subject matter thereof and supersede any prior agreements, written or oral, with respect thereto.

SECTION 10.10 Successors and Assigns.

- (a) Successors and Assigns Generally. The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the Parties hereto and thereto and their respective successors and assigns permitted hereby, except that the Borrower may not assign or otherwise transfer any of its rights or obligations hereunder or thereunder without the prior written consent of the Administrative Agent and each Lender and no Lender may assign or otherwise transfer any of its rights or obligations hereunder except (i) to an assignee in accordance with the provisions of subsection (b) of this Section, or (ii) by way of pledge or assignment of a security interest subject to the restrictions of subsection (d) of this Section (and any other attempted assignment or transfer by any party hereto shall be null and void). Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby and, to the extent expressly contemplated hereby, the Related Parties of each of the Administrative Agent and the Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement. No assignment or transfer of any Commitment or Loan shall be effective until receipt and acceptance into the Register by the Administrative Agent of a fully executed Assignment and Assumption effecting the assignment or transfer thereof, together with the required forms and certificates regarding tax matters and any fees payable in connection with such assignment, in each case, as provided in Section 10.4(b). The date of such assignment shall be referred to herein as the "Assignment Effective Date."
- (b) Assignments by Lenders. Subject to the provisions of clause (f) below, any Lender may at any time assign to one or more assignees all or a portion of its rights and obligations under this Agreement and the other Loan Documents (including all or any portion of its Commitment and the Loans at the time owing to it); provided that any such assignment shall be subject to the following conditions:
- (i) Minimum Amounts.
- (A) in the case of an assignment of the entire remaining amount of the assigning Lender's Commitment and/or the Loans at the time owing to it or contemporaneous assignments to related Approved Funds that equal at least the amount specified in paragraph (b)(i)(B) of this Section in the aggregate or in the case of an assignment to a Lender, an Affiliate of a Lender or an Approved Fund, no minimum amount need be assigned; and
- (B) in any case not described in subsection (b)(i)(A) of this Section, the aggregate amount of the Commitment (which for this purpose includes Loans outstanding thereunder) or, if the applicable Commitment is not then in effect, the principal outstanding balance of the Loans of the assigning Lender subject to each such assignment,

determined as of the date the Assignment and Assumption with respect to such assignment is delivered to the Administrative Agent or, if "Trade Date" is specified in the Assignment and Assumption, as of the Trade Date, shall not be less than \$1,000,000 unless each of the Administrative Agent and, so long as no Event of Default has occurred and is continuing, the Borrower otherwise consents (each such consent not to be unreasonably withheld or delayed);

- (ii) Proportionate Amounts. Each partial assignment shall be made as an assignment of a proportionate part of all of the assigning Lender's rights and obligations under this Agreement with respect to the Loans or the Commitment assigned; provided, however, that funded Delayed Draw Term Loans and outstanding Delayed Draw Commitment Amount shall not be required to be assigned together;
- (iii) Required Consents. In addition to any consent required by subsection (b)(i)(B) of this Section and, in addition, the consent of the Administrative Agent and the Required Lenders (such consent not to be unreasonably withheld or delayed) shall be required for assignments to a Person that is not an Eligible Assignee.
- (iv) Assignment and Assumption. Assignments and assumptions of Loans and Commitments by Lenders shall be effected by execution and delivery to the Administrative Agent of an Assignment and Assumption. Assignments made pursuant to the foregoing provision shall be effective as of the Assignment Effective Date, subject to acceptance and recording thereof in the Register by the Administrative Agent pursuant to Section 10.10(c). In connection with all assignments there shall be delivered to the Administrative Agent such forms, certificates or other evidence, if any, with respect to United States federal income tax withholding matters as the assignee under such Assignment and Assumption may be requested to deliver by the Administrative Agent, together with payment to the Administrative Agent of a registration and processing fee of \$3,500, which may be waived or reduced at the sole discretion of the Administrative Agent.
- (v) No Assignment to Certain Persons. Without limiting the provisions of Section 10.10(b)(iii), no such assignment shall be made to a Loan Party or any Affiliate or Subsidiary of a Loan Party, or any Person who, upon becoming a Lender hereunder, would constitute any of the foregoing Persons (other than to the Lenders on the date hereof and their respective Affiliates).
- (vi) Subject to acceptance and recording thereof by the Administrative Agent pursuant to subsection (c) of this Section, from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall

be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of a Lender under this Agreement, and the assigning Lender thereunder shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of the assigning Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) but shall continue to be entitled to the benefits of Sections 4.3 and 10.4 with respect to facts and circumstances occurring prior to the effective date of such assignment. Upon request, the Borrower (at its expense) shall execute and deliver a Note to the assignee Lender. Any assignment or transfer by a Lender of rights or obligations under this Agreement that does not comply with this subsection shall be null and void.

- (c) Register. The Administrative Agent, acting solely for this purpose a non-fiduciary agent of the Borrower (and such agency being solely for tax purposes), shall maintain at the Administrative Agent's Office a copy of each Assignment and Assumption delivered to it (or the equivalent thereof in electronic form) and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.
- (d) Certain Pledges. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement (including under its Note, if any) to secure obligations of such Lender, including any pledge or assignment to secure obligations to a Federal Reserve Bank; provided that no such pledge or assignment shall release such Lender from any of its obligations hereunder or substitute any such pledgee or assignee for such Lender as a party hereto.
- (e) Administrative Agent. Any corporation or association into which the Administrative Agent may be converted or merged, or with which it may be consolidated, or to which it may sell or transfer all or substantially all of its corporate trust business and assets as a whole or substantially as a whole, or any corporation or association resulting from any such conversion, sale, merger, consolidation or transfer to which the Administrative Agent is a party, will be and become the successor to the Administrative Agent under this Agreement and will have and succeed to the rights, powers, duties, immunities and privileges as its predecessor, without the execution or filing of any instrument or paper or the performance of any further act.
- (f) Right of First Refusal.
 - (i) Initial Lender Assignments. If any Initial Lender (such Initial Lender, the "Selling Lender") proposes to assign or otherwise transfer all or any portion of its Loans and/or Commitments (collectively, the "ROFR Loans") to a third party or Person

(other than an Affiliate or managed or related fund of such Selling Lender), before consummating any such assignment or other transfer with respect to such Loans and/or Commitments with any other third party or Person, such Selling Lender must first give written notice (the "ROFR Notice") to the other Initial Lender (such other Initial Lender, the "ROFR Lender") of its intention to assign or otherwise transfer the ROFR Loans. The ROFR Notice must set forth the ROFR Loans to be purchased. Such ROFR Notice will constitute a notice to the ROFR Lender that it may elect to purchase all of the ROFR Loans. At any time within ten (10) Business Days after receipt of the ROFR Notice (the "ROFR Period"), the ROFR Lender shall have the option, exercisable by delivery of a written notice to that effect to the Selling Lender (a "ROFR Exercise Notice"), to purchase all of the ROFR Loans for cash at the price specified by the Selling Lender. Prior to the expiration of the ROFR Period, the Selling Lender may not assign or otherwise transfer the ROFR Loans to any third party or Person other than the ROFR Lender.

- (ii) Sale Pursuant to Exercise of ROFR. If the ROFR Lender timely delivers a ROFR Exercise Notice, the Selling Lender and the ROFR Lender shall execute all appropriate documentation (including any documentation required by Section 10.10(b)(iv) of this Agreement) to consummate the transaction within ten (10) Business Days after receipt of such ROFR Exercise Notice (or such longer time as may be necessary to obtain any necessary regulatory approvals) and take all such other actions as may be reasonably necessary to consummate the transaction. If the ROFR Lender fails to deliver a ROFR Exercise Notice during the ROFR Period, then the Selling Lender may, for a period of 180 days after the expiration of the ROFR Period, freely assign or otherwise transfer the ROFR Loans to a third party on the terms set forth in this Agreement.
- (iii) Failure to Consummate a Transfer. If the ROFR Lender fails to deliver a ROFR Exercise Notice during the ROFR Period and the Selling Lender does not consummate an assignment or other transfer in accordance with the terms of this Section 10.10(f) within 180 days following the expiration of the ROFR Period, then the Selling Lender may not then effect an assignment or other transfer that is subject to this Section 10.10(f), without again fully complying with the provisions of this Section 10.10(f).

Notwithstanding anything to the contrary contained in this Agreement, the Administrative Agent shall not be responsible or have any liability for, or have any duty to ascertain, inquire into, monitor or enforce compliance with the provisions set forth above in this Section 10.10(f) relating to any assignment or transfer by an Initial Lender.

SECTION 10.11 Other Transactions. Nothing contained herein shall preclude any Lender or any of its Affiliates from engaging in any transaction, in addition to those contemplated by the Loan Documents, with the Borrower or any of its Affiliates in which the Borrower or such Affiliate is not restricted hereby from engaging with any other Person.

SECTION 10.12 Arbitration; Forum Selection; Consent to Jurisdiction. Any dispute, controversy or claim (of any and every kind or type, whether based on contract, tort, statute, regulation, or otherwise) arising out of, relating to, or in connection with this Agreement, or the transactions contemplated hereunder (other than any other Loan Document), including any dispute as to the construction, validity, interpretation, enforceability or breach of this Agreement (a "Dispute"), shall be submitted to resolution by final and binding arbitration. The following provisions shall apply to arbitration proceedings pursuant to this Section 10.12:

- (a) The place of arbitration will be New York, New York. The arbitration will be conducted in the English language and all documents filed or otherwise provided as part of the arbitration shall be in the English language, or include a certified English language translation if in another language.
- (b) The arbitral proceedings shall be carried out under the Rules of Arbitration of the International Chamber of Commerce ("ICC"). The arbitral tribunal shall be composed of (A) a sole arbitrator if the monetary value of the Dispute is \$5,000,000 (or its currency equivalent) or less, and (B) three arbitrators if the monetary value of the Dispute is greater than \$5,000,000 (or its currency equivalent) or if the relief sought includes any which is not monetary in nature. In the case of a sole arbitrator, the parties to the Dispute shall endeavor to mutually agree upon the identity of such arbitrator within 30 days after the date on which the respondent(s)' answer is filed in the arbitration. If there are to be three arbitrators, the claimant(s) and respondent(s) shall each nominate one arbitrator within 30 days after the date on which the respondent(s)' answer is filed and the two arbitrators will endeavor within the following 30 days to agree upon the third arbitrator who shall be the chairman of the arbitral tribunal. If any arbitrator is not nominated pursuant to the two immediately preceding sentences, the ICC shall appoint such arbitrator.
- (c) In matters of document production, the arbitral tribunal and the parties shall be guided by the 2010 International Bar Association Rules on the Taking of Evidence in International Arbitration, with the intent of the parties to limit document production to what is essential in order to resolve the Dispute. The arbitral tribunal shall not have the power to award, nor shall the arbitral tribunal award, any punitive, indirect, incidental or consequential damages or awards for diminution in value or lost profits (however any such award is denominated). The arbitral tribunal is authorized to take any interim measures as it considers necessary, including the making of interim orders or awards or partial final awards. An interim order or award may be enforced in the same manner as a final award using the procedures specified below. Further, the arbitral tribunal is authorized to make pre- or post-award interest at applicable statutory interest rates during the relevant period.

- (d) The written award of the arbitral tribunal shall be final and binding. Except to the extent set forth in the following sentence, each Party hereby waives irrevocably and unconditionally any right to appeal such arbitration award and its rights to any form of review or recourse to any court or other judicial authority, in each case to the extent such rights may be waived. Judgment upon the award rendered by the arbitral tribunal may be entered by any court having jurisdiction thereof.
- (e) Subject to Section 10.4, all arbitration costs and fees (including the costs of legal representation and witness expenses) incurred by the prevailing party or parties to a Dispute shall be borne by the party or parties against whom the applicable arbitral award is made. No arbitrator or arbitration panel under this Section 10.12 shall award any Losses for which recovery is prohibited under Section 10.4(d).
- (f) Any Dispute and any negotiations, mediation and arbitration proceedings between the parties thereto regarding such Dispute shall be confidential and shall be subject to Section 10.14.
- (g) NOTWITHSTANDING THE FOREGOING, ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT THE ADMINISTRATIVE AGENT'S OR THE REQUIRED LENDERS' OPTION, IN THE COURTS OF ANY JURISDICTION WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND AND ANY LITIGATION REGARDING ANY SECURITY AGREEMENTS GOVERNED BY THE LAWS OF ANY JURISDICTION (INCLUDING ANY SUIT SEEKING ENFORCEMENT UNDER SUCH SECURITY AGREEMENT) SHALL BE BROUGHT AND MAINTAINED IN THE COURTS OF SUCH JURISDICTION TO THE EXTENT THAT THE TERMS OF SUCH SECURITY AGREEMENTS REQUIRE SUCH FORUM AND/OR VENUE. THE BORROWER IRREVOCABLY APPOINTS CORPORATION SERVICE COMPANY (CSC) AS ITS AUTHORIZED AGENT UPON WHICH PROCESS MAY BE SERVED IN ANY SUIT OR PROCEEDING IN THE UNITED STATES, AND AGREES THAT SERVICE OF PROCESS UPON SUCH AGENT, AND WRITTEN NOTICE OF SAID SERVICE TO THE BORROWER, BY THE PERSON SERVING THE SAME TO THE ADDRESS PROVIDED IN SECTION 10.2, SHALL CONSTITUTE EFFECTIVE SERVICE OF PROCESS UPON THE BORROWER IN ANY SUCH SUIT OR PROCEEDING. THE BORROWER FURTHER AGREES TO TAKE ANY AND ALL ACTION AS MAY BE NECESSARY TO MAINTAIN SUCH DESIGNATION AND APPOINTMENT OF SUCH AGENT IN FULL FORCE AND EFFECT UNTIL ALL OBLIGATIONS HAVE BEEN PAID IN FULL. THE BORROWER IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF NEW YORK AT THE ADDRESS FOR NOTICES SPECIFIED IN SECTION 10.2. THE BORROWER HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY HAVE OR HEREAFTER MAY HAVE TO THE LAYING OF VENUE

OF ANY SUCH LITIGATION PURSUANT TO THIS CLAUSE (G) BROUGHT IN THE COURTS OF THE BOROUGH OF MANHATTAN IN THE CITY OF NEW YORK IN THE STATE OF NEW YORK OR IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM. TO THE EXTENT THAT THE BORROWER HAS OR HEREAFTER MAY ACQUIRE ANY IMMUNITY FROM JURISDICTION OF ANY COURT OR FROM ANY LEGAL PROCESS (WHETHER THROUGH SERVICE OR NOTICE, ATTACHMENT PRIOR TO JUDGMENT, ATTACHMENT IN AID OF EXECUTION OR OTHERWISE) WITH RESPECT TO ITSELF OR ITS PROPERTY, THE BORROWER HEREBY IRREVOCABLY WAIVES TO THE FULLEST EXTENT PERMITTED BY LAW SUCH IMMUNITY IN RESPECT OF ITS OBLIGATIONS UNDER THE LOAN DOCUMENTS.

SECTION 10.13 Waiver of Jury Trial. THE ADMINISTRATIVE AGENT, THE LENDERS AND THE BORROWER HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVE TO THE FULLEST EXTENT PERMITTED BY LAW ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, EACH LOAN DOCUMENT, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN) OR ACTIONS OF THE ADMINISTRATIVE AGENT, ANY LENDER OR THE BORROWER IN CONNECTION THEREWITH. THE BORROWER ACKNOWLEDGES AND AGREES THAT IT HAS RECEIVED FULL AND SUFFICIENT CONSIDERATION FOR THIS PROVISION (AND EACH OTHER PROVISION OF EACH OTHER LOAN DOCUMENT TO WHICH IT IS A PARTY) AND THAT THIS PROVISION IS A MATERIAL INDUCEMENT FOR THE ADMINISTRATIVE AGENT AND THE LENDERS ENTERING INTO THE LOAN DOCUMENTS.

SECTION 10.14 Confidential Information. Subject to the provisions of Section 10.15, at all times prior to the Termination Date, the Receiving Party shall keep confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party's employees, advisors or consultants who have a need to know such information to assist such Party in the performance of such Party's obligations or in the exercise of such Party's rights hereunder and who are subject to reasonable obligations of confidentiality consistent with this Section 10.14 (collectively, "Recipients"). Notwithstanding anything to the contrary set forth herein, any Lender may disclose Confidential Information to (i) its Affiliates, (ii) potential and actual assignees of any of such Lender's rights hereunder and (iii) potential and actual investors in, or lenders to, such Lender (including, in each of the foregoing cases, such Person's employees, advisors or consultants); provided that in each case, unless an Event of Default has occurred and is continuing, each such Recipient shall be subject to reasonable obligations of confidentiality no less restrictive than those imposed by this Agreement. In addition to the foregoing, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in order to comply with applicable Laws (including any

securities law or regulation or the rules of a securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; provided that the Receiving Party (x) will only disclose those portions of the Confidential Information that are necessary or required to be so disclosed, and (y) to the extent legally permissible, will notify the Disclosing Party of the Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow the Disclosing Party time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed.

SECTION 10.15 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:

- (a) that is or hereafter becomes part of the public domain (other than as a result of a disclosure by the Receiving Party or its Recipients in violation of this Agreement);
- (b) that is received from a Third Party without restriction on disclosure and without, to the knowledge of the Receiving Party, breach of any agreement between such Third Party and the Disclosing Party;
- (c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on disclosure prior to its receipt from the Disclosing Party;
- (d) that is generally made available to Third Parties by the Disclosing Party without restriction on disclosure;
- (e) that is required or permitted to be Publicly Disclosed in accordance with Section 7.15 as a result of a breach by Holdings, the Borrower or any Subsidiary of their obligations hereunder to not provide Inside Information to any Public-Side Lender; or
- (f) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party without use of or reference to the Confidential Information.

SECTION 10.16 No Waiver; Cumulative Remedies; Enforcement. No failure by any Lender or the Administrative Agent to exercise, and no delay by any such Person in exercising, any right, remedy, power or privilege hereunder or under any other Loan Document shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided, and provided under each other Loan Document, are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

Notwithstanding anything to the contrary contained herein or in any other Loan Document, the authority to enforce rights and remedies hereunder and under the other Loan Documents against the Loan Parties or any of them shall be vested exclusively in, and all actions and proceedings at law in connection with such enforcement shall be instituted and maintained exclusively by, the Administrative Agent in accordance with Section 11.1 for the benefit of all the Lenders; provided, however, that the foregoing shall not prohibit (a) the Administrative Agent from exercising on its own behalf the rights and

remedies that inure to its benefit (solely in its capacity as the Administrative Agent) hereunder and under the other Loan Documents, (b) any Lender from exercising setoff rights in accordance with Section 4.5 (subject to the terms of Section 4.4(e)) or (c) any Lender from filing proofs of claim or appearing and filing pleadings on its own behalf during the pendency of a proceeding relative to any Loan Party under any Debtor Relief Law or any proceedings arising out of or in connection with an Insolvency Event; provided, further, that if at any time there is no Person acting as the Administrative Agent hereunder and under the other Loan Documents, then (i) the Required Lenders shall have the rights otherwise ascribed to the Administrative Agent pursuant to Section 11.1 and (ii) in addition to the matters set forth in clauses (b) and (c) of the preceding proviso and subject to Section 4.4(e), any Lender may, with the consent of the Required Lenders, enforce any rights and remedies available to it and as authorized by the Required Lenders.

SECTION 10.17 Conversion of Currencies.

- (a) If, for the purpose of obtaining judgment in any court, it is necessary to convert a sum owing hereunder in one currency into another currency, each party hereto agrees, to the fullest extent that it may effectively do so, that the rate of exchange used shall be that at which in accordance with normal banking procedures in the Relevant Jurisdiction the first currency could be purchased with such other currency on the Business Day immediately preceding the day on which final judgment is given.
- (b) The obligations of any Loan Party in respect of any sum due to any party hereto or any holder of the Obligations owing hereunder (the “Applicable Creditor”) shall, notwithstanding any judgment in a currency (the “Judgment Currency”) other than the currency in which such sum is stated to be due hereunder (the “Agreement Currency”), be discharged only to the extent that, on the Business Day following receipt by the Applicable Creditor of any sum adjudged to be so due in the Judgment Currency, the Applicable Creditor may in accordance with normal banking procedures in the Relevant Jurisdiction purchase the Agreement Currency with the Judgment Currency; if the amount of the Agreement Currency so purchased is less than the sum originally due to the Applicable Creditor in the Agreement Currency, each Loan Party agrees, as a separate obligation and notwithstanding any such judgment, to indemnify the Applicable Creditor against such loss. The obligations of the Loan Parties contained in this Section 10.17 shall survive the termination of this Agreement and the payment of all other amounts owing hereunder.
- (c) For purposes of calculating financial covenants and reporting financial metrics hereunder (and for computing related defined financial terms herein), the applicable amount of any Canadian dollars for purposes of this Agreement shall be the U.S. Dollar Equivalent amount of such Canadian dollars.

SECTION 10.18 Payments Set Aside. To the extent that any payment by or on behalf of any Loan Party is made to the Administrative Agent or any Lender, or the Administrative Agent or any Lender exercises its right of setoff, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by the Administrative Agent or such Lender in its discretion) to be repaid to a trustee, receiver, receiver, manager, monitor or any other party, in connection with any proceeding under any Debtor Relief Law, any proceedings arising out of or in connection with an Insolvency Event or otherwise, then (a) to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred, and (b) each Lender severally agrees to pay to the Administrative Agent

upon demand its applicable share (without duplication) of any amount so recovered from or repaid by the Administrative Agent, plus interest thereon from the date of such demand to the date such payment is made at a rate *per annum* equal to the Federal Funds Rate from time to time in effect. The obligations of the Lenders under clause (b) of the preceding sentence shall survive the payment in full of the Obligations and the termination of this Agreement.

SECTION 10.19 Electronic Execution of Assignments and Certain Other Documents. The words “execute,” “execution,” “signed,” “signature” and words of like import in any Assignment and Assumption or in any amendment or other modification hereof (including waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

SECTION 10.20 No Usury; Criminal Rate of Interest.

- (a) Notwithstanding any other provision herein, the aggregate interest rate charged with respect to any of the Obligations, including all charges or fees in connection therewith deemed in the nature of interest under applicable Law shall not exceed the highest rate permitted by applicable Law. If the rate of interest (determined without regard to the preceding sentence) under this Agreement at any time exceeds the highest lawful rate permitted by applicable Law, the outstanding amount of the Loans made hereunder shall bear interest at the highest lawful rate permitted by applicable Law until the total amount of interest due hereunder equals the amount of interest that would have been due hereunder if the stated rates of interest set forth in this Agreement had at all times been in effect. Accordingly, if any Lender contracts for, charges, or receives any consideration that constitutes interest in excess of the highest lawful rate permitted by applicable Law, then any such excess shall be cancelled automatically and, if previously paid, shall at such Lender’s option be applied to the outstanding amount of the Loans made hereunder or be refunded to the Loan Parties.
- (b) If any provision of this Agreement would oblige the Borrower to make any payment of interest or other amount payable to the Lender in an amount or calculated at a rate which would be prohibited by law or would result in a receipt by that person of “interest” at a “criminal rate” (as such terms are construed under the *Criminal Code* (Canada)), then, notwithstanding such provision, such amount or rate shall be deemed to have been adjusted with retroactive effect to the maximum amount or rate of interest, as the case may be, that would not be so prohibited by applicable law or so result in a receipt by that person of “interest” at a “criminal rate”, such adjustment to be effected, to the extent necessary (but only to the extent necessary), as follows:

(i) first, by reducing the amount or rate of interest; and

(ii) thereafter, by reducing any fees, commissions, costs, expenses, premiums and other amounts required to be paid which would constitute interest for purposes of section 347 of the *Criminal Code* (Canada).

SECTION 10.21 Release from Banking Secrecy. Each Loan Party hereby expressly waives any rights it may have in respect of banking secrecy under applicable laws, including without limitation pursuant to section 38 (2) of the Austrian Banking Act (*Bankwesengesetz*), as amended and supplemented from time to time, under or in connection with any Loan Document and releases the Administrative Agent and any Lender in respect to such banking secrecy. Accordingly, the Administrative Agent and any Lender may disclose all information (including Confidential Information) concerning the Loan Documents and the transactions envisaged thereunder or any Loan Party that has been provided to the Lender by or on behalf of a Loan Party (including, but without limitation, the fact that the Administrative Agent, the Lenders and the Loan Parties entered into the business relationship established under the Loan Documents, the amount and the conditions of the Loans, the interest rate, Collateral, the presence of a Default or Event of Default, any financial information on a Loan Party) in such circumstances and to such persons as permitted under this Agreement, in particular Section 10.14 (Confidential Information) and Section 10.15 (Exceptions to Confidentiality).

SECTION 10.22 Place of Performance. The Parties agree that the sole place of performance for all rights and obligations under this Agreement shall be the Administrative Agent's Office, provided that the Administrative Agent is entitled to select another place of performance if such place is outside of Austria. This means in particular that payments under this Agreement must be made from and to bank accounts outside of Austria. The Parties explicitly agree that any performance in Austria and any payment from or to a bank account in Austria shall not effectively settle any obligations (*keine schuldbefreiende Wirkung*).

SECTION 10.23 Independent Nature of Lenders. The obligations of each Lender under this Agreement and each of the other Loan Documents are several and not joint with the obligations of any other Lender, and no Lender shall be responsible in any way for the performance of the obligations of any other Lender under this Agreement or any other Loan Document. Each Lender shall be responsible only for its own representations, warranties, agreements and covenants hereunder and under the other Loan Documents. Nothing contained in this Agreement or any other Loan Document, and no action taken by any Lender pursuant hereto or thereto, shall be deemed to constitute the Lenders as, and the Loan Parties acknowledge and agree that the Lenders do not thereby constitute, a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Lenders are in any way acting in concert or as a group with respect to the Obligations or the transactions contemplated by this Agreement or any other Loan Document, and the Loan Parties shall not assert any contrary position.

SECTION 10.24 No Fiduciary Relationship. The Loan Parties acknowledge and agree that (a) each Lender is acting at arm's length from the Loan Parties with respect to this Agreement and the Loan Parties and the transactions contemplated hereby and thereby; (b) no Lender will, solely by virtue of this Agreement or any

of the Loan Documents or any transaction contemplated hereby or thereby, become an Affiliate of, or have any agency, tenancy or joint venture relationship with, any of the Loan Parties; (c) no Lender has acted, or is or will be acting, as a financial advisor to, or fiduciary (or in any similar capacity) of, or has any fiduciary or similar duty to, any of the Loan Parties with respect to, or in connection with, this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby, and the Loan Parties agree not to assert, and hereby waives, any claim that any Lender has any fiduciary duty to any of the Loan Parties; (d) any advice given by a Lender or any of its representatives or agents in connection with this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby is merely incidental to such Lender's performance of its obligations hereunder and thereunder; and (e) the Loan Parties' decision to enter into this Agreement and the other Loan Documents has been based solely on the independent evaluation by the Loan Parties and their representatives.

ARTICLE XI

ADMINISTRATIVE AGENT

SECTION 11.1 Appointment and Authority.

- (a) Each of the Lenders hereby irrevocably appoints Wilmington Trust, National Association to act on its behalf as the Administrative Agent hereunder and under the other Loan Documents and authorizes the Administrative Agent to take such actions on its behalf and to exercise such powers as are delegated to the Administrative Agent by the terms hereof or thereof, together with such actions and powers as are incidental thereto. The provisions of this Article are solely for the benefit of the Administrative Agent and the Lenders, and neither the Borrower nor any other Loan Party shall have rights as a third party beneficiary of any of such provisions. It is understood and agreed that the use of the term "agent" herein or in any other Loan Documents (or any other similar term) with reference to the Administrative Agent is not intended to connote any fiduciary or other implied (or express) obligations arising under agency doctrine of any applicable Law. Instead such term is used as a matter of market custom, and is intended to create or reflect only an administrative relationship between contracting parties.
- (b) The Administrative Agent shall also act as the "collateral agent" under the Loan Documents, and each of the Lenders hereby irrevocably appoints and authorizes the Administrative Agent to act as the agent of such Lender for purposes of acquiring, holding and enforcing any and all Liens on Collateral granted by any of the Loan Parties to secure any of the Obligations, together with such powers and discretion as are incidental thereto. In this connection, the Administrative Agent, as "collateral agent" (and any co-agents, sub-agents and attorneys-in-fact appointed by the Administrative Agent pursuant to Section 11.5 for purposes of holding or enforcing any Lien on the Collateral (or any portion thereof) granted under the Security Agreement, or for exercising any rights and remedies thereunder at the direction of the Administrative Agent), shall be entitled to the benefits of all provisions of Article X (including Section 10.4(c)), as though such co-agents, sub-agents and attorneys-in-fact were the "collateral agent" under the Loan Documents) and this Article XI as if set forth in full herein with respect thereto.
- (c) The Administrative Agent declares that it holds the Liens on Collateral granted pursuant to the English Debenture on trust for the Secured Parties on the terms contained in this Agreement.

- (d) Each of the Lenders authorizes the Administrative Agent to perform the duties, obligations and responsibilities and to exercise the rights, powers, authorities and discretions specifically given to the Administrative Agent under or in connection with the Loan Documents together with any other incidental rights, powers, authorities and discretions.

SECTION 11.2 Rights as a Lender. The Person serving as the Administrative Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Administrative Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Administrative Agent hereunder in its individual capacity. Such Person and its Affiliates may accept deposits from, lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with any Loan Party or any Affiliate thereof as if such Person were not the Administrative Agent hereunder and without any duty to account therefor to the Lenders.

SECTION 11.3 Exculpatory Provisions. The Administrative Agent shall not have any duties or obligations except those expressly set forth herein and in the other Loan Documents, and its duties hereunder shall be administrative in nature. Without limiting the generality of the foregoing, the Administrative Agent:

- (a) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;
- (b) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Administrative Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in the other Loan Documents), provided that the Administrative Agent shall not be required to take any action or to exercise any of the rights or powers vested in it by this Agreement at the request or direction of the Lenders, pursuant to the provisions of this Agreement, unless such Lenders shall have offered to the Administrative Agent security or indemnity (satisfactory to the Administrative Agent in its sole and absolute discretion) against the costs, expenses and liabilities which may be incurred by it in compliance with such request or direction, or that, in its opinion or the opinion of its counsel, may expose the Administrative Agent to liability or that is contrary to any Loan Document or applicable Law, including for the avoidance of doubt any action that may be in violation of the automatic stay under any Debtor Relief Law; and
- (c) shall not, except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to any Loan Party or any of its Affiliates that is communicated to or obtained by the Person serving as the Administrative Agent or any of its Affiliates in any capacity.

The Administrative Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment. Subject to the proviso in Section 11.3(b), to the extent the Administrative Agent is permitted to take any discretionary action hereunder or under any Loan Document, it shall take such action if instructed in writing to do so by the Required Lenders. The Administrative Agent shall be deemed not to have knowledge of any Default or Event of Default unless and until notice

describing such Default or Event of Default is given in writing to the Administrative Agent by the Borrower, or a Lender.

The Administrative Agent shall have the right to request instructions from the Required Lenders or, as required, each of the Lenders. If the Administrative Agent shall request instructions from the Required Lenders or each of the Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Administrative Agent shall believe in good faith shall be necessary under the circumstances), as the case may be, with respect to any act or action (including the failure to act) in connection with this Agreement or any other Loan Document, the Administrative Agent shall be entitled to refrain from such act or taking such action unless and until the Administrative Agent shall have received instructions from the Required Lenders or such other number or percentage of the Lenders, as the case may be, and the Administrative Agent shall not incur any liability to any Person by reason of so refraining. The Administrative Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Article V or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Administrative Agent.

The Administrative Agent shall have no liability for any action taken, or errors in judgment made, in good faith by it or any of its officers, employees or agents, unless it shall have been negligent in ascertaining the pertinent facts. The permissive rights of the Administrative Agent to do things enumerated in this Agreement shall not be construed as a duty and, with respect to such permissive rights, the Administrative Agent shall not be answerable for other than its gross negligence or willful misconduct. Nothing in this Agreement shall require the Administrative Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties or in the exercise of any of its rights or powers hereunder.

Neither the Administrative Agent nor any of its directors, officers, employees, agents or affiliates shall be responsible for nor have any duty to monitor the performance or any action of the Loan Parties, or any of their directors, members, officers, agents, affiliates or employee, nor shall it have any liability in connection with the malfeasance or nonfeasance by such party. The Administrative Agent may assume performance by all such Persons of their respective obligations. The Administrative Agent shall have no enforcement or notification obligations relating to breaches of representations or warranties of any other Person.

The Administrative Agent shall not be responsible or liable for any failure or delay in the performance of its obligations under this Agreement arising out of or caused, directly or indirectly, by circumstances beyond its control, including without limitation, any act or provision of any present or future law or regulation or governmental authority; acts of God; earthquakes; fires; floods; wars; terrorism; civil or military disturbances; sabotage; epidemics; riots; interruptions, loss or malfunctions of utilities, computer (hardware or software) or communications service; accidents; labor disputes; acts of civil or military authority or governmental actions; or the unavailability of the Federal Reserve Bank wire or telex or other wire or communication facility.

SECTION 11.4 Reliance by the Administrative Agent.

- (a) The Administrative Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, Internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Administrative Agent

also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. In determining compliance with any condition hereunder to the making of a Loan, that by its terms must be fulfilled to the satisfaction of a Lender, the Administrative Agent may presume that such condition is satisfactory to such Lender unless the Administrative Agent shall have received notice to the contrary from such Lender prior to the making of such Loan. The Administrative Agent may consult with legal counsel (who may be counsel for the Loan Parties), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.

- (b) Reliance by the Administrative Agent and Lenders. The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic loan notices) purportedly given by or on behalf of any Loan Party even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Loan Parties shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of a Loan Party; provided that such indemnity shall not, as to any Person be available to the extent that such losses, costs, expenses or liabilities are determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from the gross negligence or willful misconduct of such Person. All telephonic notices to and other telephonic communications with the Administrative Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.

SECTION 11.5 Delegation of Duties. The Administrative Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Administrative Agent. The Administrative Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The rights, benefits and privileges (including the exculpatory and indemnification provisions) of Article X and this Article XI shall apply to any such sub-agent and to the Related Parties of the Administrative Agent and any such sub-agent, and shall apply to their respective activities in connection with the syndication of the credit facilities provided for herein as well as activities as the Administrative Agent. The Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and non-appealable judgment that the Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agents. Notwithstanding anything herein to the contrary, with respect to each sub-agent appointed by the Administrative Agent, (i) such sub-agent shall be a third party beneficiary under this Agreement with respect to all such rights, benefits and privileges (including exculpatory rights and rights to indemnification) and shall have all of the rights and benefits of a third party beneficiary, including an independent right of action to enforce such rights, benefits and privileges (including exculpatory rights and rights to indemnification) directly, without the consent or joinder of any other Person, against any or all of the Loan Parties and the Lenders, (ii) any modification to such rights, benefits and privileges (including exculpatory rights

and rights to indemnification) shall not be effective as against such sub-agent without its written consent thereto, and (iii) such sub-agent shall only have obligations to the Administrative Agent and not to any Loan Party, Lender or any other Person and no Loan Party, Lender or any other Person shall have any rights, directly or indirectly, as a third party beneficiary or otherwise, against such subagent.

SECTION 11.6 Resignation or Removal of the Administrative Agent. The Administrative Agent may resign as the Administrative Agent at any time by giving thirty (30) days advance notice thereof to the Lenders and the Borrower and, thereafter, the retiring the Administrative Agent shall be discharged from its duties and obligations hereunder. Upon any such resignation, the Required Lenders shall have the right to appoint a successor the Administrative Agent. No less than thirty (30) days' following the delivery of such written notice, the Required Lenders shall have the right, in consultation with the Borrower, to appoint a successor, which shall be a bank with an office in the United States, or an Affiliate of any such bank with an office in the United States, with whom the Lenders shall be dealing on an arm's length basis. Upon the acceptance of any appointment as the Administrative Agent hereunder by a successor the Administrative Agent, such successor the Administrative Agent shall thereupon succeed to and become vested with all rights, powers, privileges and duties of the retiring the Administrative Agent. After any retiring the Administrative Agent's resignation hereunder as the Administrative Agent or upon a removal of the Administrative Agent, the provisions of this Section 11.6 shall continue in effect for its benefit in respect of any actions taken or omitted to be taken by it while it was acting as the Administrative Agent. If no successor has accepted appointment as the Administrative Agent by the date which is thirty (30) days following a retiring the Administrative Agent's notice of resignation or removal, the retiring the Administrative Agent's resignation or removal shall nevertheless thereupon become effective and the Required Lenders shall perform all of the duties of the Administrative Agent hereunder until such time, if any, as the Required Lenders appoint a successor agent as provided for above.

SECTION 11.7 Non-Reliance on the Administrative Agent and Other Lenders. Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement. Each Lender also acknowledges that it will, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

SECTION 11.8 Administrative Agent May File Proofs of Claim. In case of the pendency of any receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition or other judicial proceeding relative to any Loan Party, the Administrative Agent (irrespective of whether the principal of any Loan shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Administrative Agent shall have made any demand on the Borrower) shall be entitled and empowered, by intervention in such proceeding or otherwise:

- (a) to file and prove a claim for the whole amount of the principal and interest owing and unpaid in respect of the Loans and all other Obligations that are owing and unpaid and to file such other documents as may be necessary or advisable in order to have the claims of the Lenders and the Administrative Agent (including any claim for the reasonable compensation, expenses, disbursements and advances of the Lenders and the Administrative Agent and their respective agents and counsel and all other amounts due the Lenders and the Administrative Agent under Section 10.4) allowed in such judicial proceeding; and
- (b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, receiver-manager, monitor, assignee, trustee, liquidator, sequestrator or other similar official in any such judicial proceeding is hereby authorized by each Lender to make such payments to the Administrative Agent and, in the event that the Administrative Agent shall consent to the making of such payments directly to the Lenders, to pay to the Administrative Agent any amount due for the reasonable compensation, expenses, disbursements and advances of the Administrative Agent and its agents and counsel, and any other amounts due the Administrative Agent under Section 10.4.

In addition, the Lenders hereby irrevocably authorize the Administrative Agent, based upon the written instruction of the Required Lenders, to (a) credit bid and in such manner purchase (either directly or through one or more acquisition vehicles) all or any portion of the Collateral at any sale thereof conducted under the provisions of the Bankruptcy Code, including under Section 363 of the Bankruptcy Code or any similar laws in any other jurisdictions to which a Loan Party is subject, including the Austrian IO, Canadian Insolvency Laws, and the French *Code de commerce*, or (b) credit bid and in such manner purchase (either directly or through one or more acquisition vehicles) all or any portion of the Collateral at any other sale or foreclosure conducted by (or with the consent or at the direction of) the Administrative Agent (whether by judicial action or otherwise) in accordance with applicable Law. In connection with any such credit bid and purchase, the Obligations owed to the Lenders shall be entitled to be, and shall be, credit bid on a ratable basis (with Obligations with respect to contingent or unliquidated claims being estimated for such purpose if the fixing or liquidation thereof would not unduly delay the ability of the Administrative Agent to credit bid and purchase at such sale or other disposition of the Collateral and, if such claims cannot be estimated without unduly delaying the ability of the Administrative Agent to credit bid, then such claims shall be disregarded, not credit bid, and not entitled to any interest in the asset or assets purchased by means of such credit bid) and the Lenders whose Obligations are credit bid shall be entitled to receive interests (ratably based upon the proportion of their Obligations credit bid in relation to the aggregate amount of Obligations so credit bid) in the asset or assets so purchased (or in the Capital Securities of the acquisition vehicle or vehicles that are used to consummate such purchase). Except as provided above and otherwise expressly provided for herein or in the other Loan Documents, the Administrative Agent will not execute or deliver a release of any Lien on any Collateral. Upon request by the Administrative Agent at any time, the Lenders will confirm in writing the Administrative Agent's authority to release any such Liens on particular types or items of Collateral pursuant to, and in accordance with, this Section. Each Secured Party whose Obligations are credit bid under this Section shall be entitled to receive interests in the Collateral or any other asset acquired in connection with such credit bid (or in the Capital Securities of the acquisition vehicle or vehicles that are used to consummate such acquisition) on a ratable basis in accordance with the percentage obtained by dividing (y) the amount of Obligations of such Secured Party that were credit bid in such credit bid by (z) the aggregate amount of all Obligations that were credit bid in such credit bid.

Nothing contained herein shall be deemed to authorize the Administrative Agent to authorize or consent to or accept or adopt on behalf of any Lender any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Lender or to

authorize the Administrative Agent to vote in respect of the claim of any Lender in any such proceeding.

SECTION 11.9 Collateral and Guarantee Matters. The Lenders irrevocably authorize the Administrative Agent, at its option and in its discretion,

- (a) to release any Lien on any Collateral granted to or held by the Administrative Agent under any Loan Document (i) upon payment in full of all Obligations, (ii) that is sold or otherwise disposed of to a Person that is not a Loan Party as part of or in connection with any sale or other Disposition permitted hereunder and under the other Loan Document or any Casualty Event, or (iii) as approved in accordance with Section 10.1; and
- (b) to release any Guarantor from its obligations under the Guarantee if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Loan Documents.

Upon request by the Administrative Agent at any time, the Required Lenders will confirm in writing the Administrative Agent's authority to release its interest in particular types or items of property, or to release any Guarantor from its obligations under the Guarantee, pursuant to this Section 11.9.

The Secured Parties will not, by virtue of any security interest they have in Intellectual Property, disturb the rights of any third party licensee of Intellectual Property under any license entered into after the Closing Date and permitted hereunder, so long as the licensee is not in breach of such license. Upon the Borrower's request with respect to a particular licensee, the Required Lenders and the Administrative Agent will negotiate, execute and deliver a non-disturbance agreement with the licensee, in form reasonably acceptable to the Required Lenders, the Administrative Agent, the Borrower, and the licensee.

In the event that any Collateral shall be attached, garnished or levied upon by any court order, or the delivery thereof shall be stayed or enjoined by an order of a court, or any order, judgment or decree shall be made or entered by any court order affecting the Collateral, the Administrative Agent is hereby expressly authorized, in its sole discretion, to respond as it deems appropriate or to comply with all writs, orders or decrees so entered or issued, or which it is advised by legal counsel of its own choosing is binding upon it, whether with or without jurisdiction. In the event that the Administrative Agent obeys or complies with any such writ, order or decree it shall not be liable to any of the Parties or to any other person, firm or corporation, should, by reason of such compliance notwithstanding, such writ, order or decree be subsequently reversed, modified, annulled, set aside or vacated.

The Administrative Agent shall have no obligation to give, execute, deliver, file, record, authorize or obtain any financing statements, notices, instruments, documents, agreements, consents or other papers as shall be necessary to (i) create, preserve, perfect or validate any security interest granted to the Administrative Agent pursuant to the Loan Documents or (ii) enable the Administrative Agent to exercise and enforce its rights under the Loan Documents with respect to any such pledge and security interest. The Administrative Agent shall not be responsible for or have a duty to ascertain or inquire into any representation or warranty regarding the existence, value or collectability of the Collateral, the existence, priority or perfection of the Administrative Agent's Lien thereon, or any certificate prepared by any Loan Party in connection therewith, nor shall the Administrative Agent be responsible or liable to the Lenders for any failure to monitor or maintain any portion of the Collateral.

SECTION 11.10 Parallel Debt.

- (a) The Borrower hereby irrevocably and unconditionally undertakes to pay to the Administrative Agent amounts equal to any amounts owing by the Borrower to any of the Secured Parties under any Loan Document as and

when, and in the currency in which, those amounts are due (the "Parallel Debt"); provided that, for the avoidance of doubt, notwithstanding any other provision hereof, the aggregate amount owed by the Borrower under or in connection with this Agreement or any other Loan Document (including in connection with the Parallel Debt or otherwise) shall not exceed the aggregate amount of the Obligations. Following this, notwithstanding anything to the contrary in any of the Loan Documents, each party agrees that the Administrative Agent shall be the joint and several creditor (*Gesamtgläubiger*) (together with each Secured Party (other than the Administrative Agent)) of each and every of the Obligations of the Borrower towards each of the Secured Parties (other than the Administrative Agent) under any of the Loan Documents, and that accordingly the Administrative Agent will have its own independent right to demand performance by the Borrower of the Obligations.

- (b) The Borrower and the Administrative Agent acknowledge that the obligations of the Borrower under paragraph (a) above are several and are separate and independent from the Obligations, and that the Collateral shall also serve, and shall at all times be deemed to be granted according to the Security Agreements, as collateral security for the Parallel Debt; provided that:
- (i) Parallel Debt shall be decreased to the extent that its Obligations have been irrevocably paid or (in the case of any guarantees hereunder) discharged;
 - (ii) the Obligations of the Borrower shall be decreased to the extent that its Parallel Debt has been irrevocably paid or discharged; and
 - (iii) the Parallel Debt of the Borrower shall not exceed its Obligations.
- (c) The Administrative Agent shall hold the claims against the Borrower under the Parallel Debt structure under this Section 11.10 as agent for the Secured Parties in accordance with the provisions of this Agreement. The Administrative Agent shall distribute any amounts received under the Parallel Debt claims among the Secured Parties in accordance with the provisions of this Agreement as if such amount was received under the Obligations.

SECTION 11.11 Appointment of Administrative Agent as Hypothecary Representative (Quebec). Without limiting the powers of the Administrative Agent hereunder or under any of the other Loan Documents, each Lender hereby appoints the Administrative Agent to act as hypothecary representative (within the meaning of Article 2692 of the Civil Code of Québec) for each present and future Secured Party (in such capacity, the "Hypothecary Representative") for the purposes of holding any hypothec granted pursuant to the laws of the Province of Quebec by any Loan Party on any collateral to secure any Obligations. Each assignee of a Lender shall be deemed to have confirmed and ratified the appointment of Administrative Agent as the hypothecary representative by execution of any document pursuant to which they become a party to this Agreement. The execution by Administrative Agent, as Hypothecary

Representative, of any Deed of Hypothec prior to the date hereof is hereby ratified and confirmed. The Administrative Agent, acting as Hypothecary Representative shall have the same rights, powers, immunities, indemnities and exclusions from liability as are prescribed in favor of the Administrative Agent in this Agreement, which shall apply *mutatis mutandis* to the Administrative Agent acting as Hypothecary Representative. Each successor Administrative Agent shall automatically (and without any further action) become the successor Hypothecary Representative for the purposes of each Deed of Hypothec executed in connection with this Agreement. Upon such replacement becoming effective, notices of replacement will be registered in each applicable register in which each hypothec created pursuant to any Deed of Hypothec is registered (as contemplated by Article 2692 of the Civil Code of Québec). Notwithstanding anything to the contrary, this provision shall be governed by the laws of the Province of Quebec and the federal laws of Canada applicable therein.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

**VALNEVA AUSTRIA GMBH,
as the Borrower**

**By: /s/
Name: [***]
Title: [***]**

**VALNEVA SE,
as Holdings**

**By: /s/
Name: [***]
Title: [***]**

**WILMINGTON TRUST, NATIONAL ASSOCIATION,
as the Administrative Agent**

**By: /s/
Name: [***]
Title: [***]**

ORBIMED ROYALTY & CREDIT OPPORTUNITIES III, LP,

**By: OrbiMed ROF III LLC,
its General Partner**

**By: OrbiMed Advisors LLC,
its Managing Member**

**By: /s/
Name: [***]
Title: [***]**

**DEERFIELD PARTNERS, L.P.,
as a Lender**

**By: /s/
Name: [***]
Title: [***]**

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “*Agreement*”) is made and entered into as of February 2, 2024 (the “*Effective Date*”), by and between Valneva Austria GMBH, a company organized under the laws of Austria (“*Seller*”), and Novartis Pharma AG, an entity organized under the laws of Switzerland (“*Buyer*”). Buyer and Seller may hereinafter be referred to individually as a “*Party*” and collectively as the “*Parties*”.

RECITALS

WHEREAS, Seller and Buyer each (i) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the “*Asset Purchase*”) and (ii) in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below); and

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties agree as follows:

ARTICLE I. DEFINITIONS

Section 1.01 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) “*Action*” means any claim, audit, examination, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, mediation, investigation, hearing, charge, complaint, demand, notice, or proceeding.

(b) “*Affiliate*” means, with respect to any Person, any other Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to “control” another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of the entity, or the ability to cause the direction of the management or policies of such entity; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(c) “*BLA*” means a human biologics license application submitted under Section 351(a) of the Public Health Service Act.

(d) “**Business Day**” means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in each of New York, New York, United States, Luxembourg, Luxembourg, Paris, France and Basel, Switzerland.

(e) “**Confidential Information**” means (i) any and all confidential and proprietary information, including but not limited to, data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. “Confidential Information” will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was independently developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient’s contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets (which, for the avoidance of doubt, shall not include any confidential and proprietary information relating to the product to which the Subject BLA relates) shall constitute Confidential Information of Buyer from and after the Closing Date.

(f) “**Contract**” means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(g) “**Encumbrance**” means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, lease, security interest, encumbrance, adverse claim, interference or restriction on use, ownership or transfer; provided, that the requirement to pay the Priority Review Fee shall not be considered an Encumbrance.

(h) “**FDA**” means the United States Food and Drug Administration.

(i) “**FDA Approval Letter**” means the letter, dated November 9, 2023 issued by the FDA to Seller evidencing the approval of BLA 125777 for Chikungunya Vaccine, Live, and granting the Priority Review Voucher.

(j) “**FDA Notification Package**” means, collectively, executed versions of the Seller Cover Letter, Seller Transfer Acknowledgement Letter and Buyer Transfer Acknowledgment Letter in the forms set forth in Exhibits B, C and E, respectively, in each case, with respect to the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA in accordance with Section 5.06.

(k) “**FDCA**” means the United States Federal Food, Drug, and Cosmetic Act.

(l) “**Fraud**” means common law fraud with respect to the making of the representations or warranties in Article IV or Article V hereof, as applicable.

(m) “**Governmental Entity**” means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental, private body or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority.

(n) “**Judgment**” means any orders, writs, injunctions, awards, judgments, settlements, stipulations, determinations, and decrees entered by or with any Governmental Entity.

(o) “**Knowledge**” means, with respect to Seller, the actual knowledge of [***] after reasonable inquiry.

(p) “**Legal Requirements**” means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders or Judgment applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, as applicable, any obligations, responsibilities, requirements, parameters and conditions relating to the Priority Review Voucher set forth in (i) the FDA Approval Letter, or (ii) any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher.

(q) “**Liabilities**” means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Legal Requirement, Action or any Contract.

(r) “**Order**” means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(s) “**Person**” means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(t) “**PHSA**” means the United States Public Health Service Act, 42 U.S.C. §201 et seq., as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

(u) “**Priority Review**” means a priority review of and action by the FDA upon a human drug application, which is submitted under Section 505(b)(1) of the FDCA or under Section 351 of the PHSA, by the FDA not later than six (6) months after the receipt of such application by the FDA, as defined in Section 524(a)(1) of the FDCA as interpreted by the FDA Guidance For Industry, Tropical Disease Priority Review Vouchers, Oct. 2016 (“Tropical Disease Guidance”), Page 4, Question 7.

(v) “**Priority Review Fee**” has the meaning set forth in Section 7.06.

(w) “**Priority Review Voucher**” means the priority review voucher assigned tracking number PRV BLA 125777 issued by the Secretary of the Department of Health and Human Services, FDA, pursuant to Section 524 of the FDCA to Seller, as evidenced by the FDA Approval Letter, that entitles the holder of such voucher to Priority Review pursuant to Section 524(a)(2) of the FDCA.

(x) “**Purchased Assets**” means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements with respect thereto afforded to the holder of the Priority Review Voucher.

(y) “**Regulatory Change**” means any (i) new Legal Requirement, amendment, change or supplement to any then-existing Legal Requirement enacted, adopted or approved by any Governmental Entity in the United States, or (ii) term or condition imposed on the Priority Review Voucher that is not generally imposed on priority review vouchers under the FDCA as of the Effective Date, that in either case (i) or (ii) has been enacted, adopted, approved or imposed between the Effective Date and the Closing Date (except as set forth in Section 4.11 hereof) and adversely impacts the manner in which Buyer would be able to use, receive, hold, transfer or otherwise exploit the Priority Review Voucher, if granted.

(z) “**Representative**” means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(aa) “**Subject BLA**” means BLA Number 125777 for Chikungunya Vaccine, Live.

(bb) “**Tax**” or “**Taxes**” means any federal, state, local or foreign income, gross receipts, branch profits, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, unclaimed property, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, ad valorem, value added, alternative or add-on minimum or estimated tax or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.

(cc) “**Tax Return**” shall mean any return, declaration, report, claim for refund or information return or statement of any kind relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof, filed or required to be filed with any Governmental Entity.

(dd) “**Third Party**” means any Person other than a Party and such Party’s Affiliates.

(ee) “**Tropical Disease Product Application**” means the tropical disease product application, as defined in Section 524(a)(4) of the FDCA, that earned the Priority Review Voucher.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.01 shall have the meanings assigned to such terms in this Agreement.

ARTICLE II. PURCHASE AND SALE

Section 2.01 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, at and as of the Closing, Buyer shall purchase from Seller, and Seller shall sell, transfer, convey, assign and deliver to Buyer all of Seller’s right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances.

(b) For the avoidance of doubt, (i) the sale, assignment, transfer and conveyance of the Purchased Assets from Seller to Buyer shall not include the transfer, conveyance or assumption of any Liabilities from Seller to Buyer, and (ii) Buyer shall not assume or be liable for any Liabilities of Seller or its Affiliates (fixed, contingent or otherwise, and whether or not accrued), including Liabilities relating to the Purchased Assets (other than such obligations as are imposed generally by applicable Legal Requirements solely on the holder of the Priority Review Voucher in respect of its use or transfer following the sale thereof pursuant to this Agreement, including, without limitation, the Priority Review Fee and any user fees required to be paid in connection with the submission of a human drug application or BLA for which the applicant seeks to redeem the Priority Review Voucher) (such Liabilities, “**Excluded Liabilities**”). Seller shall be solely responsible for all such Excluded Liabilities.

Section 2.02 **Purchase Price.** The total consideration (the “**Purchase Price**”) to be paid by Buyer to Seller for all of the Purchased Assets shall be One Hundred and Three Million Dollars (U.S. \$103,000,000.00) due and payable upon the Closing Date.

Section 2.03 **Method of Payment.** Payment of the Purchase Price to Seller shall be made in cash by wire transfer of immediately available funds to Seller’s bank account as set forth in Exhibit G.

Section 2.04 **Tax Withholding.**

(a) Buyer (and any agent or Affiliate of Buyer) shall be entitled to deduct and withhold from the amounts payable pursuant to this Agreement to Seller all amounts that such Person is required to deduct and withhold under any Legal Requirement; provided, however, that the Parties shall use commercially reasonable efforts to reduce and minimize any such withholding or deduction, or to obtain, at Seller's cost, a refund of previously withheld amounts, to the maximum extent permitted by Legal Requirements. Amounts so deducted and withheld under this Section 2.04 and remitted to the appropriate taxing authority shall be treated for all purposes of this Agreement as having been delivered and paid to Seller under this Agreement. Buyer shall promptly remit any amounts withheld and deducted on account of taxes to the appropriate taxing authority.

(b) The Purchase Price is exclusive of any and all transfer, conveyance, recordation and similar Taxes, fees or duties assessed or incurred by reason of the sale by Seller or the purchase by Buyer of the Purchased Assets hereunder ("**Transfer Taxes**"). Such Transfer Taxes shall be paid by the Party that is primarily liable for such Taxes, fees or duties under applicable Law, and such Person shall timely file any applicable tax return and timely remit such Transfer Taxes to the appropriate taxing authority.

(c) The Purchase Price is exclusive of any applicable sales, consumption, and other similar Taxes required under applicable law to be disclosed as a separate item on an invoice by reason of the sale by Seller or the purchase by Buyer of the Purchased Assets hereunder ("**Indirect Tax**"). Buyer shall be responsible for any Indirect Taxes, which shall be added to the Purchase Price and promptly paid to Seller in substantially the same manner as the Purchase Price upon receipt of a valid invoice furnished by Seller to Buyer setting forth in detail such any Indirect Taxes. Each Party shall use commercially reasonable efforts to avail itself of any available exemptions from Indirect Taxes and agrees to cooperate in good faith with the other Party and provide any information and documentation that may be necessary to minimize the amount of indirect Taxes. To the extent in each case that (i) VAT is or becomes chargeable in respect of the Asset Purchase, (ii) such VAT is owed by the Seller to a taxing authority and (iii) such VAT is recoverable (whether by credit or repayment) by Buyer, Buyer shall, against delivery of a valid VAT invoice (or equivalent, if any, as required by applicable Law), pay or cause to be paid to Seller the amount of any VAT so chargeable. If and to the extent (A) VAT due in respect of the Asset Purchase (or part thereof) under this Agreement is owed by Buyer (reverse charge) and (B) such VAT is recoverable (whether by credit or repayment) by Buyer, Buyer shall report such VAT to the relevant taxing authorities, and Seller shall issue an appropriate invoice, in each case as required by applicable Law. To the extent any invoice is not initially issued in an appropriate form or otherwise not in accordance with applicable Law, the Parties shall cooperate to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with VAT requirements. Any VAT that cannot be recovered (whether by credit or repayment) by Buyer (whether such irrecoverable VAT is charged by Seller or is paid by Buyer under any reverse charge procedure) shall be economically borne one hundred percent (100%) by Seller. Should any taxing authority determine that a transaction contemplated by this Agreement should be subject to an Indirect Tax or recoverable VAT that was not paid to the appropriate taxing authority and Seller is required to pay such Indirect Taxes or recoverable VAT to such taxing authority, Buyer shall pay to Seller or its relevant Affiliates the applicable amount of such Indirect Tax or recoverable VAT on the basis of a valid invoice furnished by Seller to Buyer setting forth in detail such Indirect Taxes or recoverable VAT.

ARTICLE III. CLOSING

Section 3.01 Closing. The closing of the transactions contemplated hereby (the "**Closing**") shall take place remotely via the electronic exchange of documents and signatures, on the Effective Date at 9:00 a.m., Eastern time, simultaneously with the execution and delivery of this Agreement by the Parties. The date on which the Closing actually takes place is referred to in this Agreement as the "**Closing Date**."

Section 3.02 Transactions to be Effected at Closing. At the Closing,

(a) Seller shall deliver, or cause to be delivered, to Buyer an executed Bill of Sale substantially in the form attached hereto as Exhibit A;

(b) Buyer shall deliver, or cause to be delivered, to Seller an executed Bill of Sale substantially in the form attached hereto as Exhibit A;

(c) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate of the secretary or an assistant secretary (or equivalent duly authorized officer or other representative) of Seller certifying (i) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby, and (ii) as to the incumbency of each person executing this Agreement and any other document delivered in connection herewith on behalf of Seller and that the signature of each such person on this Agreement and such other document is such person's genuine signature;

(d) Buyer shall pay or cause to be paid the Purchase Price to Seller by wire transfer of immediately available funds to Seller's bank account as set forth in Exhibit G;

(e) Seller shall deliver to Buyer an executed copy of the cover letter to be submitted to the FDA in accordance with Section 3.04, which shall be in the form attached hereto as Exhibit B (the "***Seller Cover Letter***");

(f) Seller shall deliver to Buyer an executed copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA by Buyer in accordance with Section 5.06, which notification shall be in the form of Exhibit C or such other form as the FDA may require as of the Closing Date (the "***Seller Transfer Acknowledgement Letter***") and

(g) Buyer shall deliver to Seller an executed copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA by Buyer in accordance with Section 5.06, which notification shall be in the form of Exhibit E or such other form as the FDA may require as of the Closing Date (the "***Buyer Transfer Acknowledgment Letter***").

Section 3.03 Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Purchased Assets shall pass to Buyer, free and clear of all Encumbrances.

Section 3.04 Filings; Notifications. Buyer and Seller agree to provide reasonable cooperation and assistance to each other with respect to all filings or notifications to the FDA related to the transfer and assignment of the Purchased Assets, subject to Section 5.06 hereof. Within thirty (30) days following the Closing, Seller agrees, as a courtesy to Buyer and without prejudice to Section 5.06 hereof, that it shall submit the FDA Notification Package to the Subject BLA and, reasonably promptly thereafter, Seller shall provide Buyer with a copy of such submission.

ARTICLE IV. REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer as of the date hereof (or in the case of representations and warranties that are made as of a specified date, as of such specified date), as follows:

Section 4.01 Organization, Standing and Power. Seller is a company duly organized, validly existing and in good standing under the laws of Austria. Seller has the requisite corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets, Seller's ability to consummate the transactions contemplated by this Agreement or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing. Seller is not in violation of its organizational or governing documents, as amended to date.

Section 4.02 Due Authority. Seller has all requisite corporate power and authority to enter into, perform its obligations under and consummate the transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Seller, and this Agreement has been duly executed and delivered by Seller. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies (whether considered in an action at Law or in equity). The approval of Seller's stockholders is not required for the execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase.

Section 4.03 Non-contravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the organizational or governing documents of Seller, in each case as amended to date, (ii) any Contract to which Seller or any of its Affiliates is a party or by which it is bound which involves or affects in any way any of the Purchased Assets or (iii) except as may be required to comply with any Legal Requirements applicable to Seller or any of the Purchased Assets.

Section 4.04 No Consents. Except for the letters referenced in Section 3.02(e) and Section 3.02(f), no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller to enter into, and to perform its obligations under, this Agreement.

Section 4.05 Title to Purchased Assets. Seller is the sole and exclusive owner of all rights, title and interest in and to the Purchased Assets and owns and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances; Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets pursuant to this Agreement; Seller has provided to Buyer's counsel a true, correct and complete copy of the FDA Approval Letter; and no Third Party is entitled to any portion of the proceeds of the transactions contemplated by this Agreement. As of the Closing, the right, title and interest in and to the Purchased Assets that are to be sold, transferred, conveyed, assigned and delivered by Seller to Buyer in accordance with this Agreement collectively constitutes the entire right, title and interest in and to the Purchased Assets and immediately following the Closing, Buyer shall have all right, title and interest in and to the Purchased Assets free and clear of all Encumbrances.

Section 4.06 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party or is bound that involves or affects (or would reasonably be expected to involve or affect) the issuance, ownership, transfer, licensing, title, or use of or to any of the Purchased Assets, or that otherwise assigned, transferred, licensed, conveyed or encumbered, or granted or allowed to exist any Encumbrance with respect to, any of Seller's right, title or interest in, to or under the Purchased Assets.

Section 4.07 Compliance with Legal Requirements. Seller and its Affiliates are, and at all times have been, in material compliance with each Legal Requirement that is or was applicable to (a) Seller's and its Affiliates' conduct, acts, or omissions with respect to any of the Purchased Assets or (b) any of the Purchased Assets. Seller and its Affiliates have not received any written notice or, to Seller's Knowledge, other communication from any Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement (it being understood, for the avoidance of doubt, that any violation of, or failure to comply with, any Legal Requirement that would affect the sale, transfer or transferability of the Purchased Assets or Buyer's unencumbered use of the Purchased Assets shall be deemed "material").

Section 4.08 Legal Proceedings. There is no pending or, to Seller's Knowledge, threatened Action involving Seller or any of its Affiliates, nor has there been any Action involving Seller or any of its Affiliates, and neither Seller nor any of its Affiliates is a party or subject to the provisions of any Judgment, (a) that involves or affects (or would reasonably be expected to involve or affect) the issuance, validity, ownership, licensing, title, or use of or to any of the Purchased Assets, including any such Action or Judgment that seeks to prohibit or limit in any respect, or place any conditions on, the ownership or use by Buyer or any of its Affiliates of any of the purchased Assets, in each case, as a result of the transactions contemplated by this Agreement, (b) that otherwise challenges or seeks to restrain, prohibit, prevent, enjoin, alter or delay the consummation of the transactions contemplated by this Agreement, or (c) that seeks to obtain from Seller, Buyer or any of their respective Affiliates in connection with the transactions contemplated by this Agreement any damages or which would result in the transactions contemplated hereby being rescinded following consummation. To Seller's Knowledge, there is no fact or circumstance that would reasonably be expected to serve as a basis for any of the foregoing Actions. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

Section 4.09 Governmental Authorizations. Neither Seller nor any of its Affiliates is required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

Section 4.10 Solvency. Seller is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will engage after the Closing. Upon and immediately following the Closing Date, after giving effect to all of the transactions contemplated by and in this Agreement (including the payment of the Purchase Price), Seller will not be insolvent.

Section 4.11 Revocation: Regulatory Change. (a) The Priority Review Voucher has been duly granted and has not been terminated, cancelled or revoked; (b) neither Seller nor any its Affiliates, nor to the Knowledge of Seller, any of their respective Representatives, has (i) made any untrue statement of material fact or a fraudulent statement to the FDA or any other Governmental Entity, (ii) failed to disclose a material fact or a fraudulent statement to the FDA or any other Governmental Entity or (iii) committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy; (c) to the Knowledge of Seller, there are no facts or circumstances that (with or without notice or lapse of time or both) would reasonably be expected to result in the termination, suspension, cancellation or revocation of the Priority Review Voucher by the FDA or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review or any other benefits associated with the Purchased Assets; (d) as exclusively related to Seller, there are no facts or circumstances that (with or without notice or lapse of time or both) would reasonably be expected to result in the termination, suspension, cancellation or revocation of the Priority Review Voucher or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review or any other benefits associated with the Purchased Assets; (e) the Priority Review Voucher has not been transferred to any Person, including any Affiliate of Seller, and the transfer contemplated by this Agreement constitutes the first and only transfer of the Priority Review Voucher; (f) since the date that the Priority Review Voucher was issued, there has not occurred any Regulatory Change (which definition, for the purpose of this Section 4.11, shall mean any change of the kind described in clause (ii) of such definition); (g) to Seller's Knowledge, there is no term or condition imposed by the FDA on the transferability or redemption of the Priority Review Voucher other than as set forth in the FDA Approval Letter; and (h) Seller has provided to Buyer true, correct and complete copies of the FDA Approval Letter (with such redactions which do not relate to the Purchased Assets) and any other material communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher or the sale thereof (it being understood, for the avoidance of doubt, that any communications relating to, or that would affect, the sale, transfer or transferability of the Purchased Assets or Buyer's unencumbered use of the Purchased Assets shall be deemed "material").

Section 4.12 Intent to Use. Neither Seller nor any of its Affiliates has filed or submitted to the FDA, or instructed or permitted any Third Party to file or submit to the FDA, a notice of intent to use the Priority Review Voucher pursuant to Section 524(b)(4) of the FDCA.

Section 4.13 No Broker. Except for [***], Seller has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary which has been authorized to act on behalf of Seller who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.14 No Other Representations and Warranties. Neither Seller nor any of its Affiliates or their respective Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, including with respect to merchantability or fitness for any particular purpose or in connection with the Purchased Assets or the accuracy or completeness of any information provided in connection with the Asset Purchase, except as otherwise expressly set forth in this Article IV and Seller and its Affiliates and their respective Representatives hereby disclaim any such other representations or warranties.

ARTICLE V. REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer hereby represents and warrants to Seller as of the date hereof, as follows:

Section 5.01 Organization, Standing and Power. Buyer is a company duly organized, validly existing and in good standing under the laws of Switzerland. Buyer has the company power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the transactions contemplated by this Agreement.

Section 5.02 Authority. Buyer has all requisite company power and authority to enter into, perform its obligations under and consummate the transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary company action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

Section 5.03 Non-contravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the organizational or governing documents of Buyer, in each case as amended to date (b) any Contract to which Buyer is a party or by which it is bound which involves or affects in any way the Asset Purchase or (c) except as may be required to comply with any Legal Requirements applicable to Buyer (except, in the case of clauses (b) and (c) above, as would not, individually or in the aggregate, reasonably be expected to adversely affect the ability of Buyer to timely consummate the transactions contemplated by this Agreement).

Section 5.04 No Consents. Except for the letters referenced in Section 3.02(e) and Section 3.02(f), no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

Section 5.05 Financing. Buyer has, and will at the Closing have, sufficient funds to consummate the transactions contemplated by this Agreement.

Section 5.06 Notice of Transfer. As between Buyer and Seller, Buyer is solely responsible for notifying the FDA of the transfer of the Purchased Assets and the delivery to the FDA of the letters referenced in Section 3.02(f) and Section 3.02(g) in accordance with the recommendations of the FDA set forth in the Tropical Disease Guidance, Page 8, Question 18.

Section 5.07 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission payable by Seller in connection with the transactions contemplated by this Agreement.

Section 5.08 Non-Reliance. Neither Seller nor any of its Affiliates nor any of their respective Representatives makes, or has made any representation or warranty, oral or written, express or implied, as to the accuracy or completeness of any information concerning the Purchased Assets, except as expressly set forth in this Agreement, and Seller, its Affiliates and their respective Representatives expressly disclaim any and all liability that may be based on such information or errors or omissions in any such representation or warranty not expressly set forth in this Agreement, other than any liabilities arising out of or in connection with Fraud. Buyer has not relied and is not relying on any statement, representation or warranty, oral or written, express or implied (including any representation or warranty as to merchantability or fitness for a particular purpose), made by Seller, any of its Affiliates or any of their Representatives, except as expressly set forth in Article IV. Neither Seller nor its Affiliates nor any of their Representatives shall have or be subject to any liability to Buyer or any other Person resulting from the distribution to Buyer, or Buyer's use of, any information, documents or materials made available to Buyer, whether orally or in writing, in any presentations, due diligence discussions or in any other form in expectation of, or in connection with, the transactions contemplated by this Agreement, except as expressly set forth in this Agreement.

ARTICLE VI. INDEMNIFICATION

Section 6.01 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller will indemnify, defend and hold Buyer and its Affiliates, and their respective Representatives, partners, members, successors and assigns (each, a "**Buyer Indemnitee**") harmless for, from and against any and all Liabilities, losses, damages, claims, costs and expenses (including reasonable attorneys' fees) (such Liabilities, losses, damages, claims, costs and expenses, "**Damages**"), whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Buyer Indemnitee may suffer, incur, sustain or become subject to, to the extent arising out of or resulting from (i) any breach of Seller's representations, warranties, covenants or obligations under this Agreement or any certificate or document delivered by or on behalf of Seller hereunder, (ii) Seller's Fraud, grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement, (iii) any claim by any Third Party against Buyer and its Affiliates pursuant to which such Third Party is entitled to any proceeds from the sale of the Priority Review Voucher pursuant hereto, and/or (iv) any Excluded Liabilities (as defined in Section 2.01).

(b) Indemnification by Buyer. From and after the Closing, Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective directors, officers, employees and agents (each, a "**Seller Indemnitee**") harmless for, from and against any and all Damages, whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Seller Indemnitee may suffer, incur, sustain or become subject to, to the extent arising out of or resulting from (i) any breach of Buyer's representations, warranties, covenants or obligations under this Agreement or any certificate or document delivered by or on behalf of Buyer hereunder, (ii) Buyer's Fraud, grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement, and/or (iii)

Buyer's, its Affiliates', or any subsequent transferee's use or ownership of the Purchased Assets from and after the Closing.

Section 6.02 Indemnification Procedures for Claims

(a) A Person entitled to indemnification pursuant to Section 6.01 will hereinafter be referred to as an "**Indemnitee**." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "**Indemnitor**."

(b) Indemnitee shall inform Indemnitor of any Third Party claim ("**Claim**") as soon as reasonably practicable after the Claim arises, it being understood and agreed that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice.

(c) If the Indemnitor has acknowledged in writing to the Indemnitee the Indemnitor's responsibility for defending such Claim and such Claim is not a class action or criminal matter, nor an Action seeking injunctive relief, the Indemnitor shall have the right to defend, at its sole cost and expense (with counsel reasonably selected by the Indemnitor and approved by the Indemnitee, such approval not to be unreasonably withheld or delayed), such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be unreasonably withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee, in which case ((A) – (C)) the Indemnitee may withhold its consent in its sole discretion. If Indemnitee determines in good faith that the defense is not being or ceases to be conducted diligently and in good faith, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' (or earlier if reasonably necessary to appropriately defend the Claim) prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed). If the Indemnitee is defending such Claim, the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. If the Indemnitor has elected to defend such Claim or if the Indemnitor has otherwise acknowledged in writing its responsibility for indemnifying a Claim, the Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(d) The Indemnitee may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnitor pursuant to this Section 6.02 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses if counsel for the Indemnitor shall have reasonably determined that such counsel may not properly represent both the Indemnitor and the Indemnitee.

(e) A claim for indemnification for any matter not involving a Claim may be asserted by written notice to the Indemnitor. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based and an estimate, if possible, of the amount of Damages suffered by the Indemnitee; provided, that the failure to give such notification or any deficiency in such notification will not relieve such Indemnitor from any obligations under this Article VI, except (i) to the extent such failure to give such notification or any deficiency in such notification actually and materially prejudices such Indemnitor or (ii) as provided in Section 6.04.

Section 6.03 Exclusivity. From and after the Closing, other than in the event of Fraud by a Party to this Agreement on the basis of the representations and warranties contained in this Agreement, this Article VI will provide the exclusive remedy against either Party hereto for any breach of any representation, warranty, covenant or other claim arising out of or relating to this Agreement and/or the transactions contemplated herein, except nothing in this Agreement will prevent or otherwise limit either Party from seeking or obtaining injunctive or other equitable relief for any breach of any covenant or agreement set forth herein. The Parties hereto agree that the provisions in this Agreement relating to indemnification, and the limits imposed on Buyer's remedies with respect to this Agreement and the transactions contemplated herein, were specifically bargained for between sophisticated parties and were specifically taken into account in the determination of the amounts to be paid to Seller hereunder.

Section 6.04 Limits on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, the maximum aggregate amount of indemnifiable Damages that may be recovered from (a) Seller pursuant to Section 6.01(a) shall equal the Purchase Price, and (b) Buyer pursuant to Section 6.01(b) shall equal the Purchase Price. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnitee pursuant to a judgment with respect to a Claim, no Party shall have any liability under any provision of this Agreement (including this Article VI) for any punitive, incidental, special or indirect damages. Each Person entitled to indemnification hereunder will take commercially reasonable steps, to the extent required by applicable Legal Requirements, to mitigate all Damages after becoming aware of any event that could reasonably be expected to give rise to any Damages that are indemnifiable or recoverable hereunder or in connection herewith. Seller shall have no liability pursuant to this Article VI or otherwise to any Buyer Indemnified Person in connection with or to the extent such liability arises as a result of Seller's compliance with the obligation contain in the second sentence of Section 3.04.

Section 6.05 Tax Treatment of Indemnity Payments. Any payments made to any Party pursuant to this Article VI shall constitute an adjustment of the Purchase Price for Tax purposes and shall be treated as such by the Parties on their Tax Returns to the extent permitted by Legal Requirements.

Section 6.06 Buyer Knowledge. The right to indemnification pursuant to this Article VI shall not be affected by any investigation conducted or any knowledge acquired by Buyer, its Affiliates or their respective Representatives at any time, whether before or after the execution and delivery of this Agreement or the Closing, with respect to the accuracy or inaccuracy of, or compliance with, any representation, warranty, covenant, or obligation.

ARTICLE VII. COVENANTS

Section 7.01 Further Assurances

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including without limitation any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets following the Closing, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Buyer, its Affiliates or their respective successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements. For clarity, Seller shall not be obligated to incur any out-of-pocket costs and expenses except for *de minimis* amounts in connection with steps taken by Seller pursuant to this Section 7.01(a).

(b) Without limiting the foregoing, Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

Section 7.02 Compliance with Legal Requirements. Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the tropical disease product for which the Priority Review Voucher was awarded, to at all times comply in all material respects with all Legal Requirements applicable to the Purchased Assets (if any), including any and all Legal Requirements applicable to the validity, maintenance, use or transfer of the Priority Review Voucher, or that would reasonably be expected to result in the revocation of the Priority Review if such Legal Requirements were not complied with (if any). Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the tropical disease product for which the Priority Review Voucher was awarded, to promptly forward to Buyer any written communications or notices it or its Affiliates receives from any Governmental Entity in respect of the Purchased Assets; provided that Seller may redact any portion of such written communications or other notices that is not relevant to the Purchased Assets.

Section 7.03 Nondisclosure.

(a) Subject to disclosures permitted or contemplated by Section 7.04, with respect to Confidential Information received from a Party, the other Party will (i) keep such Confidential Information confidential, (ii) not use any such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (iii) not disclose any such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) Each Party may disclose Confidential Information of the other Party only to its Representatives on a need-to-know basis.

(c) Each Party will (i) enforce the terms of this Section 7.03 as to its Representatives, (ii) take such action to the extent necessary to cause its Representatives to comply with the terms and conditions of this Section 7.03, and (iii) be responsible and liable for any breach of this Section 7.03 by it or its Representatives.

(d) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 7.03, such Party shall (to the extent permitted by applicable Legal Requirements) provide the disclosing Party with prompt notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 7.03. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; provided, however, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

(e) Nothing herein shall prohibit or otherwise restrict the disclosure of any Confidential Information by or on behalf of Buyer or its Affiliates to the FDA or other Governmental Entity to the extent required by the FDA or such other Governmental Entity to enable the use or transfer of the Priority Review Voucher; provided, that Buyer, its Affiliates and their respective Representatives shall use commercially reasonable efforts to obtain confidential treatment for any such disclosures.

Section 7.04 Disclosures Concerning this Agreement. The press release with respect to the execution of this Agreement that is attached as Exhibit F hereto shall be issued by Seller on or the next Business Day following the Effective Date. Buyer and Seller agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided, that the Party intending to disclose such information shall use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party). Notwithstanding the foregoing, without prior

submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate only such information concerning this Agreement as was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly traded company is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission; provided further that if a Party is obligated to so file a copy of this Agreement, such Party shall prepare a proposed redacted version thereof and request confidential treatment thereof, and the other Party may promptly provide its comments and additional proposed redactions, if any, thereon, which comments and proposed redactions, if any, shall be considered in good faith by the Party required to so file a copy of this Agreement.

Section 7.05 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity or filing that is publicly available without the prior written approval of such other Party in each instance.

Section 7.06 Expenses. Except as otherwise expressly provided herein, all costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such costs and expenses, whether or not the Closing shall have occurred. For the avoidance of doubt, Seller shall be responsible for the fees and disbursements of Jefferies, LLC.

Section 7.07 Priority Review Fee. The priority review fee required by Section 524(c) of the FDCA ("**Priority Review Fee**") and all other user fees under the FDCA applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing, shall be borne exclusively by Buyer, its Affiliates or any transferee of the Priority Review Voucher. In any event, following the Closing, Seller shall have no liability or obligation for any such fees.

**ARTICLE VIII.
GENERAL PROVISIONS**

Section 8.01 Survival. Except as expressly set forth herein, the representations and warranties and covenants which are to be performed prior to or at the Closing contained in this Agreement, and liability for the breach thereof, shall survive the Closing and shall remain in full force and effect for a period of two (2) years following the Closing Date; provided, however, that (a) the representations and warranties contained in Section 4.01, Section 4.02, Section 4.05, Section 4.12 and Section 4.13 shall survive the Closing Date and remain in full force and effect until the expiration of the applicable statute of limitations and (b) the covenants which are by their terms to be performed following the Closing shall survive the Closing and remain in full force and effect until performed in accordance with their terms.

Section 8.02 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; (b) on the date sent by e-mail of a PDF document (with confirmation of transmission) if sent prior to 5:00 p.m. in the time zone of the intended recipient on a Business Day, and otherwise on the next Business Day or (c) upon such Party's receipt after being sent by registered mail, by courier or express delivery service; in any case to the address set forth beneath the name of such Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 8.02):

- (a) if to Buyer, to:

Novartis Pharma AG
[***]

with a copy (which shall not constitute notice) to:

***]

(b) if to Seller, to:

Valneva Austria GmbH

***]

with a copy (which shall not constitute notice) to:

***]

Section 8.03 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation” and the word “or” is not intended to be exclusive unless expressly indicated otherwise. The words “will” and “shall” have the same meaning. “Extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if.”

(c) The words “hereof,” “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Except as otherwise indicated, (i) all references in this Agreement to “Articles,” “Sections,” “Schedules” or “Exhibits” are intended to refer to Articles, Sections, Schedules or Exhibits of this Agreement, and (ii) references in any Section to any clause are references to such clause of such Section.

(d) Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or).

(e) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(f) The captions, table of contents and headings in this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.

(g) Unless otherwise specified, (i) references to any applicable law or other Legal Requirement shall be deemed to refer to such law or Legal Requirement as amended from time to time and to any rules or regulations promulgated thereunder and (ii) references to any agreement or Contract are to that agreement or Contract as amended, modified, supplemented, extended or renewed from time to time in accordance with the terms hereof and thereof.

Section 8.04 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that all Parties need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission (including .pdf or any electronic signature

complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

Section 8.05 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto and the Confidentiality Agreement by and between the Parties dated January 12, 2024 sets forth the entire understanding of the Parties relating to the subject matter hereof and supersedes all prior agreements and understandings among or between the Parties relating to the subject matter hereof.

Section 8.06 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. Notwithstanding the foregoing, Buyer may assign this Agreement, in whole or in part, without Seller's consent, to any purchaser, transferee, or assignee of any of the Purchased Assets. For the avoidance of doubt, no assignment made pursuant to this Section 8.06 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

Section 8.07 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties. The Parties shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

Section 8.08 Remedies Cumulative.

(a) Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

(b) The Parties agree that irreparable harm may occur if any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise breached, and that money damages or other legal remedies may not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any breach or threatened breach of the covenants, agreements, or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to seek an injunction or injunctions to prevent or restrain any breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements, and obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

Section 8.09 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United State District Court for the Southern District of New York (or if such court does not have subject matter jurisdiction, the State Court of the State of New York located in New York County) solely and specifically for the purposes of any Action or proceeding arising out of or in connection with this Agreement.

Section 8.10 ~~WAIVER OF JURY TRIAL~~. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY. THIS WAIVER APPLIES TO ANY PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

Section 8.11 ~~Amendment; Extension; Waiver~~. Subject to the provisions of applicable Legal Requirements, the Parties may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties. At any time, any Party may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

Section 8.12 ~~Representation By Counsel; Interpretation~~. Seller and Buyer each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

Section 8.13 ~~No Benefit to Third Parties~~. Except as provided in Article VI, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BUYER:
NOVARTIS PHARMA AG

By: /s/
Name: [***]
Title: [***]

By: /s/
Name: [***]
Title: [***]

(Signature page to PRV Asset Purchase Agreement)

SELLER:
VALNEVA AUSTRIA GMBH

By: /s/
Name: [***]
Title: [***]

By: /s/
Name: [***]
Title: [***]

(Signature page to PRV Asset Purchase Agreement)

EXHIBIT A
FORM OF BILL OF SALE

BILL OF SALE

This Bill of Sale (this “**Bill of Sale**”) is entered into as of February 2, 2024, by and between Valneva Austria GmbH, a corporation organized under the laws of the Austria (“**Seller**”), and Novartis Pharma AG, a company organized under the laws of Switzerland (“**Buyer**”).

Upon the terms and subject to the conditions of the Asset Purchase Agreement, dated as of February 2, 2024 (the “**Asset Purchase Agreement**”), by and between Buyer and Seller, Seller has agreed to sell, and Buyer has agreed to purchase, all right, title and interest in, to and under the Purchased Assets, including the Priority Review Voucher, in each case free and clear of all Encumbrances.

For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Buyer and Seller, intending to be legally bound, hereby agree as follows:

1. Defined Terms: Interpretation. Except as otherwise set forth herein, capitalized terms used in this Bill of Sale shall have the meanings assigned to them in the Asset Purchase Agreement. This Bill of Sale shall be interpreted in accordance with the rules of construction set forth in Section 8.03 of the Asset Purchase Agreement.
2. Transfer of Purchased Assets. Pursuant to the terms and subject to the conditions of the Asset Purchase Agreement, Seller hereby sells, assigns, transfers, and conveys to Buyer and its successors and its assigns, and Buyer hereby does purchase from Seller, all of Seller’s right, title and interest in, to and under the Purchased Assets (including the Priority Review Voucher), in each case free and clear of all Encumbrances.
3. Effective Time. This Bill of Sale shall be effective as of the Closing.
4. Binding Effect: Amendments. This Bill of Sale shall be binding upon, inure to the benefit of, and be enforceable by, the parties hereto and their respective legal representatives, successors and permitted assigns. Neither this Bill of Sale, nor any term or provision hereof, may be amended, modified, superseded or cancelled except by an instrument in writing signed by each party hereto.
5. Governing Law. This Bill of Sale and any disputes arising under or related hereto shall be governed by the rules set forth in Section 8.09 of the Asset Purchase Agreement.
6. Counterparts. This Bill of Sale may be executed in one or more counterparts, each of which shall be deemed an original but all of which together will constitute one and the same instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Bill of Sale to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

NOVARTIS PHARMA AG

Name:
Title:

Name:
Title:

(Signature page to Bill of Sale)

VALNEVA AUSTRIA GMBH

Name:
Title:

(Signature page to Bill of Sale)

EXHIBIT B
FORM OF SELLER COVER LETTER

[Valneva Austria GmbH Letterhead]

February 2, 2024

[FDA address]

Re: BLA 125777 – Transfer of Tropical Disease Priority Review Voucher PRV BLA 125777 (the “***Voucher***”).

To Whom it May Concern:

Reference is made to the above-referenced BLA, the BLA approval letter dated November 9, 2023 (the “***Approval Letter***”) granting the Voucher to Valneva Austria GmbH (“***Valneva***”), and all related written correspondence regarding PRV BLA 125777.

Please be advised that as of February 2, 2024, Valneva has transferred complete ownership of the Voucher to Novartis Pharma AG (“***Buyer***”), and Buyer has legally accepted complete ownership of the Voucher from Valneva. Valneva and Buyer have exchanged letters acknowledging the transfer, copies of which are enclosed as Exhibit A and Exhibit B (the, “***Acknowledgment Letters***”). Valneva and Buyer acknowledge and recognize the FDA guidance provides that notification to the FDA should be made by the transferee upon redemption, however, Buyer has requested that Valneva deliver this letter along with the Acknowledgment Letters to the FDA to notify them of such transfer before its redemption. For the avoidance of doubt, this letter is being provided as a courtesy to Buyer and not as any form of notice of current intention to redeem the Voucher.

This letter contains confidential commercial information and/or trade secrets that are exempt from public disclosure under the Freedom of Information Act (5 U.S.C. §552(b)(4)), the Trade Secrets Act (18 U.S.C. §1905), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §331(j)), and 21 C.F.R. §20.61.

Sincerely,

VALNEVA AUSTRIA GMBH

By: _____
Name:
Title:

EXHIBIT C
FORM OF SELLER TRANSFER ACKNOWLEDGMENT LETTER

[Valneva Austria GmbH Letterhead]

February 2, 2024

Novartis Pharma AG.
Attn: General Counsel
Lichtstrasse 35
CH 4056 Basel
Switzerland

Re: Transfer of Tropical Disease Priority Review Voucher PRV BLA 125777 (the “*Voucher*”)

Dear Sir or Madam:

Reference is made to the above-referenced Voucher issued to Valneva Austria GmbH (“*Valneva*”) in connection with the U.S. Food and Drug Administration’s (“*FDA*”) approval of Biologics License Application 125777 (the “*BLA*”) on November 9, 2023.

Further reference is made to that certain Asset Purchase Agreement, dated as of February 2, 2024 (the “*Agreement*”), by and between Valneva and Novartis Pharma AG (“*Buyer*”). Pursuant to the Agreement, Valneva has sold, transferred, assigned, conveyed, and delivered ownership of the Voucher to Buyer, effective as of February 2, 2024 (“*Effective Date*”). As noted in the acknowledgement of transfer letter from Buyer dated February 2, 2024 (“*Buyer Acknowledgement Letter*”) Buyer has legally accepted ownership of the Voucher pursuant to this transfer from Valneva, effective as of the Effective Date.

This letter acknowledging the transfer of the Voucher from Valneva to Buyer may be presented to the FDA as evidence that Valneva acknowledges the sale and transfer of the Voucher to Buyer. This letter and the Buyer Acknowledgement Letter together serve as a complete record of transfer of the Voucher from Seller to Buyer.

Sincerely,

VALNEVA AUSTRIA GMBH

By: _____
Name:
Title:

EXHIBIT D
Form of Seller Secretary's Certificate

VALNEVA AUSTRIA GMBH

Secretary's Certificate

February 2, 2024

This Secretary's Certificate (this "***Certificate***") is delivered pursuant to Section 3.02(c) of the Asset Purchase Agreement (the "***Agreement***"), dated as of February 2, 2024, by and between VALNEVA

AUSTRIA GMBH ("***Seller***") and NOVARTIS PHARMA AG ("***Buyer***"). Unless otherwise defined herein or if the context otherwise requires, capitalized terms used in this Certificate have the meanings provided

in the Agreement.

The undersigned, in the undersigned's capacity as a duly authorized officer of Seller, solely in such capacity and not in the undersigned's individual capacity, is duly authorized to execute and deliver this

Certificate on behalf of Seller. By executing this Certificate, the undersigned hereby certifies to Buyer that as of the date hereof:

1. Attached hereto as Exhibit A are true, correct and complete copies of the resolutions duly adopted by the Managing Directors of Seller authorizing the execution, delivery and performance of the

Agreement and the transactions contemplated thereunder. Such resolutions have not been amended, modified or rescinded and are in full force and effect as of the date hereof.

2. The persons whose names are set forth on Exhibit B are authorized signatories of Seller, duly elected or appointed to the position or positions set forth opposite their respective names and held office as

of the date of such individual's execution of the Agreement or ally instrument delivered, or to be delivered, thereunder.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned has executed and delivered this Certificate as of the date first set forth above.

VALNEVA AUSTRIA GMBH

By:

Name:

Title:

(SIGNATURE PAGE TO SELLER CLOSING CERTIFICATE)

Exhibit A

Resolutions of the Board of Directors of Seller

[Attached]

Exhibit B

Authorized Signatories

NAME **TITLE**

[**] [**]

[**] [**]

[**] [**]

EXHIBIT E

FORM OF BUYER'S TRANSFER ACKNOWLEDGMENT LETTER

[Buyer Letterhead]

February 2, 2024

Valneva Austria GmbH

3 Campus Biocenter 3

1030 Vienna, Austria

Re: Transfer of Tropical Disease Priority Review Voucher PRV BLA 125777

(the “***Voucher***”)

Dear Sir or Madam:

Reference is made to the above-referenced Voucher issued to Valneva Austria GmbH (“***Valneva***”) in connection with the U.S. Food and Drug Administration’s (“FDA’s”) approval of Biologics License Application 125777 (the “***BLA***”) on November 9, 2023.

Further reference is made to that certain Asset Purchase Agreement, dated as of February 2, 2024 (the “***Agreement***”), by and between Valneva and Novartis Pharma AG (“***Buyer***”). Pursuant to the Agreement, Valneva has sold, transferred, assigned, conveyed, and delivered ownership of the Voucher to Buyer, effective as of February 2, 2024 (“***Effective Date***”). As noted in the acknowledgement of transfer letter from Valneva dated February 2, 2024 (“***Seller Acknowledgement Letter***”), Valneva has transferred ownership of the Voucher to Buyer effective as of the Effective Date. This letter acknowledges and records that Buyer has legally accepted ownership of the Voucher from Valneva, effective as of Effective Date.

This letter accepting transfer of the Voucher may be presented to the FDA as evidence that Buyer acknowledges and accepts the sale and transfer of the Voucher to Buyer. This letter and the Seller Acknowledgement Letter together serve as a complete record of transfer of the Voucher from Valneva to Buyer.

Sincerely,

[Buyer Contact]

EXHIBIT F
PRESS RELEASE (SELLER)

[Attached]

EXHIBIT G

SELLER'S BANK ACCOUNT DETAILS

1. Preliminary statement

- 1.1 The 2023 Employee Stock Option Plan governed by these Terms and Conditions (the “**2023 ESOP**”) is aiming at promoting the interests of Valneva SE (“**Valneva**” or “**the Company**”) by offering an incentive to the Beneficiary Employees (as defined below) to acquire shares in the Company. The objective is to motivate the employees, while allowing them to benefit from increases in the value of Valneva.
- Subject to the exclusions set out in the next paragraph, “**Beneficiary Employee(s)**” shall mean all individuals who, on the working day immediately preceding the Grant Date (as this term is defined in Section 3.2 below), (i) either have an active employment agreement with Valneva or one of its subsidiaries “Valneva Austria GmbH”, “Valneva Canada Inc.”, “Valneva Scotland Ltd.”, “Valneva Sweden AB”, “Valneva France SAS”, “Valneva USA, Inc.” or “Valneva UK Ltd.” (Valneva and its subsidiaries being collectively referred to herein as the “**Group**” and “**active employment**” meaning that work is being done and remuneration is being paid), or have an employment agreement with a Group entity and are on maternity, paternity or sick leave, and (ii) belong to employee grade 13 or lower. Further, for US tax reasons, those employees who are US taxpayers shall be included in the 2023 ESOP and be Beneficiary Employees only if they also met the above-mentioned conditions on November 16, 2023 and have been continuously employed by the Group between November 16, 2023 and the working day immediately preceding the Grant Date.
- Notwithstanding the foregoing, “Beneficiary Employee(s)” shall not include any individual who, on the working day immediately preceding the Grant Date, (i) is on termination notice with respect to his/her employment with a Group entity (whether on grounds of resignation, dismissal, mutual termination agreement or retirement), without continuing Group employment in another Group entity, (ii) works less than 15% of the normal full working time in the relevant Group entity, (iii) is on educational leave, (iv) is in the legal situation of external workforce (e.g. as consultant), (v) is an intern or trainee, (vi) is a student employed on a short term basis without being included in the Company’s grading system, or (vii) has been on sick leave for a continuous period of one (1) year or more.
- 1.2 The Company voluntarily grants stock options by way of this 2023 ESOP. Such grant shall not give rise to a legal right for the Beneficiary Employees to participate in a subsequent or similar plan. The 2023 ESOP shall not replace any employee stock option plan currently in effect.

2. Granting of Options

- 2.1 The Management Board shall have sole competence over the grant of stock options under the 2023 ESOP (the “**Option(s)**”). The Management Board shall determine the number of Options granted to each Beneficiary Employee and the Strike Price applicable to the subscription of each Share (as such terms are defined in Sections 3.1 and 3.9 below); this information will be provided on an individual basis, by means of a grant letter delivered to each Beneficiary Employee when the Options are granted.
- 2.2 The grant of Options to the Beneficiary Employees shall be free of charge. However, the exercise of Options is subject to all applicable fees, taxes and duties (see Section 8 below).

3. Exercise of Options

Conversion ratio

- 3.1 Subject to these Terms and Conditions (including the payment of the Strike Price and the possible adjustment provided for in Section 6.2), each Beneficiary Employee shall be entitled to convert one (1) Option into one (1) Valneva ordinary share (as referenced under ISIN FR0004056851, the “**Share(s)**”). All Shares resulting from the exercise of Options may be created by the Company through share capital increases, in accordance with French law.

Vesting of Options

- 3.2 Subject to the opening of an Exercise Period (as this term is defined in Section 3.3 below), one third (1/3) of the Options allocated to the Beneficiary Employees shall become exercisable after a period of twelve (12) months from the date such Options were granted by the Management Board of Valneva (the “**Grant Date**”), an additional one third (1/3) of the Options allocated to the Beneficiary Employees shall become exercisable after a period of twenty-four (24) months from the Grant Date and the remainder shall become exercisable after a period of thirty-six (36) months from the Grant Date. If one third of an allocation is not a whole number, it shall be rounded down for the two first tranches and rounded up for the last tranche.

Exercise periods

- 3.3 The Beneficiary Employees may exercise their Options only within specific time periods provided for that purpose (the “**Exercise Period(s)**”). Each Exercise Period will be announced by Valneva’s executive management. Subject to any Lock-Up Period (as defined in Section 7.1 below), there will be up to four (4) Exercise Periods per calendar year, each of them lasting no longer than two (2) weeks. Beneficiary Employees included in any list of insiders will not be allowed to exercise Options, even though an Exercise Period is open.
- 3.4 The Company reserves the right to postpone, suspend or terminate any Exercise Period, in accordance with applicable laws and regulations.
- 3.5 Subject to Section 4 of these Terms and Conditions, any Option which was exercisable in an Exercise Period (as per Section 3.2 above), but was not exercised during that Exercise Period, can be exercised by the relevant Beneficiary Employee during any of the following Exercise Periods.
- 3.6 In the event of a Change of Control (as defined below), all outstanding Options shall become exercisable, and an Exercise Period shall immediately begin, at the time the Change of Control is effective (this process being hereinafter referred to as the “**Acceleration**”). However, the Company shall retain the right to purchase and/or cancel the concerned Options or Shares with a cash settlement (in accordance with Section 4.5 below), provided that the same value per Share paid in the take-over transaction is applied for calculating the cash compensation amount.
- For the purposes of this Section 3.6, “**Change of Control**” means a transaction by which a single party, or two or more parties acting in concert, take over more than fifty percent (50 %) of the outstanding voting rights of the Company (be it through an acquisition, merger or transfer of essentially all of the assets of the Company).

Declaration of exercise

- 3.7 The Beneficiary Employees shall exercise their Options by sending a duly completed and signed form to the external services provider managing the plan on behalf of the Company (the “**Plan Manager**”). This form may be sent as an original or electronically.
- 3.8 Properly filled and signed exercise forms referred to in Section 3.7 above must be received by the Plan Manager not earlier than on the first day of the relevant Exercise Period, and no later than 5 p.m., Paris time, on the last day of such Exercise Period. Any form received by the Plan Manager outside this period will be void. In such a case, the relevant Beneficiary Employee may exercise his/her Options during a subsequent Exercise Period, if he/she so wishes (subject to Section 4 below).

Payment of Shares - Strike Price

- 3.9 The “**Strike Price**” shall be the amount that each Beneficiary Employee is required to pay at the time of exercising his/her Options, in order to receive the underlying Shares.
- Subject to Section 6.2 below, the Strike Price under the 2023 ESOP shall be equal to the higher of (i) one hundred percent (100%) of the volume-weighted average price of the Company’s shares on the Euronext Paris regulated market over the period of twenty (20) trading days immediately preceding the Grant Date, and (ii) one hundred percent (100%) of the average closing price of the Company’s shares on the Euronext Paris regulated market over the period of twenty (20) trading days immediately preceding the Grant Date.

- 3.10 The Strike Price must be received in full by the Plan Manager no later than the last day of the relevant Exercise Period.
- 3.11 By paying the full Strike Price, the Beneficiary Employee shall become the beneficial owner of the resulting Shares at the latest on the last day of the relevant Exercise Period, even though the Shares are held by a custodian on behalf of such Beneficiary Employee.
- 3.12 Notwithstanding Sections 3.10 and 3.11 of these Terms and Conditions and subject to the provisions of Section 7.1 below, the Company may, in its sole discretion and so long as the 2023 ESOP is managed by a Plan Manager, allow the Beneficiary Employee to exercise his/her Options and immediately sell the resulting Shares, without making any initial payment for the Strike Price. In such a case, it is understood that (i) the Plan Manager shall deduct the Strike Price and any applicable costs, fees and withholding taxes from the selling price, and (ii) if the selling price falls short of the Strike Price and such costs, fees and taxes, the Beneficiary Employee shall pay for the difference.

4. Validity period of Options - Lapse

- 4.1 The Options may be exercised within a period ending on the tenth (10th) anniversary of the Grant Date. All Options not exercised by that time shall lapse without compensation.
- 4.2 Upon termination of employment with a Group entity (whether on the grounds of resignation, dismissal, mutual termination agreement or retirement), without continuing Group employment in another Group entity, the Options of the leaving Beneficiary Employee shall lapse without compensation. Notwithstanding the foregoing, a leaving Beneficiary Employee shall retain the right to exercise those Options which were exercisable prior to termination of employment, (i) only during the first Exercise Period which will immediately follow termination of employment, and (ii) on condition that the Company had already opened an Exercise Period under the 2023 ESOP prior to such termination of employment.
- For the avoidance of doubt, any leave of a Beneficiary Employee on grounds of (i) maternity/paternity, (ii) education, or (iii) sickness, shall not be considered as termination of employment provided that the relevant employment agreement is only suspended for the duration of the leave and becomes automatically effective again when the Beneficiary Employee is back at work.
- 4.3 In the event of a Beneficiary Employee's death, all granted Options not exercisable prior to the date of death shall lapse without compensation. However, any exercisable Options may be exercised pursuant to Section 5.2 below.
- 4.4 In the event that insolvency proceedings are initiated with respect to the Company, or the Company becomes insolvent, all Options shall lapse without compensation.
- 4.5 The Company may also cancel an Option (i) pursuant to Section 3.6 above, (ii) through substitution of economically equivalent options, or (iii) if the legal form of the Company changes. In the case of a transaction referred to in Section 3.6 or a change in the legal form of the Company, any exercisable Option with a Strike Price higher than the then-current Valneva's share price (or, in the event of Change of Control, than the value per share paid in the take-over transaction) shall lapse without compensation. In addition, any acquisition, merger or transfer of essentially all of the assets of the Company which does not result in a Change of Control shall not trigger Acceleration, but may give rise to replacement of the Options by options in the successor company.
- 4.6 In the event of expiration or lapse of Options, the Company shall not be required to inform the relevant Beneficiary Employees nor to take any other action, and the Beneficiary Employees shall have no right to any compensation.

5. Unassignability of Options

- 5.1 The Options granted to the Beneficiary Employees under the 2023 ESOP shall not be transferable, negotiable or eligible as collateral, except through transfer by death (*i.e.* disposition by will or law).
- 5.2 The Options may only be exercised personally by the Beneficiary Employee during his/her lifetime or by his/her legal representative. During the six (6)-month period immediately following the date of death of a Beneficiary Employee, only his/her heir or the legal representative of the heir, in each case as identified by corresponding documentation submitted to the Company, may declare the exercise of all remaining exercisable Options. The Options shall be deemed immediately exercised if an Exercise Period is opened at the time of the declaration. If there is no Exercise Period opened at the time the exercise is declared, the Options shall be deemed exercised during the first day of the Exercise Period directly subsequent to the declaration. The Shares so received may be further assigned, subject to these Terms and Conditions and any applicable statutory and regulatory provisions.

6. Shareholder's rights

- 6.1 Before the Company actually awards the Shares, the Beneficiary Employee shall have no shareholder right in connection with these Shares, and in particular no right to receive dividends. Following the award of the Shares pursuant to these Terms and Conditions, the shareholder rights associated with the Shares, including the right to receive dividends, shall be subject to applicable laws and regulations.
- 6.2 If the Company proceeds with any of the financial transactions listed in Article L. 228-99 of the French Commercial Code, the rights of Beneficiary Employees shall be protected in accordance with that Article, which may result in a change in the conversion ratio and/or the Strike Price.

7. Disposal of Shares

- 7.1 The Beneficiary Employees may freely dispose of the Shares received following exercise of the Options. This shall not apply during a period of trading restriction (the "**Lock-up Period**"), which may be set forth at the Company's discretion as a result of the then current Company policies dealing with insider information and stock trading by employees and directors.
- During a Lock-up Period, the Beneficiary Employee shall not sell nor dispose of its Shares in any way whatsoever, including by means of collateralization or derivative transactions (*e.g.* options, futures).

8. Fees, taxes and duties

- 8.1 The Company shall bear all 2023 ESOP set-up and management costs.
- 8.2 All fees, expenses, taxes and mandatory contributions relating to securities transactions, including the cash settlement option set out in Section 3.12 above, shall be borne by the relevant Beneficiary Employee. If a Group entity is required to withhold and pay the taxes and duties owed by a Beneficiary Employee to the tax authorities, such Beneficiary Employee shall pay the corresponding amount to that entity in due time.
- The Beneficiary Employees shall further bear all expenses for personal advice, in particular with respect to legal or tax matters.

9. Miscellaneous

- 9.1 These Terms and Conditions have been drawn up in French and English. In the event of a conflict between the French and the English version, the English version shall prevail.
- 9.2 All rights and obligations under the 2023 ESOP shall be governed by French law.
- 9.3 All disputes shall be submitted to the Paris Commercial Court (France).
- 9.4 The Company shall have the right to terminate or amend the 2023 ESOP at any time, subject to applicable laws and regulations.

VALNEVA SE

1. Preliminary statement

- 1.1 The 2023 Senior Leadership Group Stock Option Plan governed by these Terms and Conditions (the “**2023 SLG SOP**”) is aiming at promoting the interests of Valneva SE (“**Valneva**” or “**the Company**”) by offering an incentive to the Beneficiary Employees (as defined below) to acquire shares in the Company. The objective is to motivate the employees and officers belonging to the Senior Leadership Group, while allowing them to benefit from increases in the value of Valneva. The 2023 SLG SOP is combined with a free share plan so that such employees and officers benefit from both stock options and free ordinary shares.
- Subject to the exclusions set out in the next paragraph, “**Beneficiary Employee(s)**” shall mean all individuals who, on the working day immediately preceding the Grant Date (as this term is defined in Section 3.2 below), (i) either have an active employment or management agreement with Valneva or one of its subsidiaries “Valneva Austria GmbH”, “Valneva Canada Inc.”, “Valneva Scotland Ltd.”, “Valneva Sweden AB”, “Valneva France SAS”, “Valneva USA, Inc.” or “Valneva UK Ltd.” (Valneva and its subsidiaries being collectively referred to herein as the “**Group**” and “**active employment**” meaning that work is being done and remuneration is being paid), or have an employment or management agreement with a Group entity and are on maternity, paternity or sick leave, and (ii) belong to employee grade 14 or higher. Further, for US tax reasons, those employees and officers who are US taxpayers shall be included in the 2023 SLG SOP and be Beneficiary Employees only if they also met the above-mentioned conditions on November 16, 2023 and have been continuously employed by the Group between November 16, 2023 and the working day immediately preceding the Grant Date.
- Notwithstanding the foregoing, “Beneficiary Employee(s)” shall not include any individual who, on the working day immediately preceding the Grant Date, (i) is on termination notice with respect to his/her employment or office with a Group entity (whether on grounds of resignation, dismissal, mutual termination agreement or retirement), without continuing Group employment in the same or another Group entity, (ii) is on educational leave, (iii) is in the legal situation of external workforce (e.g. as consultant), or (iv) has been on sick leave for a continuous period of one (1) year or more.

- 1.2 The Company voluntary grants stock options by way of this 2023 SLG SOP. Such grant shall not give rise to a legal right for the Beneficiary Employees to participate in a subsequent or similar plan. The 2023 SLG SOP shall not replace any employee stock option plan currently in effect.

2. Granting of Options

- 2.1 The Management Board, within the framework of the Supervisory Board’s authorizations, shall have sole competence over the grant of stock options under the 2023 SLG SOP (the “**Option(s)**”). The Management Board shall determine the number of Options granted to each Beneficiary Employee and the Strike Price applicable to the subscription of each Share (as such terms are defined in Sections 3.1 and 3.9 below); this information will be provided on an individual basis, by means of a grant letter delivered to each Beneficiary Employee when the Options are granted.
- 2.2 The grant of Options to the Beneficiary Employees shall be free of charge. However, the exercise of Options is subject to all applicable fees, taxes and duties (see Section 8 below).

3. Exercise of Options

Conversion ratio

- 3.1 Subject to these Terms and Conditions (including the payment of the Strike Price and the possible adjustment provided for in Section 6.2), each Beneficiary Employee shall be entitled to convert one (1) Option into one (1) Valneva ordinary share (as referenced under ISIN FR0004056851, the “**Share(s)**”). All Shares resulting from the exercise of Options may be created by the Company through share capital increases, in accordance with French law.

Vesting of Options

- 3.2 Subject to the opening of an Exercise Period (as this term is defined in Section 3.3 below), one third (1/3) of the Options allocated to the Beneficiary Employees shall become exercisable after a period of twelve (12) months from the date such Options were granted by the Management Board of Valneva (the “**Grant Date**”), an additional one third (1/3) of the Options allocated to the Beneficiary Employees shall become exercisable after a period of twenty-four (24) months from the Grant Date and the remainder shall become exercisable after a period of thirty-six (36) months from the Grant Date. If one third of an allocation is not a whole number, it shall be rounded down for the two first tranches and rounded up for the last tranche.

Exercise periods

- 3.3 The Beneficiary Employees may exercise their Options only within specific time periods provided for that purpose (the “**Exercise Period(s)**”). Each Exercise Period will be announced by Valneva’s executive management. Subject to any Lock-Up Period (as defined in Section 7.1 below), there will be up to four (4) Exercise Periods per calendar year, each of them lasting no longer than two (2) weeks. Beneficiary Employees included in any list of insiders will not be allowed to exercise Options, even though an Exercise Period is open.
- 3.4 The Company reserves the right to postpone, suspend or terminate any Exercise Period, in accordance with applicable laws and regulations.
- 3.5 Subject to Section 4 of these Terms and Conditions, any Option which was exercisable in an Exercise Period (as per Section 3.2 above), but was not exercised during that Exercise Period, can be exercised by the relevant Beneficiary Employee during any of the following Exercise Periods.
- 3.6 In the event of a Change of Control (as defined below), all outstanding Options shall become exercisable, and an Exercise Period shall immediately begin, at the time the Change of Control is effective (this process being hereinafter referred to as the “**Acceleration**”). However, the Company shall retain the right to purchase and/or cancel the concerned Options or Shares with a cash settlement (in accordance with Section 4.5 below), provided that the same value per Share paid in the take-over transaction is applied for calculating the cash compensation amount.
- For the purposes of this Section 3.6, “**Change of Control**” means a transaction by which a single party, or two or more parties acting in concert, take over more than fifty percent (50 %) of the outstanding voting rights of the Company (be it through an acquisition, merger or transfer of essentially all of the assets of the Company).

Declaration of exercise

- 3.7 The Beneficiary Employees shall exercise their Options by sending a duly completed and signed form to the external services provider managing the plan on behalf of the Company (the “**Plan Manager**”). This form may be sent as an original or electronically.
- 3.8 Properly filled and signed exercise forms referred to in Section 3.7 above must be received by the Plan Manager not earlier than on the first day of the relevant Exercise Period, and no later than 5 p.m., Paris time, on the last day of such Exercise Period. Any form received by the Plan Manager outside this period will be void. In such a case, the relevant Beneficiary Employee may exercise his/her Options during a subsequent Exercise Period, if he/she so wishes (subject to Section 4 below).

Payment of Shares - Strike Price

- 3.9 The “**Strike Price**” shall be the amount that each Beneficiary Employee is required to pay at the time of exercising his/her Options, in order to receive the underlying Shares.
- Subject to Section 6.2 below, the Strike Price under the 2023 SLG SOP shall be equal to the higher of (i) one hundred percent (100%) of the volume-weighted average price of the Company’s shares on the Euronext Paris regulated market over the period of twenty (20) trading days immediately preceding

- the Grant Date, and (ii) one hundred percent (100%) of the average closing price of the Company's shares on the Euronext Paris regulated market over the period of twenty (20) trading days immediately preceding the Grant Date.
- 3.10 The Strike Price must be received in full by the Plan Manager no later than the last day of the relevant Exercise Period.
- 3.11 By paying the full Strike Price, the Beneficiary Employee shall become the beneficial owner of the resulting Shares at the latest on the last day of the relevant Exercise Period, even though the Shares are held by a custodian on behalf of such Beneficiary Employee.
- 3.12 Notwithstanding Sections 3.10 and 3.11 of these Terms and Conditions and subject to the provisions of Section 7.1 below, the Company may, in its sole discretion and so long as the 2023 SLG SOP is managed by a Plan Manager, allow the Beneficiary Employee to exercise his/her Options and immediately sell the resulting Shares, without making any initial payment for the Strike Price. In such a case, it is understood that (i) the Plan Manager shall deduct the Strike Price and any applicable costs, fees and withholding taxes from the selling price, and (ii) if the selling price falls short of the Strike Price and such costs, fees and taxes, the Beneficiary Employee shall pay for the difference.
- 4. Validity period of Options - Lapse**
- 4.1 The Options may be exercised within a period ending on the tenth (10th) anniversary of the Grant Date. All Options not exercised by that time shall lapse without compensation.
- 4.2 Upon termination of employment or office with a Group entity (whether on the grounds of resignation, dismissal, mutual termination agreement or retirement), without continuing Group employment in the same or another Group entity, the Options of the leaving Beneficiary Employee shall lapse without compensation.
- For the avoidance of doubt, any leave of a Beneficiary Employee on grounds of (i) maternity/paternity, (ii) education, or (iii) sickness, shall not be considered as termination of employment provided that the relevant employment agreement is only suspended for the duration of the leave and becomes automatically effective again when the Beneficiary Employee is back at work.
- 4.3 In the event of a Beneficiary Employee's death, all granted Options not exercisable prior to the date of death shall lapse without compensation. However, any exercisable Options may be exercised pursuant to Section 5.2 below.
- 4.4 In the event that insolvency proceedings are initiated with respect to the Company, or the Company becomes insolvent, all Options shall lapse without compensation.
- 4.5 The Company may also cancel an Option (i) pursuant to Section 3.6 above, (ii) through substitution of economically equivalent options, or (iii) if the legal form of the Company changes. In the case of a transaction referred to in Section 3.6 or a change in the legal form of the Company, any exercisable Option with a Strike Price higher than the then-current Valneva's share price (or, in the event of Change of Control, than the value per share paid in the take-over transaction) shall lapse without compensation. In addition, any acquisition, merger or transfer of essentially all of the assets of the Company which does not result in a Change of Control shall not trigger Acceleration, but may give rise to replacement of the Options by options in the successor company.
- 4.6 In the event of expiration or lapse of Options, the Company shall not be required to inform the relevant Beneficiary Employees nor to take any other action, and the Beneficiary Employees shall have no right to any compensation.
- 5. Unassignability of Options**
- 5.1 The Options granted to the Beneficiary Employees under the 2023 SLG SOP shall not be transferable, negotiable or eligible as collateral, except through transfer by death (*i.e.* disposition by will or law).
- 5.2 The Options may only be exercised personally by the Beneficiary Employee during his/her lifetime or by his/her legal representative. During the six (6)-month period immediately following the date of death of a Beneficiary Employee, only his/her heir or the legal representative of the heir, in each case as identified by corresponding documentation submitted to the Company, may declare the exercise of all remaining exercisable Options. The Options shall be deemed immediately exercised if an Exercise Period is opened at the time of the declaration. If there is no Exercise Period opened at the time the exercise is declared, the Options shall be deemed exercised during the first day of the Exercise Period directly subsequent to the declaration. The Shares so received may be further assigned, subject to these Terms and Conditions and any applicable statutory and regulatory provisions.
- 6. Shareholder's rights**
- 6.1 Before the Company actually awards the Shares, the Beneficiary Employee shall have no shareholder right in connection with these Shares, and in particular no right to receive dividends. Following the award of the Shares pursuant to these Terms and Conditions, the shareholder rights associated with the Shares, including the right to receive dividends, shall be subject to applicable laws and regulations.
- 6.2 If the Company proceeds with any of the financial transactions listed in Article L. 228-99 of the French Commercial Code, the rights of Beneficiary Employees shall be protected in accordance with that Article, which may result in a change in the conversion ratio and/or the Strike Price.
- 7. Disposal of Shares**
- 7.1 The Beneficiary Employees may freely dispose of the Shares received following exercise of the Options. This shall not apply during a period of trading restriction (the "**Lock-up Period**"), which may be set forth at the Company's discretion as a result of the then current Company policies dealing with insider information and stock trading by employees and directors.
- During a Lock-up Period, the Beneficiary Employee shall not sell nor dispose of its Shares in any way whatsoever, including by means of collateralization or derivative transactions (*e.g.* options, futures).
- 8. Fees, taxes and duties**
- 8.1 The Company shall bear all 2023 SLG SOP set-up and management costs.
- 8.2 All fees, expenses, taxes and mandatory contributions relating to securities transactions, including the cash settlement option set out in Section 3.12 above, shall be borne by the relevant Beneficiary Employee. If a Group entity is required to withhold and pay the taxes and duties owed by a Beneficiary Employee to the tax authorities, such Beneficiary Employee shall pay the corresponding amount to that entity in due time.
- The Beneficiary Employees shall further bear all expenses for personal advice, in particular with respect to legal or tax matters.
- 9. Miscellaneous**
- 9.1 All rights and obligations under the 2023 SLG SOP shall be governed by French law.
- 9.2 All disputes shall be submitted to the Paris Commercial Court (France).
- 9.3 The Company shall have the right to terminate or amend the 2023 SLG SOP at any time, subject to applicable laws and regulations.

VALNEVA SE

Valneva SE
(the "Company")

2023-2026 Free Share Plan

Terms and Conditions

1. Background and purpose of the plan

On June 21, 2023, the General Meeting of Valneva SE's shareholders decided under its 28th resolution to grant the Company's Management Board ("MB") all powers necessary to decide the granting and issuance of free ordinary shares ("FS") for the benefit of members of the MB or employees of the Company or its subsidiaries.

In accordance with the powers and authorizations granted by the shareholders' meeting of June 21, 2023, the MB has decided to grant FS to the members of the MB and those employees of the Company or its subsidiaries whose employment grade is 14 or more (the "**Participants**") under a new 2023-2026 Free Share Plan.

The purpose of this 2023-2026 Free Share Plan (the "**2023 FSP**") is to provide a long-term incentive program for the Company's senior leadership group. The 2023 FSP is combined with the grant of stock options under the 2023 Senior Leadership Group Stock Option Plan ("**2023 SLG SOP**").

2. Purpose of these Terms and Conditions

The Terms and Conditions set forth herein aim at summarizing and complementing (i) the provisions set out in the Company's Articles of Association that are relevant to the 2023 FSP, (ii) the resolutions adopted by the General Meeting of the Company's shareholders on June 21, 2023, and (iii) the decisions made by the MB regarding the granting of free ordinary shares under the 2023 FSP (collectively, the "**Constitutional Documents**"). In the event of any discrepancy between the Constitutional Documents and these Terms and Conditions, the Constitutional Documents will prevail.

3. FS granting

3.1 Allocations

The number of FS granted to each Participant under the 2023 FSP is set forth in the MB's allocation decision.

The maximum number of FS granted by the MB cannot exceed 3% of the share capital of the Company as of the Grant Date (as defined in Section 3.2 below) or any legal threshold applicable as of the Grant Date.

3.2 Tranches

Subject to the vesting conditions set forth below, the FS granted to a Participant under the 2023 FSP will vest in and be delivered to that Participant ("*seront définitivement attribuées*") in three tranches.

Each tranche will amount to one third of the total individual allocation. If one third is not a whole number, the FS number will be rounded down for the first two tranches and rounded up for the third tranche.

The tranches will vest in the Participants as follows:

- First and second tranches: two (2) years after the date of the MB decision that initially granted the FS under the 2023 FSP (the "**Grant Date**");
- Third Tranche: three (3) years after the Grant Date.

3.3 Vesting conditions

Participants must continuously remain a corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting of the FS granted under this 2023 FSP, subject to the retirement exception set forth below. If, for any reason other than retirement, the term of office of a corporate officer is not renewed upon its expiration and the Participant concerned is not otherwise employed (full time or not less than 80%) by the Company or a direct or indirect subsidiary of the Company immediately after that expiration, the shares already vested will be kept, but the unvested shares will be lost.

3.4 Accelerated vesting after two years

If a Change of Control (as defined below) occurs not earlier than 2 years after the Grant Date, all tranches will vest immediately.

"**Change of Control**" means that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L. 233-3 of the French Commercial Code.

3.5 No compulsory holding period

Following FS vesting in accordance with these Terms and Conditions, no compulsory FS holding period will be applicable to the Participants.

3.6 Retirement

Participants who will retire in accordance with the age requirements of their applicable retirement regime before complete vesting of their FS under the 2023 FSP will remain entitled to a prorated amount of shares, for each unvested tranche, based on the period from the Grant Date until retirement, as compared to the total duration of the tranche in question; provided, however, that for purposes of this calculation, the duration of the first tranche will be deemed to be one year.

By way of example, a Participant retiring 6 months after the Grant Date will remain entitled to:

- 50% of tranche 1;
- 25% of tranche 2; and
- 16.66% of tranche 3.

If the number of vested shares calculated in accordance with the above is not a whole number, it will be rounded down.

3.7 Death

In accordance with Article L. 225-197-3 of the French Commercial Code, heirs can request the vesting of a Participant's FS within six months after the death of that Participant.

3.8 Change of Control occurring less than 2 years after the Grant Date

If a Change of Control takes place less than two years after the Grant Date, and Section III of Article L. 225-197-1 of the French Commercial Code does not apply, the 2023 FSP will be canceled and the Company will indemnify the Participants for the loss of unvested FS granted under this canceled plan, subject however to all required shareholder approvals where corporate officers are concerned. The gross amount of this indemnity will be calculated as though such FS had been vested upon the Change of Control. The conditions and limitations set forth in these Terms and Conditions will apply to this calculation, *mutatis mutandis*.

4. Additional provisions

On March 9, 2023, with confirmation on June 21, 2023, the Company's Supervisory Board decided that in accordance with Section II of Article L. 225-197-1 of the French Commercial Code, each corporate officer (including the CEO) should keep not less than 20% of the vested FS of each tranche under the 2023 FSP until termination of his/her office as a corporate officer.

Valneva SE
(the "Company")

2022 Special Free Share Plan Number 2

Terms and Conditions

1. Background and purpose of the Program

On June 23, 2021, the general meeting of Valneva SE's shareholders decided under its 24th resolution to grant the Company's Management Board ("MB") all powers necessary to decide the granting and issuance of free ordinary shares ("FS") for the benefit of members of the MB or employees of the Company or its affiliates.

On June 29, 2021 and March 15, 2022, the Company's Supervisory Board approved Management Agreements between the Company's subsidiary Valneva Austria GmbH and a member of the Management Board (the "**Participant**") by which free shares would be granted to the Participant in 2022 after his appointment on the Management Board. On May 4 and October 12, 2022, the Supervisory Board authorized the Management Board to grant such free shares, in accordance with section 19.1(xiv) of the Company's articles of association (the "**Articles**").

Therefore, the MB plans to grant FS to the Participant.

The purpose of the 2022 Special Free Share Plan Number 2 (the "**Program**") is to provide the Participant with a mid-term incentive program in accordance with the Participant's employment terms.

2. Purpose of these terms and conditions

The terms and conditions set forth herein aim at summarizing and complementing the Program-related or Program-relevant provisions set out in the Company's Articles, the resolutions adopted by the general meeting of the Company's shareholders on June 23, 2021 as well as the decisions made or to be made by the MB regarding the granting of free shares (collectively, the "**Constitutional Documents**"). In the event of any discrepancy between the Constitutional Documents and these terms and conditions, the Constitutional Documents will prevail.

3. FS granting

3.1 Amount granted

The number of FS to be granted to the Participant will be calculated as set forth below.

The amount of FS to be granted will be worth two hundred thousand euros (EUR 200,000) based on the volume-weighted average price of the Company's ordinary shares on EuroNext Paris over the ninety (90) trading days immediately preceding the MB's granting decision. No fractional shares shall be allowed, and the number of shares granted shall be rounded down to the nearest whole number.

The maximum number of FS that can be allotted by the MB cannot exceed 3% of the share capital of the Company as of the Grant Date (as defined in Section 3.2 below) or any legal threshold applicable as of the Grant Date.

3.2 Single tranche

Subject to the vesting conditions set forth below, the FS granted to the Participant will vest in and be delivered to the Participant ("*seront définitivement attribuées*") two (2) years after the date of the MB decision that initially granted the FS under this Program (the "**Grant Date**").

3.3 Vesting conditions

The Participant must continuously remain a MB member, corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting.

3.4 No compulsory holding period

Following FS vesting in accordance with these terms and conditions, no compulsory FS holding period will apply.

3.5 Death

In accordance with Article L 225-197-3 of the French commercial code, heirs can request vesting within six months after the death of the Participant (if that occurs prior to vesting and the employment condition set forth in section 3.3 above is satisfied).

3.6 Change of Control occurring less than 2 years after the Grant Date

If (a) a Change of Control (as defined below) takes place less than two years after the Grant Date, (b) the employment condition set out in section 3.3 above is met until the Change of Control, and (c) section III of Article L225-197-1 of the French commercial code does not apply, the Program will be canceled and the Company will indemnify the Participant for the loss of unvested free shares granted under the canceled Program, subject however to all required shareholder approvals. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. A calculation example is given in Appendix 1 to these terms and conditions.

"**Change of Control**" means that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L 233-3 of the French commercial code.

4. Additional provisions

In accordance with the Supervisory Board's decisions dated May 4 and October 12, 2022, the Participant shall keep not less than 10% of the vested FS under this Program until termination of his office as MB member or corporate officer.

Appendix 1

Example of Change of Control Indemnity:

The sole purpose of this example is to explain the calculation method. The number of shares actually granted may be different from the number used below.

Assuming, for illustration purposes only, that 20,000 free shares have been granted to the Participant under the Program and that the stock price upon the Change of Control is ten (10) euros, then the gross indemnity to be paid under section 3.6 of these terms and conditions, before deduction of mandatory contributions and withholding taxes, shall be $20,000 \times 10 = \text{€}200,000$.

Subsidiaries of the Registrant

Name of Subsidiary	State or Other Jurisdictions of Incorporation
Valneva Austria GmbH	Austria
Valneva Canada Inc.	Canada
Valneva France SAS	France
Vaccines Holdings Sweden AB	Sweden
Valneva Scotland Ltd	Scotland
Valneva Sweden AB	Sweden
Valneva UK Ltd	England and Wales
Valneva USA Inc.	Delaware
VBC 3 Errichtungs GmbH	Austria

EXHIBIT 12.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas Lingelbach, certify that:

1. I have reviewed this annual report on Form 20-F of Valneva SE (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 22, 2024

By: /s/ Thomas Lingelbach
Thomas Lingelbach
Chief Executive Officer

EXHIBIT 12.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Bühler, certify that:

1. I have reviewed this annual report on Form 20-F of Valneva SE (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 22, 2024

By: /s/ Peter Bühler
Peter Bühler
Chief Financial Officer

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Thomas Lingelbach, Chief Executive Officer of Valneva SE (the “Company”) hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 13.1 (the “Annual Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Thomas Lingelbach

Thomas Lingelbach
Chief Executive Officer
(Principal Executive Officer)

** This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Valneva SE under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.*

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Peter Bühler, Chief Financial Officer of Valneva SE (the “Company”) hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 13.2 (the “Annual Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Peter Bühler

Peter Bühler
Chief Financial Officer
(Principal Financial Officer)

** This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Valneva SE under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.*

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-266839 on Form F-3 of our reports dated March 22, 2024, relating to the financial statements of VALNEVA SE and the effectiveness of VALNEVA SE's internal control over financial reporting appearing in this Annual Report on Form 20-F for the year ended December 31, 2023.

/s/ Deloitte & Associés

Bordeaux, France

March 22, 2024

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form F-3 (No. 333-266839) of Valneva SE of our reports dated March 22, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appear in this Form 20-F.

/s/ PricewaterhouseCoopers Audit

Neuilly-sur-Seine, France

March 22, 2024

VALNEVA SE

Incentive Compensation Recoupment Policy

Adopted by the Board of Directors on December 20, 2023

(in connection with the Company's change of governance on the same date, and as previously adopted by the Company's Supervisory Board)

1. Introduction

In order to comply with Rule 10D-1 and the Listing Standards (as defined below), the Board of Directors of Valneva SE, a European Company (*Societas Europaea*) (the “**Company**”), deems appropriate to adopt this Incentive Compensation Recoupment Policy (this “**Policy**”) to provide for the Company’s recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and remains subject to interpretation and operation to be consistent with, the rules and regulations promulgated by the SEC, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder (“**Rule 10D-1**”), the Nasdaq Listing Rules (particularly Nasdaq Listing Rule 5608) (the “**Listing Standards**”), any applicable SEC or Nasdaq guidance or interpretations issued from time to time regarding such Incentive Compensation recovery requirements, and French law and the laws of any other jurisdiction which apply to the Company, including further to management or employment agreements governing employment or appointment of the Covered Officers (collectively, the “**Applicable Rules**”). Notwithstanding anything in this Policy to the contrary, at all times, this Policy remains subject to interpretation and operation in accordance with the Applicable Rules.

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the “**Effective Date**”). Incentive Compensation is deemed “**received**” in the Company’s financial year in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

“**Accounting Restatement**” means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“**Accounting Restatement Date**” means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

“**Administrator**” means the Board.

“**Board**” means the Board of Directors of the Company.

“**Code**” means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

“**Covered Officer**” means each current and former Executive Officer.

“**Exchange**” means the Nasdaq Stock Market.

“**Exchange Act**” means the U.S. Securities Exchange Act of 1934, as amended.

“**Executive Officer**” means any of the Company’s current or former executive officers, as determined by the Board, which will include at a minimum the Company’s chief executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company’s parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant.

“**Financial Reporting Measures**” means measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures derived wholly or in part from such measures, including Company share price and total shareholder return (“**TSR**”). A measure need not be presented in the Company’s financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

“**Incentive Compensation**” means any compensation that is granted, earned or vested wholly or in part upon the attainment of a Financial Reporting Measure, including, without limitation, any annual or pluriannual variable compensation, non-compete indemnities, severance pay, and the award or vesting of free shares and/or stock options.

“**Lookback Period**” means the three completed financial years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company’s financial year) within or immediately following those three completed financial years (except that a transition period of at least nine months shall count as a completed financial year). Notwithstanding the foregoing, the Lookback Period shall not include financial years completed prior to the Effective Date.

“**Recoverable Incentive Compensation**” means Incentive Compensation received by a Covered Officer on or after the Effective Date during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax or social security withholdings and other deductions, subject to compliance with Applicable Rules and provided that the amount of Recoverable Incentive Compensation to be recouped from a Covered Officer employed by the Company in France shall not exceed the amount of Incentive Compensation actually received by the Covered Officer following withholding of social security charges by the Company). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on share price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

“**SEC**” means the U.S. Securities and Exchange Commission.

4. **Recoupment**

(a) **Applicability of Policy.** This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a U.S. national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly (generally within 180 days of the Administrator's determination of the necessity for recoupment under this Policy and the calculation of the Recoverable Incentive Compensation, unless otherwise decided by the Administrator in light of the circumstances) recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Administrator has made a determination, upon decision of at least a majority of the independent directors serving on the Board, that recoupment would be impracticable, in which case recoupment may be foregone. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate French law or other home country law which applies to the Company or to a Covered Officers' employment agreement, where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation, and shall provide such opinion to the Exchange in accordance with the Listing Standards; or

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of U.S. Code Section 401(a)(13) or U.S. Code Section 411(a) and regulations thereunder, or analogous non-U.S. tax-qualified retirement plans, to the extent permitted by Applicable rules.

Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly (as this expression is more specifically defined in Section 4(b) herein). The Administrator may, in its discretion, seek recoupment from a Covered Officer from, without limitation, any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with U.S. Code Section 409A (if applicable) or any equivalent local laws applicable to the Covered Officer; and (v) any other method authorized by the Applicable Rules. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation of the Covered Officer previously deferred. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(d) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's articles of association or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or

advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(e) **Indemnification of Administrator.** Any members of the Administrator who assist in the administration of this Policy shall not be personally liable for any action, determination or interpretation made in good faith with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator in accordance with the Applicable Rules. The Administrator shall have full and final authority to make any and all determinations required under this Policy, including the authority to correct any defect, supply any omission or reconcile any ambiguity, inconsistency or conflict in this Policy, subject to the Applicable Rules. The Administrator will review this Policy from time to time and will have full and exclusive authority to take any action it deems appropriate. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties, except as otherwise required by applicable law, and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with such committees of the Board as may be necessary or appropriate as to matters within the scope of such committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator reasonably deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee). This Policy shall not preclude any other compensation recoupment or clawback policies, arrangements or provisions of the Company.

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company or any subsidiary thereof is a party or which the Company of any subsidiary thereof has adopted or may adopt and maintain from time to time.

8. Amendment; Termination

The Administrator will administer this Policy and may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion, subject to compliance with any Applicable Rules. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Applicable Rules.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC or as may be required by the French Financial Market Authority (AMF). This Policy, and any recovery of Recoverable Incentive Compensation by the Company pursuant to this Policy that is required to be disclosed in the Company’s filings with the SEC, will be disclosed as required by the U.S. Securities Act of 1933, as amended, the Exchange Act, and related rules and regulations.

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