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, 2022

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
6 rue Alain Bombard
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: 138,367,482 outstanding as of December 31, 2022**

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:

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). ☐

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

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

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" and other trademarks or service marks of Valneva SE appearing in this Annual Report are the property of Valneva or its subsidiaries. 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, pre-clinical studies and regulatory submissions, particularly with respect to the potential approval of our chikungunya vaccine candidate VLA1553 and the Phase 3 clinical trial of our Lyme disease vaccine candidate;
- the timing or likelihood of regulatory filings and approvals, including the potential eligibility to receive a Priority Review Voucher for VLA1553;
- our ability to successfully expand, develop and advance our pipeline of product candidates;
- 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;
- our expectations and forecasts for sales of our approved products;
- our ability to sell the inventory of our COVID-19 vaccine and to utilize our Almeida manufacturing facility for other products;
- the present and future effects of the COVID-19 pandemic or other 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 safely and effectively scale up our manufacturing capabilities and supply a sufficient quantity of our products and product candidates;
- our ability to meet our obligations under our various collaboration, partnership and distribution arrangements;
- estimates of market opportunity for our approved products and vaccine candidates;
- 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;

- statements regarding future revenue, 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, 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 and our Lyme disease vaccine candidate is undergoing Phase 3 clinical trials which may be altered or delayed following Pfizer's decision as the trial sponsor to discontinue approximately half of the enrolled trial participants as a result of violations of Good Clinical Practice at certain trial sites run by a third party. 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.
- DUKORAL and IXIARO are aimed at diseases that largely threaten travelers. If international travel is substantially disrupted, for example due to a development in the ongoing COVID-19 pandemic or 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 substantial funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- 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.
- We are subject to various ongoing risks following the development of our COVID-19 vaccine.
- 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 are dependent on single source suppliers for some of the components and materials used in our products.
- We rely primarily on our manufacturing facilities (and, if our chikungunya vaccine candidate is approved, will rely in part on a third party's manufacturing facility) 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 face substantial competition, and many of our competitors have significantly greater resources and experience, which may negatively impact our commercial opportunities.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- There are 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.
- 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 €143.3 million, €73.4 million and €64.4 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated net loss of €450.3 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 VLA15 and VLA1553;
- initiate, conduct and complete any ongoing, anticipated or future pre-clinical studies and clinical trials for our current and future product candidates, including the Phase 3 clinical trial for VLA15 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 marketing approval, particularly VLA1553;
- invest in our manufacturing facilities;
- seek to discover and develop additional product candidates;
- 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 the ongoing COVID-19 pandemic or other events such as the ongoing conflict between Ukraine and Russia;
- market and distribute vaccines for new third parties, such as VBI Vaccines; and
- incur ongoing and additional 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 Lyme disease and chikungunya vaccine candidates have not received regulatory approval. 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 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. 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.

Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations.

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 currently expected, 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.

DUKORAL and IXIARO are aimed at diseases that largely threaten travelers. If international travel is substantially disrupted, for example due to a development in the ongoing COVID-19 pandemic, this will significantly adversely affect the sale of these vaccines.

DUKORAL and IXIARO are aimed at diseases that largely threaten travelers to particular regions. Due to the COVID-19 pandemic, travel significantly decreased worldwide, and many countries instituted travel restrictions and advisories. As a result, sales of these vaccines decreased significantly in 2020 and 2021, adversely impacting our financial results. While international travel recovered significantly in 2022, if another disruption causes a substantial decrease in international travel, our revenues will be significantly adversely affected, and we may not be able to continue the development of one or more of our vaccine candidates without additional financing. Additionally, if our chikungunya vaccine candidate receives regulatory approval and international travel has not resumed to expected levels at that point in time, sales of this vaccine may be less than expected, because we anticipate that it would also be used by travelers.

Sales of DUKORAL and IXIARO 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 will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

As of December 31, 2022, we had total assets of €621.3 million, including cash and cash equivalents of €289.4 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. We will 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;
- the costs, timing and outcome of regulatory review and approval of our product candidates, including the U.S. FDA's review of our chikungunya vaccine candidate VLA1553, as well as the potential receipt of a Priority Review Voucher for VLA1553;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- 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 the COVID-19 pandemic or 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; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

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. 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 ongoing COVID-19 pandemic and the war between Russia and Ukraine. 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. 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 Management Board. 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 loan bears 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, 2022, we had $100.0 million (€92.3 million) drawn down in two tranches under the Financing Agreement, including an additional $40 million made available to us in an amendment signed

in April 2022. This amendment also extended the interest-only period to the third quarter of 2024 and the maturity date of the loan to the first quarter of 2027.

The Financing Agreement contains covenants for minimum revenue and liquidity. 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. In July 2020, we reached an agreement with our lenders that this minimum revenue covenant would not apply until December 31, 2020, in exchange for a minimum cash requirement of €75 million (instead of €35 million) during that period. On January 15, 2021, a new amendment was executed to (i) modify the minimum revenue covenant to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.75 million in 2022 and €115.0 million thereafter and (ii) bring the minimum liquidity covenant to the amount of €50.0 million in 2021 and 2022 and €35.0 million thereafter. As part of an amendment signed in April 2022, the minimum liquidity covenant was lowered to €35.0 million prior to the start of 2023. If our consolidated net revenues (excluding grants) or our liquidity were to fall below the amounts required, this could result in additional costs (up to 10 additional points of interest over the duration of the default) and/or an early repayment obligation (payment of the principal increased by 8% and of an indemnity representing the interests expected until March 2023).

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. The funds under these grants will be received over three years, beginning in March 2022. Valneva SE will provide 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.

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 regulatory approval for VLA1553, our chikungunya vaccine candidate, on the timelines we expect. On December 23, 2022, we announced completion of the rolling submission of the Biologics License Application, or BLA, for VLA1553 to the FDA. On February 20, 2023, we announced that the FDA had accepted the filing and classified the review as Priority, with a current Prescription Drug User Fee Act, or PDUFA, review goal date at the end of August 2023, subject to progress of the BLA review. If the FDA's decision regarding the approval of VLA1553 is delayed beyond our expectations, it would have a significant impact on our business plans and our results of operations. A delay could occur because the FDA revokes the Priority designation as a result of our failure to provide requested information according to the FDA's timelines, or because the review results in a Complete Response Letter, for example due to noncompliance findings following an expected pre-approval inspection of one of our manufacturing facilities or clinical trial sites or due to other major deficiencies. In particular, our financial planning assumes that we may receive a Priority Review Voucher, or PRV, upon approval of VLA1553 by the FDA. A delay in approval by the FDA would impact when we could receive the PRV as well as potentially the resale value of such PRV, or it could prevent us from receiving the PRV altogether, if the delay is such that another company receives approval for its own chikungunya vaccine before we may receive approval for VLA1553. Failure to receive the PRV when expected or at all would have a significant impact on our financial position and results of operations. Finally, we expect that the U.S. Centers for Disease Control's Advisory Committee for Immunization Practices, or ACIP, may issue recommendations relating to vaccination against chikungunya in February 2024 if VLA1553 has received FDA approval by that time. The scope of such a recommendation from ACIP will influence the commercial success of VLA1553. For example, if ACIP recommends vaccination against chikungunya in a narrower set of circumstances, this would likely decrease the demand for VLA1553 relative to a broader recommendation for vaccination. ACIP meets three times per year and sets its agenda at its discretion,

so if the FDA has not approved VLA1553 prior to the February 2024 meeting, it may not be clear at what point ACIP would potentially issue a recommendation following FDA approval. A narrow and/or delayed ACIP recommendation would have a significant impact on the commercialization of VLA1553 and on our financial position and results of operations.

While we have obtained regulatory approval in major markets for three of our products, we may not be able to obtain regulatory approval, at all or in all of the desired markets or for all of the desired labels, of the product candidates we are currently developing or may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any product candidates in the European Economic Area, or EEA, the United States or any other geographies until we or our collaborators receive regulatory approval from the European Commission, FDA, or applicable regulatory agency. The time required to conduct clinical trials and obtain approval or other marketing authorizations by the European Commission, FDA and other regulatory authorities is unpredictable and 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 the EEA, the United States or any other geographies, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the European Medicines Agency, or EMA, FDA or other regulatory authorities, 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 European Commission, FDA and other regulatory authorities. Additionally, the EMA, FDA or other regulatory authorities may also require us to conduct additional pre-clinical studies or clinical trials for our product candidates either prior to or post-approval or may object to elements of our clinical development program, requiring their alteration. For example, the FDA and EMA will need to agree to proposed modifications to the Phase 3 clinical trial of our Lyme disease vaccine candidate following Pfizer's decision as the trial sponsor to discontinue approximately half of the enrolled trial participants as a result of violations of Good Clinical Practice, or GCP, at certain trial sites run by a third party. Modifications to this clinical trial may result in significant additional costs and may result in a delay to the target BLA filing date. 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. Approval by one regulatory authority does not guarantee approval by another regulatory authority on the basis of the same data or at all.

Of the large number of products in development, only a small percentage successfully complete the European Commission's, FDA's or other 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 approval or marketing authorization 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 a BLA or foreign marketing application for our product candidates, the European Commission, FDA or other comparable regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The European Commission, FDA or other comparable regulatory authorities may also provide regulatory approval for a product candidate for a more limited indication or patient population than we originally request, and the European Commission, FDA or other comparable regulatory authorities 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.

Furthermore, even if we obtain regulatory approval for our product candidates, successful commercialization will depend on a number of factors. We may still need to develop a commercial organization to support commercialization of the product or allocate additional resources to our existing commercial organizations. We will also need to establish a commercially viable pricing structure, obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities, and generate knowledge of and demand for our products. 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. 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 regulatory approval. For example, we cannot guarantee that the ongoing Phase 3 trial of our Lyme disease vaccine candidate will produce efficacy or safety data on par with those of the Phase 1 and 2 trials. 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 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, or EUA, 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 without obtaining marketing approval from the European Commission, FDA or other comparable regulatory authority, and we may never receive such approvals. The time required to obtain approval by the European Commission, FDA and other comparable regulatory authorities 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, in February 2023 we announced Pfizer's decision as the trial sponsor to discontinue approximately half of the participants enrolled in the Phase 3 trial of our Lyme disease vaccine candidate as a result of violations of GCP at certain trial sites run by a third party. We and Pfizer intend to work with the relevant regulatory authorities to modify the trial design with the aim of being able to meet the target of filing a BLA in 2025, but we cannot guarantee that the agencies will accept the proposed modifications or that the trial will proceed on schedule despite the acceptance of such modifications. Additionally, any delays arising in the course of the ongoing Phase 3 trial of our Lyme disease vaccine candidate could result in a delay in the overall trial schedule by one year or more due to the limited tick biting season. Any of these delays would increase development costs and could lead to a negative perception of Valneva or VLA15.

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;
- clinical trials of our product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, after review of an IND or amendment, an application for the authorization of a clinical trial or related amendment, or equivalent application or amendment or 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 or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease, which already caused us to delay initiation of the Phase 3 clinical trial for VLA1553 (chikungunya), and could cause other or additional disruptions.

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 and following Pfizer's decision as the trial sponsor to discontinue approximately half of the enrolled trial participants as a result of violations of GCP at certain trial sites run by a third party. 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.

The European Commission, FDA and other 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 the European Commission, FDA or any other 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, equivalent regulations in the EEA or other foreign countries or that we are exposing participants to unacceptable health risks, or if the competent authorities of individual EEA countries, FDA or other regulatory authorities find deficiencies in our investigational new drug applications, or INDs, or our applications for the authorization of clinical trials, respectively, or 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 are developing VLA15 for Lyme disease and VLA1553 for chikungunya, and we intend to develop other vaccine candidates in the future. 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, or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease. 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 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. We may also face particular challenges in enrolling subjects in clinical trials of VLA15 due to the seasonal nature of Lyme disease. We only have a short window each year in which to fully enroll subjects in a VLA15 clinical trial, and failure to enroll an adequate number of subjects, or any other delays in enrollment, could cause substantial delay in our VLA15 clinical program, as it could force us to wait another year for the applicable enrollment window for this disease.

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. For example, our announcement of Pfizer's decision as the trial sponsor to discontinue approximately half of the enrolled VLA15 Phase 3 trial participants as a result of violations of GCP at certain trial sites run by a third party may make ongoing recruitment for this trial at other sites more difficult. 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 intend to 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.

We are subject to various ongoing risks following the development of our COVID-19 vaccine. Any of these risks could negatively impact our business and results of operations.

In April 2020, we announced our intent to develop VLA2001, a vaccine against the SARS-CoV-2 virus that causes COVID-19. In order to facilitate the development and manufacture of VLA2001, we entered into a number of agreements and made other strategic decisions which have significantly impacted and, despite the fact that we have suspended manufacturing of VLA2001 and do not anticipate further COVID-related activity, will continue to impact our business.

In September 2020, we entered into a supply agreement, or the UK Supply Agreement, with the government of the United Kingdom, pursuant to which the UK Government would provide up-front investment in the development of the vaccine and the scale-up of our manufacturing facilities, notably the construction of our Almeida manufacturing facility in Scotland. On September 13, 2021, we received notice of the UK Government's intent to terminate the UK Supply Agreement, and on June 15, 2022, we entered into a settlement agreement with the UK Government to resolve certain

matters relating to our respective obligations following the termination of the UK Supply Agreement. Certain of our obligations under the UK Supply Agreement survive its termination. See "Item 10.C—Material Contracts—UK Supply Agreement" for further details.

In November 2021, we entered into an advance purchase agreement, or the EC APA, with the European Commission, or EC, pursuant to which the EU Member States agreed to purchase up to 60 million doses of VLA2001 over two years. The EC APA included a provision allowing for termination of the EC APA if VLA2001 had not received a marketing authorization from the European Medicines Agency by April 30, 2022, and on May 13, 2022, we received a notice from the EC of its intent to terminate the EC APA on this basis. We entered into an amendment to the EC APA on July 29, 2022, under which five EU Member States ordered a total of 1.25 million doses which have now been delivered. We received advance payments totaling €116.9 million from the EU Member States and are not required to repay these advance payments if they were spent or committed prior to May 13, 2022. We have submitted documentation of our use of these advance payments as required by the EC APA and do not anticipate that we will be required to repay any of these amounts. However, the EU Member States are continuing to review our documentation, and we cannot completely exclude the possibility that they may question our spending or commitment of the advance payments. As a result, we cannot completely exclude the possibility that we may have to repay some of these amounts. However, we have assessed this possibility as remote.

In November 2021, we entered into an agreement, or the IDT Agreement, with IDT Biologika, or IDT, pursuant to which IDT would manufacture the bulk drug substance of VLA2001. As a result of the significant reduction in orders from EU Member States in the amended EC APA, on September 16, 2022, we announced that we had terminated the IDT Agreement and would pay IDT up to €36.2 million in cash and the equivalent of €4.5 million in kind, in the form of specified equipment purchased by Valneva.

In February 2022, we announced that Valneva Scotland was awarded 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 VLA2001 and our other vaccine candidates. Payments under these grants will be possible over three years, until March 2025. 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 up to that time, for which Valneva SE has provided a parent guarantee. Notably, the terms of the grants include requirements relating to employees at our Livingston site, which is one of the sites most impacted by the reshaping of our operations following the amendment to the EC APA, as discussed further below. As of the date of this Annual Report, we have received €5.1 million (£4.3 million) of grant funds from Scottish Enterprise. We do not currently anticipate that we will be required to repay any of these funds but cannot exclude the possibility that further changes to our business and operations in Scotland may lead Scottish Enterprise to consider that such repayment is necessary.

We announced in August 2022 that we had suspended manufacturing of VLA2001. We built our new Almeida manufacturing facility at our site in Livingston intending that it would be used, in the first instance, for the manufacture of VLA2001. We are evaluating whether we will be able to repurpose the facility for the manufacture of IXIARO and, if approved, our chikungunya vaccine candidate. If we are unable or unwilling, for any reason, to use the Almeida facility for our own purposes, we will need to find customers who would outsource their manufacturing to us or to sell the facility to a third party. Both of these possibilities would require significant time and attention from management, and there can be no guarantee that we will be able to find potential customers or buyers for the facility, or that we will be able to agree on satisfactory terms with such potential customers or buyers. If we are unable to use or sell the Almeida facility or its equipment, this would have a significant impact on our business and results of operations.

We decided to re-shape our operations following the decision to suspend manufacturing of VLA2001. This will result in a reduction of 20-25% of the workforce we had at the beginning of 2022. We have initiated a first phase of this reduction in workforce, and a second phase will follow in the first half of 2023. These plans are subject to ongoing discussions with local works councils, and we cannot exclude the possibility that plans could be delayed or altered as a result of these discussions. Such delays or alterations could impact our business and results of operations.

Although we received approvals for VLA2001 from four regulatory bodies, we have been unable to make VLA2001 a commercial success. Because we had already purchased most of the materials needed to fulfil the original order volume from the EU Member States and had manufactured a substantial number of doses prior to suspending manufacturing of VLA2001, we have a significant amount of inventory of VLA2001 doses remaining. Although we are still actively seeking to sell these remaining doses, we may ultimately be unable to sell them. We have taken the decision to write off €176.9 million of remaining VLA2001 inventory as of December 31, 2022, as described further in the notes to our financial statements filed with this Annual Report.

Additionally, we continue to have obligations to regulatory agencies relating to the marketing authorizations that we have received for VLA2001. Although we have stopped recruitment on our ongoing VLA2001 clinical trials, these trials continue to generate data that we will report to the regulatory agencies. We also have an ongoing obligation to report information about safety to the agencies pursuant to pharmacovigilance requirements applicable to all pharmaceutical products. These obligations will continue to require time and expense, and failure to comply with these obligations could lead to other consequences from the regulatory agencies.

Finally, our stock price has historically reacted to news about our COVID-19 vaccine program. Further updates regarding this program may prompt further changes to our stock price and overall shareholder value.

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 2023, is to expand our product pipeline. Following the FDA's acceptance in February 2023 of the BLA for our chikungunya vaccine candidate for review 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. 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, our reputation may be harmed, which would harm our business, financial condition, results of operations 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, IXIARO and DUKORAL for prevention of Japanese encephalitis and cholera, respectively, as well as development of our product candidates for the prevention of chikungunya and Lyme disease. 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. 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 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, it 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 face substantial competition, and many of our competitors 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, 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 the European Commission, FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, 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 vaccine candidates for Japanese encephalitis vaccines (such as Substipharm's IMOJEV), cholera (such as Emergent's Vaxchora, which Bavarian Nordic expects to acquire and 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 when these vaccines are 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 significant sales if other, more effective vaccines under development by our competitors are also approved.

In order to effectively compete, 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. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become 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 (including, in the case of COVID-19 vaccines, possible future opposition to multiple rounds of vaccination even among those who have already received a primary vaccination);
- 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;
- 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, 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 NDA, BLA or other application for regulatory approval. For example, our Livingston manufacturing facility will be subject to a pre-approval inspection by the FDA in connection with the BLA for our chikungunya vaccine candidate. 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 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.

The European Commission's, FDA's and other 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 the EEA, the United States or elsewhere.

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 European Commission's, FDA's and other regulatory authorities' ability to exercise their regulatory authority. If these executive actions impose constraints on the European Commission's, FDA's and other 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 have engaged in the off-label promotion of our products, pre-approval promotion of our product candidates or disseminated 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 nonclinical 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;
- reduced 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.

The scale of these risks and uncertainties may expand if we are able to commercialize VLA2001 in markets where we have not previously done business.

In addition, due to the conflict between Russia and Ukraine, the United States, 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., 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. 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. Additionally, concerns about security and any increase in the cost of travel resulting from the rising cost of fuel could further limit the recovery of the travel industry in the context of the COVID-19 pandemic. 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, may be unable to satisfy their purchasing or reimbursement obligations, or 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 will lead late-stage development of the vaccine candidate, including the Phase 3 clinical trial, and 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. At this time, 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 the Advisory Committee for Immunization Practices of the Centers for Disease Control and Prevention;
- 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 European Commission, FDA, or other 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 requiring 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, the impact of such reform could nevertheless 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 has 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 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 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 and damage our reputation and could 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, result in the suspension, variation, or termination of, or prevent further conduct of clinical studies or regulatory approval;
- 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 time frame 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.

VLA1553 (chikungunya) 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 (Lyme disease) and VLA1553 both received Fast Track designation from the FDA, and VLA1553 was granted Priority Review upon the FDA's acceptance in February 2023 of our BLA filing. 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 either 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 are seeking approval for the FDA's accelerated approval pathway for VLA1553 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. 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, 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.

A Breakthrough Therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that a product candidate will receive marketing approval.

In July 2021, we announced that we received Breakthrough Therapy designation for VLA1553 from the FDA, and we may seek a Breakthrough Therapy designation for other product candidates we may pursue in the future. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that are designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

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, which 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, 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:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts 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;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- 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
- establishment of the Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or 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 2031. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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 will take effect progressively starting in fiscal year 2023, although they may be 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. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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, it may refuse to reimburse a product at the price set by the manufacturer or it may instead 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 entered into force on 11 January 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 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, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive 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). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

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 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 outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in 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 in the EU for our product candidates on the basis of clinical trials conducted in the UK.

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 governments of the United States, and authorities in the European Union and the United Kingdom, including applicable export control regulations, economic sanctions on countries and persons, 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, and the United Kingdom adopted a series of financial and trade sanctions in relation to Russia and Russian listed citizens and entities. We expect an increase in the number of sanctions regulations against Russia for 2023.

Exports of our products and product candidates must be made in compliance with these laws and regulations. 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 or product candidates to certain governments, persons, entities, countries, and territories. Changes in our products and product candidates or changes in applicable export or import laws and regulations may create delays in the introduction or provision of our products and product candidates in other 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 and product candidates 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 offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the 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 for international operations.

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.

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 European public company with limited liability with its registered office in France, we will be subject to the sustainability disclosure requirements set out in the EU Corporate Sustainability Reporting Directive and the disclosure requirements set out in the EU Taxonomy Regulation, and as a foreign private issuer listed in the United States, we expect to be subject to the SEC's proposed climate rules.

On December 14, 2022, the EU adopted Directive 2022/2464/EU, or the Corporate Sustainability Reporting Directive or CSRD, which amends the non-financial reporting requirements set out in Directive 2013/34/EU, or the Accounting Directive. The CSRD introduces new mandatory reporting obligations that will require in-scope entities to publish audited sustainability information in their Management Reports addressing environmental, social and governance, or ESG matters in line with new mandatory European sustainability reporting standards, or ESRS, that will be adopted by the European Commission through secondary legislation.

The First Set of ESRS which will apply to EU reporting entities are due to be formally adopted by June 30, 2023. Drafts of these standards have already been published and consulted on and are currently pending formal approval by the European Commission. 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

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

1. themselves,
2. entities in their group whether EU or non-EU, and
3. businesses in their value chains (both upstream and downstream).

Certain disclosures for large EU reporting entities, including Valneva, are mandatory, even if the entity considers that there are no material impacts, risks or opportunities. For example, disclosure of scopes 1-3 greenhouse gas emissions is always required.

Certain disclosures are only required if "material" impacts, risks and 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 from the investor perspective are material to the company's development, performance and position) and impact materiality (i.e., the impact of corporate activity on sustainability matters from the perspective of citizens, consumers, employees etc.). Impacts, risks and opportunities are material if they satisfy one or both of these materiality tests.

All EU Reporting Entities must have the sustainability section of their Management Report audited by a third-party accredited auditor 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.

As a European public company with limited liability with its registered office in France, we will fall under the scope of application of the new sustainability-related reporting requirements. This will require us to set up processes to gather the relevant data, conduct materiality assessments and prepare a CSRD-compliant report, which will likely be a time-consuming and costly exercise.

The disclosure requirements under the CSRD will 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 EU Accounting Directive, including those brought into scope by the CSRD, to disclose, from January 1, 2022, the proportion of turnover, capital and operational expenditure directed towards activities that qualify as "environmentally sustainable" (this information should be disclosed even if the contribution is none).

The disclosures set out in 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, will set new due diligence duties for the following entities:

- Large EU-based limited liability companies with (a) more than 500 employees and (b) a net worldwide turnover of over EUR 150 million generated in the last financial year for which financial statements have been prepared.
- Non-EU companies that have generated a net worldwide turnover of more than EUR 150 million in the EU in the financial year preceding the last financial year.
- EU and non-EU companies that do not reach the thresholds set out above but generated a specific amount of their net turnover in high-risk sectors (agriculture, food, textile and extraction of mineral resources).

These entities will be required to identify and, where necessary, prevent, end or mitigate the potential and actual adverse impacts of their activities on human rights, such as child labor and exploitation of workers, and on the environment, for example pollution and biodiversity loss. The CSDDD, if adopted, will impose substantive due diligence obligations and also influence the information gathering process required by entities that are also subject to the CSRD. It will also have an impact on the mandatory disclosures to be made under the CSRD on the entity's due diligence process (which will need to show compliance with the CSDDD if the entity is subject to both the CSRD and CSDDD). It is estimated that the CSDDD will be adopted by the end of Q2 2024 and become enforceable towards 2026-2030.

If adopted, the CSDDD will require France to amend the *Loi de Vigilance* (Law N. 2017/399), which currently requires companies and groups with a registered office in France and with more than 5,000 employees in France or more than 10,000 employees in France and worldwide to carry out due diligence. The EU proposed CSDDD, if adopted, would require France to amend the *Loi de Vigilance* to significantly lower the thresholds to trigger the due diligence obligations.

Additionally, we expect to be subject to the rules proposed by the U.S. Securities and Exchange Commission on climate-related disclosure. The SEC announced the proposed rules in March 2021 and has not yet published the final version of the rules following a long public comment period. We expect the requirements of the final rules to be similar to those of the CSRD in terms of resources required for compliance. According to the proposed rules, compliance with certain provisions would be required beginning with our annual report for the year ending December 31, 2023.

Compliance with both the CSRD and the SEC's proposed 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 limit the duration of the patent protection of our technology and product candidates. For example, two of our patents have been limited in scope in opposition proceedings in Europe. One of these opposed patents relates to vaccine compositions comprising an aluminum component with low heavy metal and copper impurities, and covers IXIARO. The other opposed patent covers VLA84. These decisions are under appeal, and the patents could ultimately be revoked. We would not expect that the potential revocation of the opposed patent to have a significant impact on further commercialization of IXIARO, because other patents protecting IXIARO exist and have not been opposed. Revocation of the opposed patent relating to VLA84 could limit our ability to stop others from commercializing a similar product to VLA84 and could dissuade third parties from collaborating with us to develop VLA84. 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. In the United States, the Hatch-Waxman Act, and similar legislation in the European Union, permits 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 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 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 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 which proceeding is currently still pending.

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 or misappropriating or from 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, and 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*), Dynavax for the adjuvant used in VLA2001 (SARS-CoV-2) 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 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 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. 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 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 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 February 2023, Bavarian Nordic announced that it had entered into an agreement to acquire two of Emergent BioSolutions’ travel vaccines, including the Vaxchora cholera vaccine, which would be a competitor of DUKORAL if marketed in Europe, where it has received approval. We do not yet know if or how this acquisition may impact any of our agreements with Bavarian Nordic. However, if we are unable to maintain these agreements and to make alternative arrangements in a timely manner, our business could be significantly adversely impacted. 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 4.17 and 4.18 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 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 our COVID-19 vaccine and other vaccine candidates. A loss of our 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 will 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.

Throughout the ongoing COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products. 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 development of product candidates and the financing of their development. For example, we entered into an agreement 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 and 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 VLA2001 and other vaccine candidates. Additionally, IDT Biologika will

perform the lyophilization and filling that are part of the process of manufacturing VLA1553 and thus a key component of the manufacturing of VLA1553, if it is approved, will be performed by a third party. 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. To build and maintain such a network under acceptable terms, we face intense competition. Such external collaborators may terminate, at any time, their involvement. 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. In addition, the ongoing COVID-19 pandemic and government measures taken in response have also had a significant impact on our collaborators, and we expect that if they face further disruption it may affect our ability to initiate and complete our pre-clinical studies and clinical trials.

Risks Related to the Manufacture of Our Products and Product Candidates

We may be unable to successfully scale up our manufacturing in sufficient quality and quantity, which would delay or prevent us from developing and commercializing our product candidates.

We may be unable to successfully increase our manufacturing capacity to meet demand for future approved products in a timely or cost-effective manner, or at all, as needed for our commercialization efforts. 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 and may encounter unexpected challenges relating to manufacturing efficiency or quality control that could impact the consistency of quantity and quantity manufactured across batches. 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 FDA or other comparable regulatory 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.

Delays in manufacturing or our inability to manufacture sufficient doses of an approved product could adversely affect our business, financial condition, prospects and results of operations. We have outsourced an important step in the manufacturing of VLA1553 to a third party, IDT Biologika, which could result in delays, concerns about manufacturing consistency, or other manufacturing failures if VLA1553 is approved. Per the standard industry practice, we rather than the third-party provider would bear the risk of such problems. 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. If we are required to make such refunds, this could result in a material adverse impact on our business, prospects, financial condition, and results of operations. 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 due to the faster than expected recovery of the travel market and could experience shortages again in 2023, which could expose us to the possibility of fines.

Any of these factors 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 our Japanese encephalitis vaccine and will be the sole source of bulk drug substance for our chikungunya vaccine candidate VLA1553. 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 VLA1553 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 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, 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 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 may have to suspend 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, if we progress the development of any of our product candidates, 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. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and 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 continue to 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, 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 certain recommendations from this opinion must now be considered as questions of law by the judicial committee in charge of the proceedings. 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, 2022 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, 2022, we had 719 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 continue to be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic. 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 continue to be materially adversely affected by the effects of pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease. Beginning in late 2019 and continuing into 2023, the outbreak of COVID-19 has resulted in the declaration of a global pandemic and adversely affected economic activity across virtually all sectors and industries on a local, national, and global scale. While many people have been vaccinated globally and certain jurisdictions, including Saint-Herblain, France, Vienna, Austria, Solna, Sweden and Livingston, Scotland, where our primary offices, production facilities and laboratories are located, have reopened businesses and governmental agencies, we are unable to accurately predict the full impact that the COVID-19 pandemic will have 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, the impact on our business including our existing and future clinical programs and timelines, and the impact to the business of our service providers and partners. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

While the potential economic impact brought by, and the duration of, the ongoing COVID-19 pandemic, may be difficult to assess or predict, it has resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ordinary shares and ADSs.

The global pandemic of COVID-19 has rapidly evolved since the beginning of 2020. The ultimate impact of the ongoing COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole that could result from future developments relating to the COVID-19 pandemic. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

We have in the past 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 in the past 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;
- 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 earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, armed conflict, wars, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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 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, such as the ongoing crisis in Ukraine, 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 recently raised interest rates multiple times in response to concerns about inflation among other things, and it may raise them again. In fact, it has indicated its intention to continue to raise interest rates. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including 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, more costly or more dilutive. 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 internal computer systems, or those of our collaborators, service providers or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively, and adversely affect our business, financial condition, results of operations and prospects.

Our internal computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other contractors or consultants are potentially vulnerable to malware,

malicious code (such as computer viruses and worms), data corruption, cyber-based attacks, natural disasters, public health pandemics or epidemics, terrorism, war and telecommunication and electrical failures that may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information, and other similar threats. We have in the past experienced and may in the future experience security breaches of our information technology systems. The techniques used to sabotage or to obtain unauthorized access to information systems, and networks in which cyber threat actors store data or through which they transmit data, change frequently and we may be unable to implement adequate preventative measures. Such threats are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. The growth in state-sponsored cyber activity, including the increased rate of cyberattacks arising from the war in Ukraine and the risk that these cyberattacks could spread globally, showcases the increasing sophistication of cyber threats and could dramatically expand the global threat landscape. Any significant system failure, accident 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 could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could 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 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 internal computer and information technology systems, cloud-based computing services 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 cyber-attacks, that may expose confidential information, intellectual property, proprietary business information or personal information to unauthorized persons. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber-attacks in the future. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. If a data security breach affects our systems, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, 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 federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. These may include state breach notification laws, and 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 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, federal, state and international laws and regulations, such as the 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. 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, 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. 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.

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 European Economic Area's and United Kingdom's implementation of the General Data Protection Regulation, known 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 and 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 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, 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 significant 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 or 4% of global annual revenue of any noncompliant company 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 believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. One of the primary safeguards allowing U.S. companies to import personal data from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the EU-U.S. Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU, in a case known colloquially as "Schrems II." On October 7, 2022, President Biden signed an Executive Order on "Enhancing Safeguards for United States Signals Intelligence Activities", which implements into U.S. law the agreement in principle announced in March 2022 on a new EU-U.S. Data Privacy Framework. However, if this new transatlantic data transfer framework is not adopted and we are unable to continue to rely on one of the primary alternative mechanisms, namely, the European Commission's Standard Contractual Clauses or SCCs, this may materially and adversely affect our business, financial condition, and results of operations. The CJEU's decision in Schrems II also raised questions about whether the

Standard Contractual Clauses, can lawfully be used for personal data transfers from the EEA to the United States or other third countries that are not the subject of an adequacy decision of the European Commission. While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle in Schrems II, it made clear that reliance on those Clauses alone may not necessarily be sufficient in all circumstances. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data.

In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and/or applicable European law, the decision in Schrems II and subsequent draft guidance from the European Data Protection Board, or EDPB, would require the parties to that transfer to implement certain supplementary technical, organizational and/or contractual measures to rely on the Standard Contractual Clauses as a compliant "transfer mechanism." However, the EDPB recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data, adopted on November 10, 2020 conclude that no combination of such measures could be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data "in the clear" to recipients in countries where the power granted to public authorities to access the transferred data goes beyond that which is "necessary and proportionate in a democratic society" – which may, following the CJEU's conclusions in Schrems II on relevant powers of United States public authorities and commentary in that draft EDPB guidance, include the United States in certain circumstances (e.g., where Section 702 of the US Foreign Intelligence Surveillance Act applies). At present, there are few, if any, viable alternatives to the Standard Contractual Clauses. As such, if we are unable to implement a valid solution for personal data transfers 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. Inability to import 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 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 reference methodologies (such as MR-001) imposing stringent rules to process health-related data Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains unclear. However, on June 28, 2021, the European Commission adopted an adequacy decision in relation to the United Kingdom. This decision permits personal data to flow freely from the EEA to the United Kingdom where it benefits from an essentially equivalent level of protection to that guaranteed under EU law. This adequacy decision has, however, a limited duration of four years, meaning that the decision will automatically expiry after this period. After expiry of the period, the adequacy decision will be renewed only if the United Kingdom continues to ensure an adequate level of data protection. Additionally, as noted above, the United Kingdom has transposed the GDPR into United Kingdom domestic law by way of the UK GDPR with effect from in January 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations.

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.

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.

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 and 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 €13.9 million, €20.2 million and €8.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. Our French Research Tax Credits were €1.5 million, €1.8 million and €1.1 million for the years ended December 31, 2022, 2021 and 2020, 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 €821.6 million, €628.3 million and €529.5 million for the years ended December 31, 2022, 2021 and 2020, 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 are generated in the United States for IXIARO, with 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, a substantial part of our sales are generated in the United States for IXIARO, with production costs in GBP, and in Canada for DUKORAL, with production costs in SEK. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. 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 depositary. 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 Management Board and of our Supervisory Board 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 Management Board 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 depositary 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 Management Board and the Supervisory Board.

Most of the members of our Management Board and Supervisory Board 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 Management and Supervisory Boards 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 Management 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 Supervisory Board appoints the members of the Management Board and shall fill any vacancy within two months;
- our Supervisory Board has the right to appoint members of the Supervisory Board to fill a vacancy created by the resignation or death of a member of the Supervisory 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 Supervisory Board;
- our Management Board can be convened by the Chairman of the Management Board, our chief executive officer or at least half of the members of the Management Board;
- our Supervisory Board can be convened by the Chairman or the Deputy Chairman or one member of the Supervisory Board. A member of the Management Board or one-third of the members of the Supervisory Board may send a written request to the Chairman to convene the Supervisory Board. If the chairman does not convene the Supervisory Board 15 days following the receipt of such request, the authors of the request may themselves convene the Supervisory Board;
- our Supervisory 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 Supervisory 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 Management Board and/or members of the Supervisory Board 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 Supervisory Board or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a member of the Supervisory 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 Management and Supervisory Boards, and election and removal of members of the Management and Supervisory Boards 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.

There are 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 our remediation efforts, and we have engaged outside consultants who will 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. We anticipate that the process to document and evaluate our internal control over financial reporting will be both costly and challenging.

We have identified material weaknesses in our internal control over financial reporting in connection with the preparation of the consolidated financial statements included with this Annual Report. 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 constitute material weaknesses, either

individually or in the aggregate, are pervasive in nature and impact 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 included with this Annual Report. 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 identified, see Item 15 of this Annual Report.

We have taken steps to address these material weaknesses and expect to continue to develop and implement remediation plans. While we are working to remediate these material weaknesses as quickly and efficiently as possible, we cannot at this time provide the expected timeline in connection with implementing our remediation measures. We will not be able to conclude that we have remediated the material weaknesses until all relevant controls are fully implemented and have operated effectively for a sufficient period of time. These remediation measures may be time-consuming and costly, and might place significant demands on our financial and operational resources. See Item 15 of this Annual Report for further details about past and ongoing remediation measures. We cannot assure you that our remediation efforts will be effective, that we will be able to remedy these material weaknesses 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 will 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 has 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, our Management Board and Supervisory Board members 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 our Supervisory Board members to be independent and although the corporate governance code to which we currently refer (the Middlenext code) recommends that, in a widely-held company like ours, a majority of the Supervisory Board members 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 Supervisory Board as members of our nomination and compensation committee, and our independent Supervisory Board members would not necessarily hold regularly scheduled meetings at which only independent members of the Supervisory Board are present. 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, 2023. In the future, we would lose our foreign private issuer status if we to 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 Management Board or Supervisory Board are residents or citizens of the United States, we could lose our foreign private issuer status. As of December 31, 2022, 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, 2022. 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. subsidiary 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 may 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, as well as 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 countries;
- 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 the COVID-19 pandemic and macroeconomic factors such as geopolitical instability, rising interest rates and inflation.

In addition, the trading prices of other biopharmaceutical companies have been highly volatile as a result of the ongoing COVID-19 pandemic. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic may impact our business, pre-clinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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. Following our announcement on September 13, 2021 of the termination of the UK Supply Agreement, a number of law firms in the United States announced the commencement of "investigations" for possible violations of U.S. federal securities laws. As of the date of this Annual Report, we have not received notice of any actual claims, but we cannot exclude the possibility of a lawsuit relating to these investigations or any others that may be announced.

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 eight 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, and Valneva France SAS, a *société par actions simplifiée* formed under the laws of France in 2019.

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, 2022, 2021, and 2020 totaled €29.2 million, €92.2 million and €18.9 million, respectively, primarily related to investments in our manufacturing facilities in Scotland and Sweden. We expect our capital expenditures in 2023 to be primarily financed from our existing cash and cash equivalents.

B. Business Overview

We are a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet needs to ensure we can make a difference in peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there

are limited effective treatment options. Today we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

Our current clinical portfolio is composed of a number of highly differentiated vaccine candidates that are designed to provide preventative solutions to diseases with high unmet need. VLA1553, targeting the chikungunya virus, is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data and the first for which a Biologics License Application, or BLA, has been submitted to the U.S. Food and Drug Administration, or FDA. We believe that, as a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection compared to other chikungunya assets being evaluated in clinical trials. Chikungunya has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. 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 active vaccine candidate against Lyme disease currently undergoing 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.

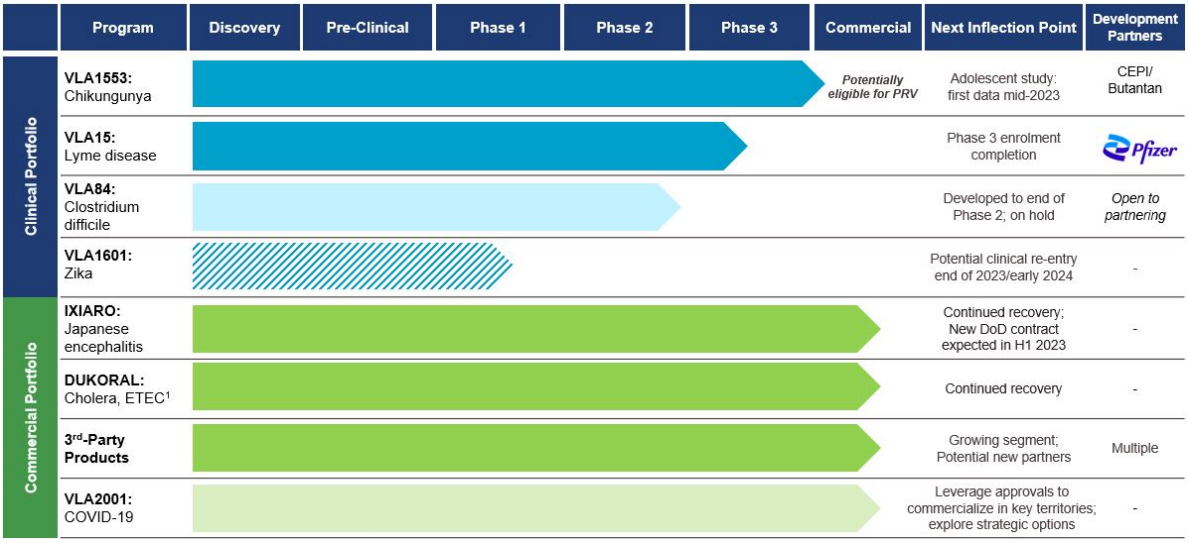
We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand and Thailand, prevention of diarrhea caused by Enterotoxigenic Escherichia coli, or ETEC, the leading causes of travelers' diarrhea. We also 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 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- or best-in class and address unmet needs in infectious diseases. Our aim is to either develop them for future commercialization 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 vaccine candidate against the chikungunya virus, or CHIKV, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available and VLA1553 is the only chikungunya vaccine candidate that successfully completed pivotal Phase 3 studies and the first chikungunya vaccine candidate for which a regulatory filing process is ongoing with the FDA. Additionally, we believe that, as a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection compared to other chikungunya assets being evaluated in clinical trials. In our Phase 1 clinical trial, we

observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants, which results were sustained after 12 months. 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 and 12-month antibody persistence data in December 2022. In the pivotal Phase 3 trial, we observed a very high seroconversion level of 98.9% in participants 28 days after receiving the single administration, and this immunogenicity profile was maintained over time, with 99% of participants showing protective CHIKV neutralizing antibodies twelve months after receiving a single vaccination in a dedicated antibody persistence trial. We initiated BLA rolling submission with the FDA for approval of VLA1553 in persons aged 18 years and above in August 2022 and completed the submission in December 2022. In February 2023, the FDA accepted the filing and classified the review as Priority. Currently, VLA1553 has been assigned a Prescription Drug User Fee Act, or PDUFA, review goal date at the end of August 2023, which is the date by which the FDA intends to take action on the application. VLA1553 previously received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher, or PRV. VLA1553 was also granted PRIority MEdicine, or PRIME, designation by the European Medicines Agency, or EMA, in 2020, and we plan to make regulatory submissions for VLA1553 in Europe in the second half of 2023. We also initiated a Phase 3 trial in adolescents conducted in Brazil by Instituto Butantan, which may support future regulatory submissions in this age group following a potential initial regulatory approval. In February 2023, Valneva completed enrollment and vaccination of 254 adolescents and first results are expected mid-2023.

- **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 strains found in the United States 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 initial 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 strains. In August 2022, 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 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. The companies intend to work with regulatory authorities, and as previously announced, aim for Pfizer to potentially submit a BLA to the FDA and a Marketing Authorization Application, or MAA, to the EMA in 2025, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan. According to the terms of our collaboration with Pfizer, 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 this collaboration 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.

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. Additionally, we initiated pre-clinical work on vaccine candidates targeting parvovirus B19, a virus most commonly causing fifth disease, and Campylobacter, a bacterium often associated with food poisoning.

We commercialize our fully owned travel vaccines IXIARO/JESPECT and DUKORAL and have 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 €41.7 million in the year ended December 31, 2022 compared to €45.1 million and €48.5 million in the years ended December 31, 2021 and 2020, respectively. Sales in 2020 and 2021 were significantly impacted by the COVID-related decline in travel. In September 2020, the Defense Logistics Agency, or DLA, awarded us a new contract for the supply of IXIARO. 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. Due to the impact of the COVID-19 pandemic on Department of Defense operations, the option terms for the first year were amended in 2021 and the DLA did not exercise the second option year in 2022. This was partly offset in 2022 by the significant recovery of the private travel markets.

- **DUKORAL** – an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and, in Canada and other countries, heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. We acquired DUKORAL in 2015 and recorded €17.3 million, €2.4 million, and €13.3 million of revenues in the years ended December 31, 2022, 2021 and 2020, respectively. Sales in 2022 benefited from a significant recovery in the travel markets after being impacted by the COVID-related decline in travel in 2020 and 2021. 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.
- **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 has been 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. During the third quarter of 2022, the World Health Organization, or WHO, 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. In November 2021, we signed an advance purchase agreement with the European Commission, or EC, 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 August 2022, we announced that we had suspended manufacturing of the vaccine in light of the reduced order volume from EU Member States. We are continuing discussions on potential additional supply agreements with various other governments around the world to deploy the remaining eight to ten million doses of inventory. These inventories were fully written-down as of December 31, 2022, as explained further in the Notes to our financial statements. VLA2001's shelf life is expected to be extended to up to 24 months, compared to 21 months currently.

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, and commercialization. We have strategically entered into 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:

- **Seek regulatory approval for, and commercialize, VLA1553 as a prophylactic vaccine candidate against chikungunya virus.** We initiated BLA rolling submission with the FDA for approval of VLA1553 in persons aged 18 years and above in August 2022 and completed the submission in December 2022. In February 2023, the FDA accepted the filing and classified the review as Priority. Currently, VLA1553 has been assigned a PDUFA review goal date at the end of August 2023, which is the date by which the FDA intends to take action on the application. As the first company to complete a Phase 3 clinical trial and file for approval of a chikungunya vaccine, we believe we are in a strong position to compete for the PRV that the FDA intends to award related to the first chikungunya vaccine approved in the United States. If VLA1553 is approved by the FDA, we would target commercialization in the United States as early as late 2023. A clinical trial of VLA1553 in adolescents is also ongoing in Brazil for which first results are expected mid-2023. This trial may support further regulatory submissions and label extensions in countries where we will seek initial regulatory approvals in adults. This ongoing clinical trial conducted by Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations, or CEPI, is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region. If approved for such use, Instituto Butantan will be responsible for manufacturing and commercializing the vaccine in low- and middle-income countries.
- **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 the United States 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. As per the terms of the collaboration agreement, we received a $25 million milestone payment from Pfizer in October 2022 following initiation of the Phase 3 study. In February 2023, Pfizer, as the study sponsor, decided to discontinue half of the total enrolled participants in the trial following violations of 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. The companies intend to work with regulatory authorities, and as previously announced, aim for Pfizer to potentially submit a BLA to the FDA and an MAA to the EMA in 2025, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

- **Grow product sales including through successfully launching our chikungunya vaccine, if approved, and build a leading position in the travel vaccines market.** Sales from our proprietary products, IXIARO and DUKORAL, and potentially in the future VLA1553, as well as products that we commercialize for third parties such as RABIPUR and ENCEPUR, are expected to generate proceeds which we will be able to reinvest in our research and development programs.
- **Expand our pipeline of pre-clinical and 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 have notably initiated pre-clinical programs focusing on hMPV and EBV.
- **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.
- **Maintain an attractive workplace by strengthening our ESG (environmental, social, and governance) strategy.** 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.

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 chikungunya, 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 candidate 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.

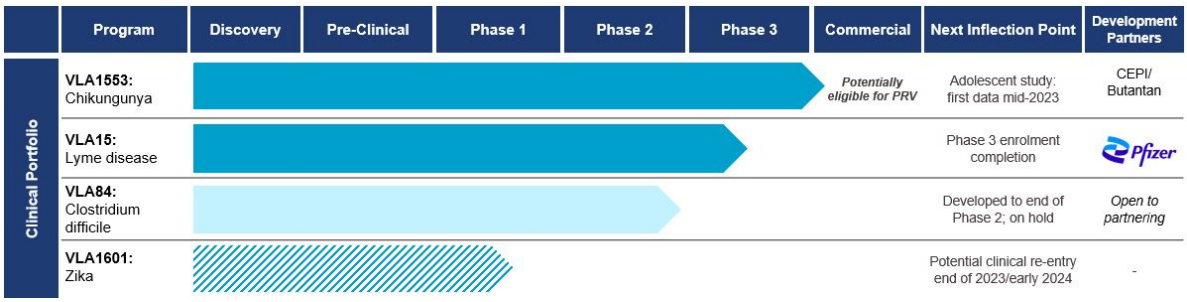
In addition to the vaccine's primary component, such as an inactivated virus, vaccines may contain adjuvants, which are used to improve the immune response to the vaccine, for example through producing more antibodies. Adjuvants used in human vaccines include alum (aluminium hydroxide) and others (e.g. 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—Our vaccine candidate targeting the chikungunya virus

VLA1553 is a vaccine candidate for chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further through infected travelers who carry the virus to their home countries. The risk of a significant outbreak is increasing particularly in the southern United States and Europe, where tiger mosquitoes, which are particularly associated with the spread of the disease, are established. There are no preventive vaccines or effective

treatments available and, as such, chikungunya is considered to be a major public health threat. The global market for a chikungunya vaccine is estimated to exceed $500 million annually by 2032.

In our Phase 1 clinical trial, we observed that VLA1553 led to the development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants in the trial and that these levels were sustained after 12 months. 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. Under this pathway, we plan to seek licensure of VLA 1553 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 twelve-month antibody persistence data in December 2022. These antibody persistence results confirmed a very high level of seroconversion, with 99% of participants showing protective CHIKV neutralizing antibodies twelve months after receiving a single vaccination. The final Phase 3 clinical trial data that we announced in March 2022 indicated a seroresponse rate of 98.9% at 28 days compared to the 70% threshold (for non-acceptance) agreed with the FDA.

The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a PRV. VLA1553 has received Fast Track and Breakthrough Therapy designation from the FDA and PRIME designation from the EMA. In August 2022, we initiated BLA rolling submission with the FDA for approval of VLA1553 in persons aged 18 years and above and completed the submission in December 2022. This BLA submission is part of the accelerated approval pathway agreed with the FDA in 2020. In February 2023, the FDA accepted the filing and classified the review as Priority. Currently, VLA1553 has been assigned a PDUFA review goal date at the end of August 2023, which is the date by which the FDA intends to take action on the application. If VLA1553 is approved, we intend to market it as a traveler vaccine in North America and Europe.

Additionally, in May 2020, we partnered with the Instituto Butantan in Brazil to develop, manufacture and market VLA1553 in 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 February 2023, Valneva announced enrollment completion and vaccination of the 754 adolescents. First results are expected mid-2023. 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.

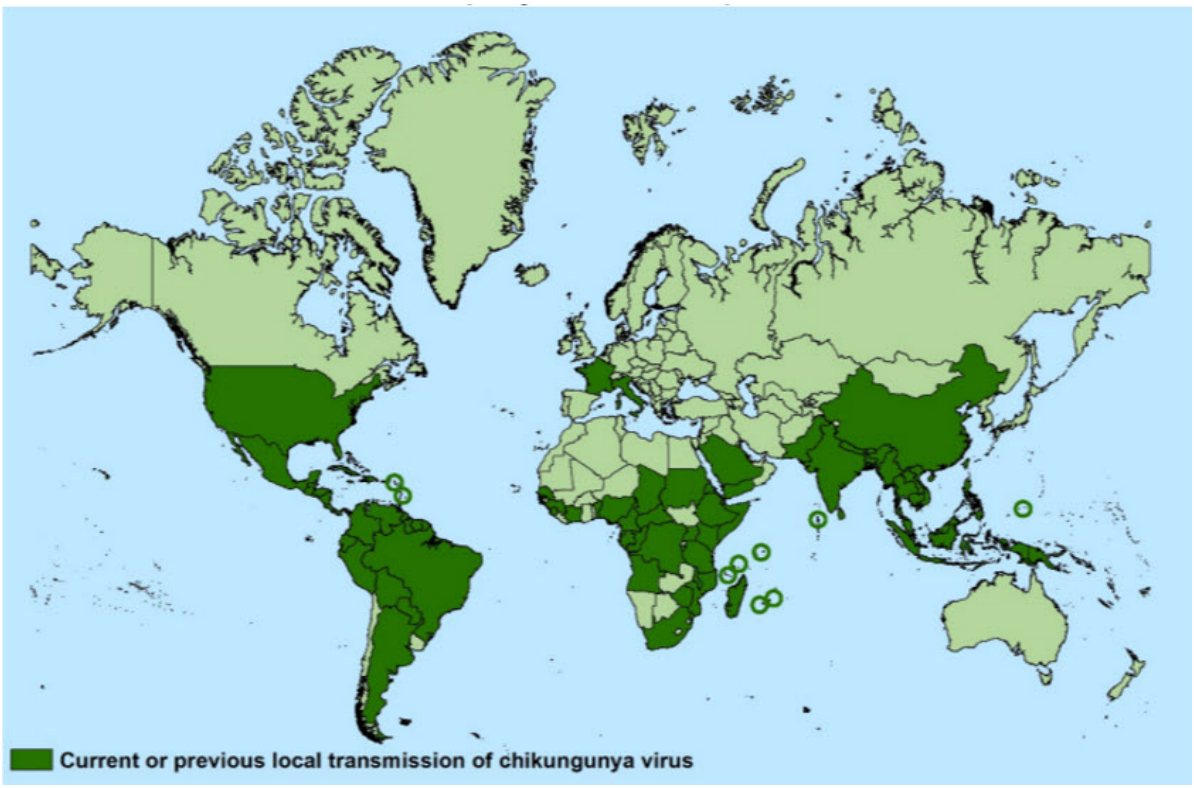
Overview of the chikungunya virus

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. There have been more than 3 million reported cases in the Americas since the virus first arrived there in 2013. In 2020, there were approximately 95,000 suspected cases reported in the Americas as well as approximately 32,000 suspected cases in India and 11,000 in Thailand. 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; 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, Pacific Ocean and 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 where chikungunya cases have been reported as of March 2, 2022 (it does not include countries or territories where only imported cases have been documented):



Without a vaccine, 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.

No vaccine to prevent chikungunya infection has been approved. 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, preventive measures rely on avoiding mosquito bites. Effective mosquito control has proven challenging, even in higher income countries.

In addition to VLA1553, there are two third-party advanced chikungunya vaccine candidates. The first is an inactivated vaccine candidate manufactured by Bharat Biotech of India, which has initiated a seamless Phase 2/3 clinical trial in August 2021. The second is a virus-like particle vaccine candidate developed by Emergent BioSolutions, which has announced initiation of Phase 3 clinical trials in October 2021. We believe that all of these potential vaccine candidates may face limitations relative to VLA1553, including VLA1553 being designed to only require a single administration, while Bharat's and potentially Emergent BioSolutions' vaccine candidates are likely to require multiple shots to either reach or maintain high levels of effectiveness.

VLA1553 Approach

VLA1553 is a live-attenuated chikungunya vaccine candidate 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 VLA1553 as a live-attenuated vaccine, we believe it may confer life-long immunity.

VLA1553 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 VLA1553 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 Lancet in 2020. In this trial we examined three doses of VLA1553: a low dose having a viral titer of 3.2×10^3, a medium dose of 3.2×10^4, and a high dose of 3.2×10^5. 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 twelve 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 NT_{50}. Seroconversion was defined as having an NT_{50} 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 3 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.

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, 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, we reported twelve-month data for this trial. 99% of participants retained neutralizing antibody titers above the seroresponse threshold of 150 twelve months after the single-dose vaccination. 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 adolescents. The VLA1553-321 trial is funded by CEPI and is intended to support the label extension in this age group following a potential initial regulatory approval in adults from the FDA. This trial is also expected to support licensure of VLA1553 in Brazil, which would be the first potential approval for use in endemic populations.

Conducted in Brazil by Instituto Butantan, VLA1553-321 is a prospective, double-blinded, multi-center, randomized and placebo-controlled Phase 3 trial. On February 14, 2023 we announced recruitment completion with 754 adolescents from 12 to 17 years old randomized at a 2:1 ratio to receive either VLA1553 or placebo. The primary objective of the trial is to evaluate safety and immunogenicity following a single vaccination with VLA1553. Participants will be evaluated after 28 days and followed up to 12 months. The study will also provide safety and immunogenicity data in participants previously exposed to chikungunya.

VLA15— Our vaccine candidate targeting Lyme disease

We are developing VLA15 as a vaccine against Borrelia, the bacterium that causes Lyme disease. VLA15 is a recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. We have reported initial results of three Phase 2 clinical trials of VLA15 in over 900 healthy adults and interim analyses have demonstrated the presence of high titers of antibodies against all six strains. 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 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 clinical trial remains ongoing with other sites not operated by the third party. 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 companies intend to work with regulatory authorities, and as previously announced, aim for Pfizer to potentially submit a BLA to the FDA and an MAA to EMA in 2025, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

In April 2020, we announced a collaboration with Pfizer for late phase development and commercialization of VLA15, if approved, 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. Pfizer will lead late-stage development and have sole control over commercialization. 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 paint, 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 *B. burgdorferi*)**	**Anti-OspA antibodies from vaccine enter tick via consumed blood**	**Antibodies kill *B. burgdorferi* 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 the United States 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 post 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 adults 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 subjects 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 subjects 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 subjects that changed from seronegative at baseline to seropositive. Additionally, subjects 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 topline data in February 2022. 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 burgdorferia* 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 will receive 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.

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 5 years of age and older and is being conducted in areas where Lyme disease is highly endemic, including Finland, Germany, the Netherlands, Poland, Sweden and the United States. Participants will receive three doses of VLA15 180 µg or saline placebo (1:1 ratio) as a primary vaccination series followed by one booster dose of VLA15 or saline placebo.

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, we and Pfizer announced that 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 companies intend to work with regulatory authorities, and as previously announced, aim for Pfizer to potentially maintain the original submission timelines, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

VLA1601—Our Zika virus development program that remains on hold

Zika virus disease 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.

We have developed VLA1601, a highly purified inactivated vaccine candidate targeting the Zika virus which we developed using the same manufacturing platform as IXIARO, our approved Japanese encephalitis vaccine. We reported positive interim results for the Phase 1 study evaluating VLA1601 in November 2018. The inactivated vaccine candidate met the study's primary endpoint showing a favorable safety profile in all doses and schedules tested. 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 (Interim Analysis of Data up to Day 56).

We are currently evaluating a reactivation of this program. 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 also 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 WHO, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection to date but no vaccine is yet available for the prevention of Zika virus infection. As a result, we may choose to reactivate this program in the future if warranted.

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 choose to reactivate this program and find a suitable partner.

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 target hMPV and EBV and are presented below. Additionally, we initiated pre-clinical work on vaccine candidates targeting parvovirus B19, a virus most commonly causing fifth disease, and Campylobacter, a bacterium often associated with food poisoning.

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 treatment.

Our hMPV vaccine candidate, VLA1554, is a pre-fusion recombinant F protein subunit vaccine. 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 pre-fusion 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. Despite the high frequency of pneumoviral 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. 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 several 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.

Evaluation of external and internal antigen designs is ongoing. The vaccine candidate will comprise the combination of antigens that best neutralize infection of both epithelial cells and B cells. The addition of an adjuvant to further optimize immune responses will be investigated prior to development.

Our Commercial Portfolio

Our commercial portfolio is composed of three vaccines, our travel vaccines IXIARO/JESPECT and DUKORAL, and our inactivated COVID-19 vaccine, VLA2001. 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 2019, over 35 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 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 the shelf life of IXIARO 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.

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 €17.3 million, €2.4 million and €13.3 million in the years ended December 31, 2022, 2021 and 2020, respectively, of which Canada represented €11.4 million, €0.6 million and €6.8 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 increased by 610.3% compared to 2021, benefiting from the significant recovery in the private travel markets.

VLA2001—Our SARS-CoV-2 Vaccine

VLA2001 is 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, 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.

Clinical trials of VLA2001

We previously reported data from various clinical trials of VLA2001, including:

- VLA2001-201, a Phase 1/2 clinical trial,
- VLA2001-301 (Cov-Compare), a pivotal Phase 3 clinical trial comparing VLA2001 to AstraZeneca's AZD1222 vaccine,
- Booster extensions of the VLA2001-201 and VLA2001-301 clinical trials, evaluating VLA2001 as a booster following primary vaccination with VLA2001 or AZD1222,
- VLA2001-304, a Phase 3 clinical trial evaluating primary and booster vaccination with VLA2001 in adults aged 56 and over, and
- VLA2001-307, a clinical trial evaluating VLA2001 used as a booster in participants who had received two or three doses of an mRNA vaccine, with or without previous natural SARS-CoV-2 infection.

As of the date of this Annual Report, we continue to wind-down activities for the ongoing VLA2001 clinical studies VLA2001-301, VLA2001-304 and VLA2001-307, as indicated below:

- VLA2001-301 (Cov-Compare): we have updated our clinical study report to include immunogenicity, safety, and neutralization data for Day 208. We intend to prepare a final analysis including the additional safety data that were collected in adults as well as data from the few adolescents that were recruited, with results expected in the second quarter of 2023;
- VLA2001-304: we continue to collect safety data as per the trial protocol and expect to have final results in the second quarter of 2023.
- VLA2001-307: we recruited a total of six of the expected nine cohorts and decided to stop recruitment for the remaining three cohorts due to recruitment challenges. We will continue to collect safety data and should have final study data by the third quarter of 2023.

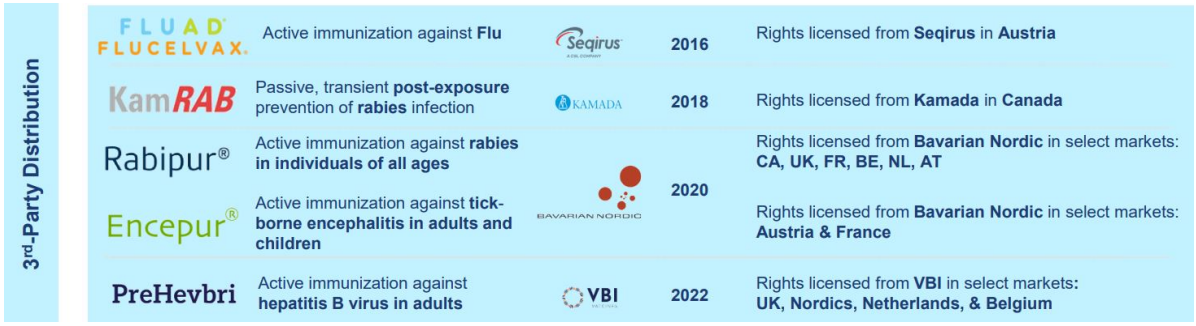
Sales of VLA2001

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. We are continuing to explore potential additional supply agreements to deploy the remaining eight to ten million doses of inventory. These inventories were fully written-down as of December 31, 2022, as explained further in the Notes to our financial statements. VLA2001's shelf life is expected to be extended to up to 24 months, compared to 21 months currently.

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, 2022, third party product sales grew to €26.5 million compared to €15.4 million in the year ended December 31, 2021, an increase of 72.1%.

The following table summarizes our current third-party agreements:



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 85% of total IXIARO revenues in 2022.

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 Substipharm, 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 86% of DUKORAL sales in 2022, with Canada alone representing over 65%. 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 intended acquisition of Emergent BioSolutions' oral cholera vaccine, Vaxchora in February 2023. The vaccine 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. However, to date, it has only been launched in a limited number of European markets.

Competition related to our product pipeline

Chikungunya

We are aware of companies such as Bavarian Nordic (which has announced its intent to acquire Emergent BioSolutions' chikungunya program), 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, GenPhar are developing vaccine candidates with similar mechanism of action although they are currently at pre-clinical stage of development.

Lyme disease

Companies such as GlaxoSmithKline, Sanofi and Baxter had clinical programs against Lyme disease. LYMErix, from GSK, achieved approval in the US 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. Other companies like Takeda Pharmaceuticals, Inovio Pharmaceuticals and Euroimmun are developing antibody-mediated treatment and are in pre-clinical and/or Phase 1/2 clinical stage. Apart from vaccines, we are also aware of potential treatments to prevent Lyme disease that are in early clinical development. We are also aware of companies developing mRNA such as Moderna Therapeutics, or therapeutic antibiotic drug candidates such as Ixodes; however, these remain in the very early stages of clinical development.

Sales and Marketing

We have a specialist commercial capability comprising approximately 50 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 VLA1553 Phase 3 clinical supply and future 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 light of the amended EC APA, we stopped manufacturing of our COVID-19 vaccine and are now evaluating various options for these two production units, including repurposing them for the production of our existing vaccines and vaccine candidates.

Solna (Stockholm), Sweden

Our Solna facility can operate on a multi-product basis and comprises approximately 12,000 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. With around 180 employees, the site operates as a dedicated and integrated production unit for DUKORAL as well as a Clinical Trial Manufacturing Unit currently operating as a contract manufacturing business. As part of our COVID-19 vaccine program, we expanded our existing fill-finish capacity by fitting out a nearby site for formulation, filling and packaging of our COVID-19 vaccine candidate, VLA2001. In light of the amended EC APA, we stopped manufacturing of our COVID-19 vaccine and are now evaluating various options for this additional site. 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, 2022, we had a portfolio of 459 issued patents, including 73 granted in Germany, France, the United Kingdom, Spain and Italy, 40 issued in the United States, and 232 pending patent applications, including 18 pending in Europe and 7 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, we own a patent family that includes 5 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. This patent family also included a granted European patent with claims that were directed to compositions comprising an aluminum component (with low heavy metal impurities and in particular low copper impurities) and a protein within formaldehyde inactivated virus particles, and to methods for preparing such compositions that was opposed at the EPO. In the subsequent oral hearing held in March 2020 before the EPO opposition division, we were able to defend our claims to the method of preparing said composition as granted. We and the opposer each filed a notice of appeal. In view of the negative preliminary opinion of the Board of Appeal we decided to withdraw our consent to the patent as granted and thus the patent was revoked in March 2022.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.

We also own a pending PCT application with claims covering the use of the cholera bacteria used in DUKORAL in the treatment or prevention of an autoimmune disease. Patent applications claiming the benefit of this PCT application, 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.

VLA15—Borrelia vaccine candidate

In regards to our Borrelia vaccine candidate VLA15 which is currently licensed to Pfizer, as of December 31, 2022 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 2 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 five 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 patent applications pending in the U.S., Canada, Europe, 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, 2022 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, 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, 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.

VLA1553—Chikungunya vaccine candidate

In regards to our chikungunya vaccine candidate, VLA1553, as of December 31, 2022, we own two patent families that include four granted U.S. patents with claims covering methods of preparing and methods of purifying VLA1553 and two 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 2 U.S. patents and over 20 pending patent applications in such jurisdictions as the U.S., Europe, Australia, 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, 2022, we also own two patent families with claims covering formulations and manufacturing processes of VLA1553. Each of these 2 families were nationalized in 17 jurisdictions and all are still pending, 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.

VLA2001—SARS-CoV-2 vaccine candidate

In regards to our SARS-CoV-2 vaccine candidate, VLA2001, as of December 31, 2022, we own one pending U.S. patent application and over twenty foreign patent applications with claims relating to the antigen and processes preparing the antigen of VLA2001, furthermore we co-own together with Dynavax two patent families with one U.K. patent and over twenty national patent applications with claims related to adjuvant formulation and processes of preparing the formulation of VLA2001. 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.

VLA84—Clostridium difficile candidate

In regards to our *C. difficile* candidate VLA84, as of December 31, 2022, 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, five granted and foreign patents and three pending foreign patent applications 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 in a European patent owned by a third party that has claims that might cover our *C. difficile* vaccine candidate. The European Patent Office recently revoked this patent and an appeal has been filed and is currently pending. We also recently filed a further opposition against a European patent derived from the revoked patent that has claims that might cover our *C. difficile* vaccine candidate. The European Patent Office has revoked also this patent, and an appeal has been filed and is currently pending.

VLA1601—Zika vaccine candidate

In regards to our Zika vaccine candidate VLA1601, as of December 31, 2022, we own a patent family with two granted U.S. patents with claims covering the formulation VLA1601, one pending U.S. patent application, and over 10 pending foreign patent applications and four 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. We have received a third party observation against the European patent application of the above case.

We also own two patent families that include one granted U.S. patent and three U.S. patents with claims covering methods of preparing and methods of purifying VLA1601 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. One of the granted U.S. patents has recently been the object of an *Inter Partes* Proceeding by a third party wherein the proceeding has not been instituted yet.

Other protection mechanisms

Our core technologies, 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 key products, technologies and product candidates, namely IXIARO, JESPECT, DUKORAL, EB66 and IC31, and the number of trademarks related to these products held by us at December 31, 2022 are shown in the table below.

Trademarks	Number of registrations or applications
IXIARO®, IXIARO logo	136
JESPECT®	19
DUKORAL®	59
EB66®	11
IC31®	8
Valneva®, Valneva logos	78
SBL trademarks	20
IXCHIQ	13
IXFIDENTIA	28

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”.

“DUKORAL” trademark

Various prior rights agreements related to the trademark “DUKORAL” 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 DUKORAL, and to tolerate new applications and modifications of the prior DUKORAL 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. Then Crucell 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, 2022, we hold 147 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 require 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 and the COVID-19 pandemic. 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, or 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 many 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, may impose a REMS and/or post-market surveillance to monitor the effects of an approved product, or the FDA may 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, warning 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 ACA, signed into law in 2010, includes a subtitle called The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which 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. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

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

Pursuant to the Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the EU was implemented through national legislation of the individual EU Member States. Under this system, an applicant was required to obtain approval from the competent national authority of a EU Member States in which the clinical trial is to be conducted or in multiple EU Member States if the clinical trial is to be conducted in a number of EU Member States. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee had issued a favorable opinion. The clinical trial application, or CTA, was required to be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the EU Member States and further detailed in applicable guidance documents.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. The new Clinical Trials Regulation entered into force on January 31, 2022 with a three-year transition period for certain aspects of on-going clinical trials. The Clinical Trials Regulation, which is directly applicable in all the EU Member States, repealed the Clinical Trials Directive 2001/20/EC.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the Regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed first by a single "reference" Member State whose conclusions are then assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted, the "concerned" Member States. Part II is assessed separately by each concerned Member State. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

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 destination, 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.

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). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

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 outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in 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 in the EU for our product candidates on the basis of clinical trials conducted in the UK.

The MHRA offers new assessment procedures now that Great Britain is no longer covered by the EU centralized procedure for MAs. The procedures can lead to a marketing authorization in Great Britain (England, Scotland, and Wales), the United Kingdom, or Northern Ireland, depending on the procedure and pre-existing authorizations, as further explained below. The new assessments include:

- The European Commission Decision Reliance Procedure will be in place until January 1, 2023, and is a targeted assessment of new applications for products containing new active substances or biosimilars which have previously been granted authorization via the centralized procedure by the European Commission. The MHRA will review the application, CHMP assessment report, and applicant responses to the CHMP over a period of 67 days, leading to the grant of a marketing authorization in Great Britain as soon as possible after European Commission authorization. The centralized marketing authorization in the EU will permit the marketing of the relevant product in Northern Ireland;
- A full assessment as a national authorization, that industry can choose for new active substances, with a timeline of no more than 150 days (excluding clock-off periods where further information is requested) which can lead to the grant of a marketing authorization in Great Britain, the United Kingdom, or Northern Ireland. If the application includes Northern Ireland then it must comply with the relevant EU requirements;
- The Unfettered Access Procedure for medicines already approved in Northern Ireland via the EU procedures or via the Northern Ireland national route which if successful will lead to a Great Britain marketing authorization;
- The decentralized and mutual recognition reliance procedure for marketing authorizations, where the MHRA has the power to have regard to marketing authorizations previously granted nationally in a country within the EEA through the decentralized or mutual recognition procedures. Acceptable marketing authorizations are intended to be granted within 67 days of the marketing authorization application being validated by the

MHRA and which will, if successful, lead to a Great Britain or United Kingdom Marketing Authorization; and

- A “rolling review”, for new active substances and biosimilars, which would allow companies to make an application in stages, throughout the product’s development, to better manage development risk which can lead to the grant of a marketing authorization in Great Britain, the United Kingdom, or Northern Ireland. If the application includes Northern Ireland then it must comply with the relevant EU requirements.

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, 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 such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;

- established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, effective as of 2019) point-of-sale discounts 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;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established the Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

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 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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, 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. At the federal level, the Trump used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives.

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 will take effect progressively starting in fiscal year 2023, although they may be 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. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. We expect that additional U.S. federal healthcare reform measures will be adopted in the future.

European Healthcare Laws and Regulations

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 January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment (the HTA Regulation). In December 2021, the HTA Regulation was adopted and entered into force on 11 January 2022. It will apply from 2025. The 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 the EU level for joint clinical assessments in these areas. Entry into application of the Regulation could impose stricter and more detailed procedures to be followed by MAHs concerning conduct of HTA in relation to their products which may influence related pricing and reimbursement decisions.

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.

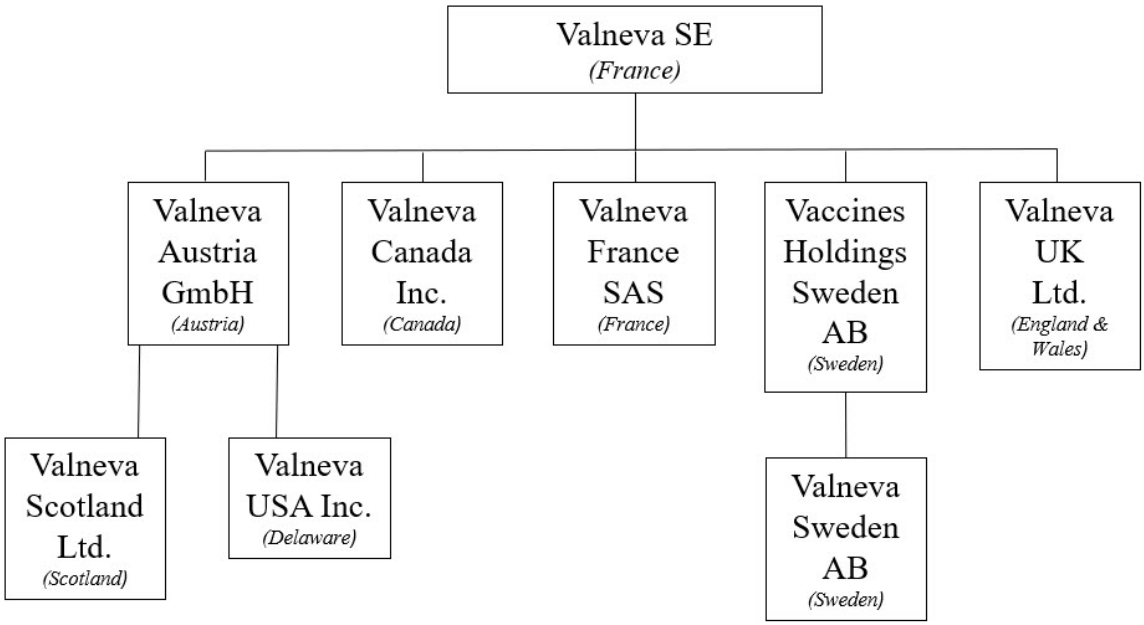
In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, 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”).

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 entered into force on 11 January 11, 2022. It will apply from 2025.

C. Organizational Structure

The chart below presents our significant subsidiaries as of December 31, 2022. Each subsidiary shown is 100% owned by the relevant parent company.



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. Currently, about 183.2 square meters are subleased to Vital Meat SAS, a Groupe Grimaud affiliate; and
- 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".

We lease the following facilities:

- a 10,725 square meter building located in Vienna, Austria, used as laboratories and offices (of which 461 square meters are currently subleased to Haplogen Bioscience GmbH);
- 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;
    - 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;
- 27 square meters of office space in Fleet, England, dedicated to sales and marketing activities;
- Approximately 4,600 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.

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, 2022 and 2021 and the three years ended December 31, 2022 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 focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet needs to ensure we can make a difference in peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

Our current clinical portfolio is composed of a number of highly differentiated vaccine candidates that are designed to provide preventative solutions to diseases with high unmet need. VLA1553, targeting the chikungunya virus, is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data and the first for which a Biologics License Application, or BLA, has been submitted to the U.S. Food and Drug Administration, or FDA. We believe that, as a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection compared to other chikungunya assets being evaluated in clinical trials. Chikungunya has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. 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 active vaccine candidate against Lyme disease currently undergoing 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.

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 causes of travelers' diarrhea. We also 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 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, 2022, we had €289.4 million in cash and cash equivalents.

Our operating losses were €113.4 million, €61.4 million and €55.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. Our net losses were €143.3 million, €73.4 million and €64.4 million for the years ended December 31, 2022, 2021 and 2020, 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, IXIARO and DUKORAL, in their respective markets, as well as from sales of VLA2001 and third-party products. 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. We report revenues under four segments: commercialized products, COVID, vaccine candidates and technologies and services. See "—Financial Operations Overview—Segment Information" for additional information on our segment reporting.

Product Sales of IXIARO, DUKORAL, VLA2001 and Third-party Products

Product sales of IXIARO and DUKORAL, our travel vaccines, represented in aggregate 51.1%, 75.5% and 56.0% of our revenues for the years ended December 31, 2022, 2021 and 2020, respectively. We primarily sell IXIARO in the United States, Canada and Germany and DUKORAL in Canada.

Product sales of VLA2001 represented 25.8% of our revenues for the year ended December 31, 2022, during which we sold VLA2001 to the Kingdom of Bahrain and certain European Union member states. There were no VLA2001 sales for the years ended December 31, 2021 and 2020, respectively.

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 23.1%, 24.4% and 3.8% of our revenues for the years ended December 31, 2022, 2021 and 2020, 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. A COVID-19-driven travel reduction accounted for a material reduction in our revenues for the years ended December 31, 2021 and 2020 compared to the year ended December 31, 2019. However, the partial recovery of the travel market led to an increase in sales of our travel vaccines in the year ended December 31, 2022, compared to the years ended December 31, 2021 and 2020.

While COVID-19 has impacted sales of our travel vaccines to the general public, sales of IXIARO to the U.S. Government 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. In September 2020, DLA awarded us a new contract for the supply of IXIARO. 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. 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. Valneva 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 (€4.9 million) recognized as at December 31, 2022 (December 31, 2021: $5.4 million). In August 2022, we announced that DLA had decided not to exercise the second option year of the contract, as DLA considered its existing IXIARO supply to meet current needs.

For the years ended December 31, 2022, 2021 and 2020, 10.9%, 60.5%, and 52.6%, respectively, of our total product sales were from sales of IXIARO 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% (compared to royalties starting at 19% in the initial agreement). Pfizer is obligated to pay us up to $178 million (of which we have received €35 million as of December 31, 2022) in development milestones and tiered royalties on net sales of licensed products, subject to specified offsets and reductions, and Valneva is eligible for up to $100 million on the achievement of cumulative sales targets.

As of December 31, 2022 and 2021, we recognized €135.5 million and €79.6 million, respectively, as discounted refund liabilities relating to the Collaboration and License Agreement. In addition, we recognized negative revenue of €45.9 million during the year ended December 31, 2022, while €14.3 million was recognized as other revenues during the year ended December 31, 2021. As of December 31, 2022 and December 31, 2021, €3.70 million and €3.0 million, respectively, in contract costs were included in other assets, and €0 and €0.9 million, respectively, were included in contract liabilities.

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, 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 in revenues led to a de-recognition of the corresponding refund liabilities in 2022 to nil for the year ended December 31, 2022.

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 €20.0 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. We are continuing to explore potential additional supply agreements to deploy the remaining eight to ten million doses of inventory. These inventories were fully written-down as of December 31, 2022, as explained further in the Notes to our financial statements.

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 €104.9 million, €173.3 million and €84.5 million for the years ended December 31, 2022, 2021 and 2020, 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 mainly due to the phasing of clinical trial expenses and accelerated wind-down of VLA2001-related activities. Our research and development costs in 2022 mainly comprised expenses relating to VLA2001, the Phase 3 clinical trial for our chikungunya vaccine candidate (VLA1553), the Lyme program (partnered with Pfizer), the development of our Zika vaccine candidate and work on pre-clinical projects. We expect to decrease R&D expenses further in 2023, as there are fewer VLA2001-related activities expected and an onerous agreement provision of €7.0 million for expenses expected in 2023 have been already taken as of December 31, 2022. 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.

In 2022, advertising and promotional spend increased in line with a significant resumption of international travel. We expect that marketing and distribution expenses will continue to increase if we receive approval for our chikungunya vaccine candidate during 2023. Our marketing spend for the chikungunya program has started already and will increase over the next years if VLA1553 is approved.

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 plan to manufacture our chikungunya vaccine candidate at our facilities in Livingston. We anticipate we will need limited additional infrastructure and employees for this program and that we will incur relatively low raw materials costs.

The bulk drug substance for our COVID-19 vaccine was manufactured at our facility in Livingston, Scotland and by IDT Biologika in Germany, and fill-finishing 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. The manufacturing of the COVID-19 vaccine was stopped in 2022. Cost of goods and services were €324.4 in the year ended December 31, 2022 (December 31, 2021: €187.9 million), thereof €159.4 million (2021: €121.4 million) related to VLA2001 and 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 COGS in 2022 related to onerous agreements provision and settlement costs.

We expect a decrease of COGS in 2023 as expenses related to VLA2001 will drastically decrease.

General and Administrative Expenses

General and administrative expenses have increased as we have become a more complex organization, and as a result of our Nasdaq listing, requiring more corporate support. In 2022 we saw a decrease in stock-based compensation expense as programs vested and new programs have been implemented late in the year. Furthermore, employer contribution costs on share-based compensation plans are driven by the development of our share price.

Grants

We seek grants from governmental agencies and non-governmental organizations to partially offset our increasing research and development costs. Grant income, including research and development tax credits, which are recorded in other income, decreased from €23.6 million for the year ended December 31, 2021 to €15.5 million for the year ended December 31, 2022, mainly due to decreased research and development tax credits but also due to a reduction of €1.5 million of grant income in 2022 related to our funding agreement with the Coalition for Epidemic Preparedness Innovations, or CEPI. In the years ended December 31, 2021 and 2020, we received grants related to the COVID-19 pandemic situation from various governments.

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.

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 our 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. 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.

Impact of COVID-19

The COVID-19 pandemic has 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. Our primary commercial products, DUKORAL and IXIARO, are aimed at diseases that primarily threaten travelers to particular regions (e.g. Asia). As a result, sales of these vaccines decreased significantly in 2020 and 2021, adversely impacting our financial results. For the years ended December 31, 2021 and 2020, €5.4 million and €7.4 million, respectively, 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 year ended December 31, 2022, resulting in higher sales of our travel vaccines and a release of €2.8 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.

The trend of growing international travel is expected to continue in the new year. The Group's product sales will continue to be affected by the amount of international travel, and Valneva may not be able to complete the development of its vaccine candidates without additional financing if the travel industry does not recover as expected.

For more information as to the risks associated with COVID-19, see “Item 3.D—Risk Factors”.

Financial Operations Overview

Segment Information

Operating segments are reported in a manner consistent with internal reporting provided to the chief operating decision maker. We have identified the Management Board as our chief operating decision maker. The Management Board reviews the consolidated operating results regularly to make decisions about resources and to assess overall performance.

The Management Board primarily uses a measure of operating profit/(loss) to assess the performance of the operating segments. In addition, the Management Board also receives information about the segments’ product sales on a monthly basis.

The individual segments consist of following:

- “Commercialized products” — marketed vaccines, currently our IXIARO and DUKORAL vaccines, as well as third-party products.
- “COVID” — development, manufacturing and distribution related to our COVID-19 vaccine, VLA2001.
- “Vaccine candidates” — proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding our COVID-19 vaccine, VLA2001, which was developed during the periods presented in this Annual Report.
- “Technologies and services” — services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements.

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 and Germany, Nordics (being Denmark, Finland, Norway and Sweden together), France and Benelux. We primarily sell DUKORAL in Canada and Nordics. In 2022 we derived product revenues from the sale of our COVID-19 vaccine to certain European countries and the Kingdom of Bahrain.

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 5.3 to our consolidated financial statements as of and for the years ended December 31, 2022 and 2021 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 Notes 5.30.2 and 5.18 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, 2022, 2021 and 2020, such as for CROs, and other contracted research and development activities, as well as for raw materials, related to our COVID-19 vaccine (in 2020 and 2021), our chikungunya vaccine candidate, 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 have been provisioned as of December 31, 2022. 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, 2022, 2021 and 2020, no research and development expenses were recorded as intangible assets. As of December 31, 2022 and 2021, we had previously capitalized research and development costs recorded as intangible assets in an aggregate amount of €1.4 million and €1.6 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 started to incur incremental costs for preparation of

market access and launch activities of our chikungunya vaccine candidate, following the progression of VLA1553 into Phase 3 clinical development in 2020 and based on the expected timeline for possible regulatory approval.

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 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 will increase in the future as a result of one-time effects in the year ended December 31, 2022 where we recorded reversals of previously recognized share-based compensation expenses, which we do not anticipate for the future. We also anticipate continued increased 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 incur additional accounting expenses to comply with the Sarbanes-Oxley Act of 2002 in the United States that will require us to test the effectiveness of our internal controls over financial reporting.

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 funds we receive from CEPI are accounted for in accordance with IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance* and presented as other income within operating income in our statement of operations.

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. Furthermore, finance income or expenses include fair value gains or losses, respectively, on derivative financial instruments relating to various foreign currency option and forward contracts, which we entered into to limit the risk of foreign currency losses on expected future cash flows.

Results from Investments in Associates - Assets held for Sale

We hold a 48.9% equity interest in BliNK Biomedical SAS, or BliNK, a private company not listed on a stock exchange. BliNK is run as an independent business by its own management team. We do not have control or joint-control over BliNK, but rather hold a significant influence in BliNK in accordance with IAS 28.3.

As at December 31, 2022, the investment in associate (BliNK) was reclassified to an asset held for sale in accordance with IFRS 5, whereas as at December 31, 2021 this investment was recognized as an investment in associates and accounted for by using the equity method in accordance with IAS 28. Management's intent to sell the equity interest by June 30, 2023 triggered the change in the classification.

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, 2022, 2021 and 2020. 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, 2022, 2021 and 2020 are summarized in the table below.

	Year ended December 31,		
(In € thousand)	**2022**	**2021**	**2020**
Product sales	114,797	62,984	65,938
Other revenues	246,506	285,101	44,383
TOTAL REVENUES	**361,303**	**348,086**	**110,321**
Cost of goods and services	(324,441)	(187,920)	(54,302)
Research and development expenses	(104,922)	(173,283)	(84,454)
Marketing and distribution expenses	(23,509)	(23,643)	(18,264)
General and administrative expenses	(34,073)	(47,606)	(27,539)
Other income and expenses, net	12,199	22,976	19,117
OPERATING PROFIT (LOSS)	**(113,443)**	**(61,390)**	**(55,120)**
Finance income	260	249	516
Finance expenses	(19,054)	(16,964)	(10,738)
Foreign exchange gain/(loss), net	(12,587)	8,130	173
Result from investments in associates	9	(5)	(133)
PROFIT (LOSS) BEFORE INCOME TAX	**(144,815)**	**(69,979)**	**(65,302)**
Income tax income (expense)	1,536	(3,446)	909
PROFIT (LOSS) FOR THE PERIOD	**(143,279)**	**(73,425)**	**(64,393)**

Results of Operations—By Segment

The following table presents our results of operations by segment for the years ended December 31, 2022, 2021 and 2020:

	Commercialized products			COVID			Vaccine candidates			Technologies and services			Corporate overhead			Total		
(In € thousand)	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**	**2022**	**2021**	**2020**
Product sales	85,228	62,984	65,938	29,568	—	—	—	—	—	—	—	—	—	—	—	114,797	62,984	65,938
Other Revenue	23	18	1	280,010	253,314	—	5,565	3,257	31,604	(39,091)	28,512	12,779	—	—	—	246,506	285,101	44,383
REVENUES	**85,251**	**63,002**	**65,939**	**309,578**	**253,314**	**—**	**5,565**	**3,257**	**31,604**	**(39,091)**	**28,512**	**12,779**	**—**	**—**	**—**	**361,303**	**348,086**	**110,321**
Cost of goods and services	(46,475)	(40,017)	(41,830)	(267,113)	(122,843)	—	(1,112)	—	(3,305)	(9,742)	(25,061)	(9,167)	—	—	—	(324,441)	(187,920)	(54,302)
Research and development expenses	(1,067)	(2,094)	(2,711)	(72,762)	(113,907)	(18,962)	(29,907)	(53,181)	(62,140)	(1,186)	(4,101)	(640)	—	—	—	(104,922)	(173,283)	(84,454)
Marketing and distribution expenses	(13,107)	(18,455)	(17,554)	(2,773)	(1,182)	—	(7,334)	(3,811)	(638)	(57)	(194)	(72)	(238)	—	—	(23,509)	(23,643)	(18,264)
General and administrative expenses	(5,137)	(6,102)	(13,412)	(19,392)	(23,003)	(2,374)	(3,910)	(8,323)	(7,781)	(1,919)	(5,495)	(2,274)	(3,715)	(4,684)	(1,697)	(34,073)	(47,606)	(27,539)
Other income and expenses, net (*)	105	2,196	1,101	9,625	11,546	1,578	4,811	7,033	14,073	1,111	2,458	117	(3,454)	(257)	2,248	12,199	22,976	19,117
OPERATING PROFIT (LOSS)	**19,570**	**(1,469)**	**(8,466)**	**(42,836)**	**3,927**	**(19,759)**	**(31,888)**	**(55,025)**	**(28,189)**	**(50,884)**	**(3,881)**	**743**	**(7,406)**	**(4,941)**	**551**	**(113,443)**	**(61,390)**	**(55,120)**

(1) For the year ended December 31, 2022, our other income and expenses, net, in other corporate overhead mainly consisted of €3.1 million, which included an increase in the Intercell/Vivalis merger litigation provision. For the year ended December 31, 2021, our other income and expenses, net, in other corporate overhead consisted of €4.7 million of expenses derived mainly from consulting fees and auditing fees relating to the Nasdaq IPO and capital increase, which are not allocable to a segment. For the year ended December 31, 2020, our other income expenses, net in other corporate overhead of €1.6 million mainly derived from an early termination of a rental contract in Sweden and of €0.6 million COVID-19 pandemic related grants, which are not allocable to a segment.

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. In the COVID segment 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. In the Commercialized Products segment in the year ended December 31, 2022, the increase is mainly due to the continued recovery of travel vaccine sales. In the Technologies and services segment in the year ended December 31, 2022, negative revenues amounted to €39.1 million and 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 vaccine candidate revenues amounted to €14.3 million.

	Year ended December 31,	
(In € thousand)	**2022**	**2021**
Commercialized products	85,251	63,002
COVID	309,578	253,314
Vaccine candidates	5,565	3,257
Technologies and services	(39,091)	28,512
TOTAL REVENUES	**361,303**	**348,086**

Product sales

	Year ended December 31,	
(In € thousand)	**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.

	Year ended December 31,	
(In € thousand)	**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

The following table presents our other revenues (from collaboration, licensing and services), by segment, for the years ended December 31, 2022 and 2021.

	Year ended December 31,	
(In € thousand)	**2022**	**2021**
Commercialized products	23	18
COVID	280,010	253,314
Vaccine candidates	5,565	3,257
Technologies and services	(39,091)	28,512
TOTAL OTHER REVENUES	**246,506**	**285,101**

In the year ended December 31, 2022, total other revenues were €246.5 million, a decrease of €38.6 million compared to €285.1 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.

Technologies and services revenues decreased from €28.5 million in the year ended December 31, 2021 to €39.1 million of negative revenue in the year ended December 31, 2022, primarily resulting from a reversal of revenue of €45.9 million 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 product segment 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 product segment 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. COGS from the Lyme disease vaccine candidate has been included in the Technologies and Services segment from January 1, 2021 onward.

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:

	Year ended December 31,	
(In € thousand)	**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, or 1678.8%, 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 as well as general and administrative expenses by nature of cost:

	Year ended December 31,	
(In € thousand)	**2022**	**2021**
Employee benefit expense other than share-based compensation (*)	(56,393)	(85,334)
Share-based compensation expense	5,215	(14,678)
Consulting and other purchased services	(141,631)	(169,158)
Raw materials and consumables used	(12,723)	(14,676)
Cost of services and change in inventory	(190,086)	(105,648)
Depreciation and amortization & 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:

	Year ended December 31,	
(In € thousand)	**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:

	Year ended December 31,	
(In € thousand)	**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:

	Year ended December 31,	
(In € thousand)	**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)**

Comparisons for the Years Ended December 31, 2021 and 2020

Revenue

Consolidated Revenue

Revenue increased by €237.8 million, or 215.5%, to €348.1 million for the year ended December 31, 2021 compared to €110.3 million for the year ended December 31, 2020. The main revenue in the year ended December 31, 2021 was €253.3 million of payments received under the UK Supply Agreement. These payments were recognized as revenue in the COVID segment as of the date the termination of the UK Supply Agreement became effective, once the future performance obligation (to deliver vaccines) was no longer valid and based on judgment that the likelihood of repayment is remote. The new revenue in the COVID segment in the year ended December 31, 2021 was partially offset by lower product sales reflected in other segments due to the continued effects of COVID-19 travel restrictions on sales of commercialized products.

The breakdown of revenue by operating segment is as follows:

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Commercialized products	63,002	65,939
COVID	253,314	—
Vaccine candidates	3,257	31,604
Technologies and services	28,512	12,779
TOTAL REVENUES	**348,086**	**110,321**

With the transfer of the license of our VLA15 Lyme vaccine candidate to Pfizer in December 2020, all related revenues and costs were moved from the vaccine candidates segment to the technologies and services segment for periods from January 1, 2021 onward. In the year ended December 31, 2021, the VLA15 Lyme vaccine candidate revenues amounted to €14.3 million compared to €31.6 million in the year ended December 31, 2020 and included the revenues for the transfer of the license.

Product sales

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
IXIARO	45,118	48,480
DUKORAL	2,440	13,300
Third-party products	15,426	4,158
TOTAL PRODUCT SALES	**62,984**	**65,939**

Product sales decreased by €3.0 million, or 4.5%, to €63.0 million for the year ended December 31, 2021 compared to €65.9 million in the year ended December 31, 2020.

In the year ended December 31, 2021, IXIARO product sales were €45.1 million, a decrease of €3.4 million, or 6.9%, compared to €48.5 million in the year ended December 31, 2020. In the year ended December 31, 2021, IXIARO product sales were largely driven by demand in the United States, mainly by military personnel through our supply agreement with the DLA.
In the year ended December 31, 2021, DUKORAL product sales were €2.4 million, a decrease of €10.9 million, or 81.7%, compared to €13.3 million in the year ended December 31, 2020, mainly due reduced sales in Canada.

In the year ended December 31, 2021, DUKORAL product sales were driven by demand in European countries, and, to a lesser extent, product sales in Canada.

Sales of IXIARO and DUKORAL remained lower in 2021 as a result of the COVID-19 pandemic, as travel restrictions significantly reduced demand for travel vaccines in our main markets. The decreased demand for travel vaccines was partially mitigated by continued sales of IXIARO to the U.S. military.

In the year ended December 31, 2021, third-party product sales increased by €11.3 million, or 271.0%, to €15.4 million, compared to €4.2 million in the year ended December 31, 2020. This increase was primarily due to the marketing and distribution partnership with Bavarian Nordic, pursuant to which first sales of Rabipur and Encepur started in 2021, and to higher sales of influenza vaccine.

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.

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
United States (military)	38,048	34,659
United States (non-military)	2,291	1,755
Canada	4,226	8,965
Germany	9,341	7,060
Nordics	2,707	2,866
Austria	2,436	3,333
United Kingdom	726	1,847
Other Europe	3,075	2,068
Rest of world	134	3,384
TOTAL PRODUCT SALES	**62,984**	**65,938**

Total product sales in the United States increased by €3.9 million, or 10.8%, to €40.3 million in the year ended December 31, 2021, compared to €36.4 million in the year ended December 31, 2020. Sales in the United States increased primarily as a result of increased sales under our supply agreement with the DLA. Product sales in Canada decreased by €4.7 million, or 52.9%, from €9.0 million in the year ended December 31, 2020, to €4.2 million in the year ended December 31, 2021. Sales in Canada decreased primarily as a result of the COVID-19 pandemic, partly offset by an increase in sales of third-party products.

Other revenues

The following table presents our other revenues (from collaboration, licensing and services), by segment, for the years ended December 31, 2021 and 2020.

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Commercialized products	18	1
COVID	253,314	—
Vaccine candidates	3,257	31,604
Technologies and services	28,512	12,779
TOTAL OTHER REVENUES	**285,101**	**44,383**

In the year ended December 31, 2021, total other revenues were €285.1 million, an increase of €240.7 million compared to the year ended December 31, 2020. The amount in the year ended December 31, 2021 included €253.3 million of payments received which were recognized as revenue in 2021 due to the termination of the UK Supply Agreement, as there is no longer a future performance obligation to be fulfilled, and following management's judgment that the likelihood of repayment is remote.

Technologies and services revenues increased from €12.8 million in the year ended December 31, 2020 to €28.5 million in the year ended December 31, 2021, primarily resulting from our Lyme research and development collaboration with Pfizer. In the year ended December 31, 2021, this collaboration contributed €14.3 million of revenues. Revenues from the collaboration with Pfizer were included in the Vaccine candidates segment in the year ended December 31, 2020.

Operating Income and Expenses

Cost of Goods and Services

Cost of goods and services, or COGS, increased by €133.6 million, or 246.1%, to €187.9 million with a gross margin on product sales of 36.5% for the year ended December 31, 2021, as compared to COGS of €54.3 million and gross margin on product sales of 36.6% for the year ended December 31, 2020. The decline in the gross margin was primarily due to the negative gross margin for DUKORAL, resulting from impairment of short-dated or expired product and idle capacity costs in the manufacturing plan.

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. COGS from the Lyme disease vaccine candidate has been included in the Technologies and Services segment from January 1, 2021 onward.

COGS was €54.3 million, or 32.8% of our total operating income (expenses), for the year ended December 31, 2020. Of this total COGS, €24.8 million related to IXIARO sales, yielding a product gross margin of 48.9%, and €14.3 million related to DUKORAL sales, yielding a product gross margin of negative 7.3%. Gross margins for IXIARO and DUKORAL sales were negatively impacted by decreased demand resulting from the COVID-19 pandemic, although gross margin for IXIARO sales was impacted to a lesser extent due to continued sales of IXIARO to the U.S. military. In the year ended December 31, 2020, COGS related to the third-party product distribution business was €2.8 million, yielding a product gross margin of 33.2%, and cost of services was €12.2 million.

Research and Development Expenses

Research and development expenses increased by €88.8 million, or 105.2%, to €173.3 million for the year ended December 31, 2021 from €84.5 million in the year ended December 31, 2020. Research and development expenses were 42.3% of our total operating expenses for the year ended December 31, 2021, as compared to 51.0% of our total operating expenses for the year ended December 31, 2020. This increase was driven primarily by investments in our clinical stage vaccine candidates, notably our COVID-19 and chikungunya vaccine candidates, which resulted in an increase in consulting and other purchased services, employee benefit expense and raw materials and consumables used. 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. €3.4 million related to the Pfizer partnership were recognized as cost of service in 2021.

For the year ended December 31, 2021, research and development expenses consisted primarily of €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, of €117.6 million of external research and development services, including costs for clinical studies and external manufacturing, as well as €5.0 million of material consumptions. For the year ended December 31, 2020, research and development expenses consisted primarily of €19.9 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, of €47.0 million external research and development services, including costs for clinical studies and external manufacturing as well as €6.8 million of material consumptions.

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:

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Chikungunya (VLA1553)	(43,975)	(31,746)
Lyme (VLA15)	(3,761)	(25,948)
COVID-19 (VLA2001)	(113,907)	(18,962)
IXIARO	(1,125)	(1,373)
hmPV	(2,111)	(1,327)
DUKORAL	(969)	(1,338)
Other research projects	(7,434)	(3,760)
TOTAL RESEARCH AND DEVELOPMENT EXPENSES	**(173,283)**	**(84,454)**

* In 2021 and 2020, Other research projects included €3.7 million and €1.4 million, respectively of expenses related to IFRS2 (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 increased by €95.0 million, or 500.7%, to €113.9 million in the year ended December 31, 2021 from €19.0 million in the year ended December 31, 2020. This increase was primarily driven by the progression into the Phase 3 clinical trials and related cost for manufacturing of clinical trial material.

VLA1553. Our research and development expenses related to our chikungunya vaccine candidate program increased by €12.2 million, or 38.5%, to €44.0 million in the year ended December 31, 2021 from €31.7 million in the year ended December 31, 2020. This increase was primarily driven by the progression of our program in preparation for the Phase 3 clinical trial.

VLA15. Our research and development expenses related to our Lyme vaccine candidate program decreased by €22.2 million, or 85.5%, to €3.8 million in the year ended December 31, 2021 from €25.9 million in the year ended December 31, 2020. This decrease was primarily driven by the completion of our VLA15-201 and VLA15-202 clinical studies. In 2021, Lyme studies of €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 increased by €3.8 million, or 49.3%, to €11.6 million in the year ended December 31, 2021. This increase was primarily related to increased expenses related to our pre-clinical stage programs.

Marketing and Distribution Expenses

Marketing and distribution expenses increased by €5.4 million, or 29.5%, to €23.6 million in the year ended December 31, 2021 from €18.3 million in the year ended December 31, 2020. Marketing and distribution expenses comprised 5.8% of our total operating expenses for the year ended December 31, 2021, compared to 11.0% of our total operating expenses for the year ended December 31, 2020. The increase in 2021 was primarily the result of share-based compensation expenses and related social security contributions.

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. For the year ended December 31, 2020 marketing and distribution expenses consisted primarily of €8.8 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €2.5 million of advertising expenses, including media and public relations expenses, €1.9 million of warehousing and distribution costs and €1.8 million of costs related to third-party services.

General and Administrative Expenses

General and administrative expenses increased by €20.1 million, or 72.8%, to €47.6 million for the year ended December 31, 2021 from €27.5 million for the year ended December 31, 2020. General and administrative expenses comprised 11.6% of our total operating expenses for the year ended December 31, 2021 compared to 16.6% of our total operating expenses for the year ended December 31, 2020. This increase was primarily driven by increased costs to support corporate transactions and projects, including our offerings on Nasdaq, and costs related to our share-based compensation programs.

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, and as well as of €20.6 million in costs and fees for professional services, such as consulting, legal and financial services. For the year ended December 31, 2020, general and administrative expenses consisted primarily of €16.2 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, and as well as of €9.5 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 as well as general and administrative expenses by nature of cost:

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Employee benefit expense other than share-based compensation(*)	(85,334)	(58,264)
Share-based compensation expense	(14,678)	(6,328)
Consulting and other purchased services	(169,158)	(65,212)
Raw materials and consumables used	(14,676)	(12,434)
Cost of services and change in inventory	(105,648)	(10,778)
Depreciation and amortization & impairment	(14,281)	(9,939)
Building and energy costs	(10,960)	(8,140)
License fees and royalties	(7,409)	(4,384)
Supply, office and IT-costs	(4,865)	(3,333)
Advertising costs	(2,176)	(2,496)
Warehousing and distribution costs	(1,419)	(1,898)
Travel and transportation costs	(538)	(529)
Other expenses	(1,309)	(822)
OPERATING EXPENSES	**(432,452)**	**(184,558)**

(*) As of December 31, 2021, the position “employee benefit expense other than share-based compensations” includes an amount of €26.5 million of employer contribution fees, which are payable at the exercise of the share-based payment programs (December 31, 2020: €7.4 million).

The increase in operating expenses of €247.9 million in the year ended December 31, 2021 compared to the prior year primarily resulted from the increased research and development expenses due to the Company's advanced clinical trial programs, and the inventory write-off due to the impact of the COVID-19-pandemic on demand for commercialized products as well as a write-down on COVID-19 vaccine related inventory related to the termination of the UK Supply Agreement. See Note 5.5.3 to our consolidated financial statements included elsewhere in this Annual Report for more information about this termination.

Other Income (Expenses)

The table below summarizes the other operating income (expenses) for the years ended December 31, 2021 and 2020:

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Research and development tax credit	21,949	9,937
Grant income	1,684	7,680
Profit/(loss) on disposal of fixed assets and intangible assets, net	(42)	(10)
Profit/(loss) from revaluation of lease agreements	—	1,584
Taxes, duties, fees, charges, other than income tax	(212)	(168)
Miscellaneous income/(expenses), net	(403)	95
TOTAL OTHER OPERATING INCOME (EXPENSES), NET	**22,976**	**19,117**

Other operating income and expenses increased by €3.9 million, or 20.2%, to €23.0 million for the year ended December 31, 2021 from €19.1 million for the year ended December 31, 2020. This increase was mainly driven by increased research and development tax credits directly resulting from increased qualifying research and development expenses. For the years ended December 31, 2021 and 2020, of the research and development tax credit, €20.2 million and €8.9 million, respectively, related to the research and development programs executed in Austria, mainly for COVID-19 and chikungunya vaccine candidates, whereas the remainder of €1.8 million and €1.1 million, respectively, related to the CIR from 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, 2021 and 2020, CEPI and COVID-19-pandemic related grants totaled €5.8 million and €0.8 million, respectively.

Financial Income (Expense)

The table below summarizes our financial income (expense) for the years ended December 31, 2021 and 2020:

	Year ended December 31,	
(In € thousand)	**2021**	**2020**
Finance income		
Interest income from other parties	249	119
Fair value gains on derivative financial instruments	—	397
Foreign exchange gains, net	8,130	173
	8,379	**689**
Finance expense		
Interest expenses on loans	(7,273)	(6,162)
Interest expense on refund liabilities	(8,478)	(3,640)
Interest expenses on lease liabilities	(903)	(907)
Other interest expense	(309)	(30)
Fair value losses on derivative financial instruments	**—**	—
	(16,962)	**(10,738)**
FINANCE INCOME/(EXPENSES), NET	**(8,584)**	**(10,049)**

Finance expenses, net were €8.6 million for the year ended December 31, 2021 compared to €10.0 million for the year ended December 31, 2020. This decrease in finance expenses, net was mainly due to positive foreign exchange gains, net,

but was impacted by the increase of interest expense on non-current refund liabilities. The foreign exchange gains in the year ended December 31, 2021 are related to the development of the USD and GBP exchange rates and our corresponding balance sheet accounts.

Income Tax

We recorded €3.4 million of income tax expense for the year ended December 31, 2021 compared to an income tax benefit of €0.9 million for the year ended December 31, 2020. This change in income tax benefit (expense) was primarily driven by a change in deferred income taxes.

Profit/(Loss) for the Period

Our loss for the period for the year ended December 31, 2021 was €73.4 million, increased from a loss of €64.4 million in the year ended December 31, 2020. The increased loss in the 2021 period was primarily driven by increased research and development expenses for our vaccine candidate programs, increased COGS and increased general and administrative expenses over the prior year period.

Adjusted EBITDA

Our Adjusted EBITDA loss was €47.1 million for the year ended December 31, 2021, compared to a loss of €45.2 million for the year ended December 31, 2020. The increased Adjusted EBITDA loss was primarily driven by higher net loss in the 2021 period. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure, is set forth below:

€ in thousands	**Year ended December 31,**	
	2021	**2020**
Loss for the period	(73,425)	(64,393)
Add:		
Income tax expense	3,446	(909)
Total finance income	(249)	(516)
Total finance expense	16,964	10,738
Foreign currency gain/(loss) - net	(8,130)	(173)
Result from investments in associates	5	133
Amortization	6,600	5,957
Depreciation	7,681	3,843
Impairment	—	140
ADJUSTED EBITDA	**(47,108)**	**(45,181)**

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, 2022, we had €289.4 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, 2022 will fund our current operating plans for at least the next 12 months following the publication of the FY2022 financial statements.

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 issued 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 €11.1 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 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 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, 2022, 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, 2022, we had borrowings and lease liabilities of €152.4 million, of which €98.8 million were other loans and €53.6 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 April 2022. 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, 2022, $95.0 million (€89.2 million) was outstanding under the Financing Agreement. 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 extends until the third quarter of 2024, and the loan will mature in the first quarter of 2027. 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 the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, we would not be able to comply with the financial covenants in the financing agreement with Deerfield and OrbiMed, which could result in additional costs (up to 10 additional points of interest over the duration of the default) and an early repayment obligation (payment of the principal increased by 8% and of an indemnity representing the interests expected until March 2023). We do not expect these limitations to affect our ability to meet our cash obligations.

In February 2022, we announced that Valneva Scotland had been awarded 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 candidate and our other vaccine candidates. The funds under these grants will be available over three years, beginning in March 2022. As of December 2022, we received €5.1 million (£4.3 million) under the first grant of up to £12.5 million, which would support development related to the manufacture of our COVID-19 vaccine. We did not receive any payments in 2022 relating to the second grant of up to £7.5 million, which will support development connected to our manufacturing processes for other vaccines. The funds received were classified as current liabilities as at December 31, 2022.

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, 2022 and 2021

The table below summarizes our cash flows for the years ended December 31, 2022 and 2021:

	Year ended December 31,	
(In € thousand)	**2022**	**2021**
Net cash generated from operating activities	(245,343)	76,901
Net cash used in investing activities	(29,054)	(93,116)
Net cash generated from 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.

Comparisons for the Years Ended December 31, 2021 and 2020

The table below summarizes our cash flows for the years ended December 31, 2021 and 2020:

		Year ended December 31,	
	(In € thousand)	**2021**	**2020**
Net cash generated from operating activities		76,901	137,738
Net cash used in investing activities		(93,116)	(19,340)
Net cash generated from/(used in) financing activities		154,504	21,740
NET CHANGE IN CASH AND CASH EQUIVALENTS		**138,288**	**140,138**

Operating Activities

Net cash generated from operating activities for the year ended December 31, 2021 was €76.9 million compared to €137.7 million for the year ended December 31, 2020.

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 candidate and other cash expenses.

Net cash generated from operating activities for the year ended December 31, 2020 was primarily derived from the $130.0 million (€116.9 million) of upfront payment we received from Pfizer and the £98.5 million (€107.7 million) payment we received from the UK Government, partially offset by €55.1 million of operating losses. The payment from Pfizer related to our Lyme research collaboration and license agreement and was reflected in working capital and non-current assets. The payment from the UK Government related to the UK Supply Agreement and was reflected in working capital.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was €93.1 million, compared to €19.3 million for the year ended December 31, 2020 and was comprised primarily of construction of the building and equipment purchases in both periods. The increased equipment purchases in the year ended December 31, 2021 mainly relate to the site expansion activities for COVID-19 vaccine manufacturing in both Scotland and Sweden.

Financing Activities

Net cash generated from financing activities was €154.5 million for the year ended December 31, 2021 compared to €21.7 million used in financing activities for the year ended December 31, 2020. The increase was primarily due to proceeds from issuance of new shares in our U.S. initial public offering and European private placement in May 2021 as well as in our U.S. public offering and European private placement in November 2021. 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.

Net cash generated from financing activities for the year ended December 31, 2020 consisted primarily of €48.8 million net proceeds from the financing arrangement with Deerfield and OrbiMed, partially offset by €20.0 million (carrying amount was €19.8 million) in repayments of our borrowings with the EIB. We had to pay an additional €0.6 million penalty for early repayment of the loan.

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, 2022 and 2021, we had accumulated a net loss of €450.3 million and €307.0 million, respectively. Our net loss was €143.3 million, €73.4 million and €64.4 million for the years ended December 31, 2022, 2021 and 2020, 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 substantially in connection with our ongoing activities, as we:

- invest in our vaccine candidate programs, including our VLA1553 and VLA1601 vaccine candidates, and our other pre-clinical and research programs; 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;
- 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, 2022 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, 2022 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	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
TOTAL	**178,401**	**80,731**	**57,565**	**22,207**	**338,904**

The amounts disclosed in the table above are the contractual undiscounted cash flows.

Borrowings

As of December 31, 2022, the outstanding 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. The repayments will start in 2024, while the loan will mature in 2027. 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 €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.

As of December 31, 2021, the outstanding amount of bank borrowings and other loans was €57.8 million. Of this, €49.7 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 €4.7 million and the CEPI loan in the amount of €3.5 million, which relates to advanced payments received which are expected to be paid back in the future.

As of December 31, 2020, the outstanding amount of bank borrowings and other loans was €53.4 million. Of this, €46.2 million related to the Financing Agreement with Deerfield and OrbiMed. Part of the loan was used to fully repay the existing loan of €20.0 million with EIB. Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €5.9 million and the CEPI loan in the amount of €1.3 million, which relates to advanced payments received which are expected to be paid back in the future.

Lease Liabilities

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, which we expect will terminate in 2031 and 2037, respectively. Base rent will increase based on an inflation index. €23.2 million related to the lease agreements for premises in Vienna, Austria. We expect that this lease will terminate in 2023 and that we will incur a final payment to buy the leased assets. Regular installment payments are variable and based on EURIBOR. Other lease liabilities of €3.2 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of December 31, 2021, the outstanding, discounted amount of lease liabilities was €56.8 million. Of this, €30.5 million related to the lease agreements for two premises in Sweden. €24.0 million related the lease agreements for premises in Vienna, Austria. We expect that this lease will terminate in 2023 and that we will incur a final payment to buy the leased assets. Regular installment payments are variable and based on EURIBOR. Other lease liabilities of €2.3 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

Refund Liabilities

As of December 31, 2022, the carrying amount of refund liabilities was €143.1 million. Of this, €135.5 million (of which nil non-current) 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 (£70.8) million.

As of December 31, 2021, the carrying amount of refund liabilities was €254.6 million. Of this, €166.9 million (of which €77.3 million non-current) related to uncertain restrictions and repayment obligations from the terminated UK Supply

Agreement, €79.6 million (thereof €75.2 million non-current) related to the collaboration with Pfizer as (until the amendment executed in April 2022) we were to fund 30% of Phase 3 clinical trial costs performed by Pfizer; €6.4 million (thereof €6.3 million non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 and €1.3 million (all current) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products. Other releases mainly refer to changes in the refund liability related to changes in assumptions and estimates.

As of December 31, 2020, the carrying amount of refund liabilities was €111.4 million. Of this, €81.9 million (of which €70.0 million non-current) related to the collaboration with Pfizer Inc. for development of our Lyme disease vaccine, as we were required to contribute 30% of Phase 3 clinical trial costs for this vaccine. €20.9 million (all non-current) related to the agreement with the UK Government to develop and commercialize a COVID-19 vaccine, €6.3 million (all non-current) related to expected payment to GSK related to the termination of the SAA with payments expected in 2024, and €2.3 million (all current) related to refund liabilities to customers related to rebate programs and right to return products.

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. 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 and separation 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, 2022, 2021 and 2020, €135.5 million, €79.6 million and €81.9 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. The transaction price was determined taking into account our refund obligation and was modified during 2021 and 2022. The agreement includes various performance obligations including: research and development and service performance obligations for which revenue is recognized over time, as well as a license performance obligation for which revenue was recognized at a point in time when Pfizer can benefit and use the license, which occurred in the fourth quarter of 2020. Judgement and estimates were applied when determining the transaction price (including the valuation of the refund liability) as well as at the allocation of the transaction price to the performance obligations. For the years ended December 31, 2022, 2021 and 2020, minus €45.9 million, €14.3 million and €31.6 million, respectively, was recognized as revenue from collaboration, licensing and services. The amount recognized in the year ended December 31, 2022 and, 2021 included adjustments of revenues recognized in 2020 due to a modification of the agreements. €3.7 million, €3.0 million and €2.8 million of costs to obtain a contract are included in other assets as of December 31, 2022, 2021 and 2020, respectively. In case the refund liability varies from the estimates, the revenue will be adjusted in the period where the estimate is updated.

In September 2020, we announced a collaboration with the UK government (the UK Authority) for our COVID-19 vaccine, VLA2001. The UK Supply Agreement also provided for up-front investments in the scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the collaboration. According to IFRS 15, this agreement included two performance obligations: first, the delivery of 60 million doses, and second, an option to sell an additional 40 million doses at a lower price than the expected market price and an option to sell an additional 90 million

doses at the expected market price. We received notice from the UK Authority on September 10, 2021 of its intent to terminate the agreement and the termination became effective on October 10, 2021. The termination of the UK Supply Agreement was extensively assessed in 2021 and payments received, where judgment was necessary and we assessed the likelihood of repayment to be remote, totaled €253.3 million and were recognized as revenue in the year ended December 31, 2021 (year ended December 31, 2020: zero). We also recognized refund liabilities of €166.9 million (thereof €77.3 non-current) related to uncertain restrictions and repayment obligations (2020: €20.9 million) as at December 31, 2021. As at December 31, 2022 these restrictions and repayment obligations have been assessed and the likelihood for future obligation was assessed as remote. Therefore €169.2 million were recognized as revenue in the year ended December 31, 2022.

In November 2021, Valneva signed an Advance Purchase Agreement (EC APA) with the European Commission to supply up to 60 million doses of VLA2001 over two years. The EC APA was amended in July 2022 to reduce the amount of doses of VLA2001 ordered. For more information, refer to note 5.1 of the financial statements filed with this Annual Report. 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, 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.

Accounting for Grants

In July 2019, we announced an agreement with CEPI, which includes performance obligations and refund obligations. Management's judgment is required to determine whether such components of an agreement are revenues from customers or fall within the standard of accounting for government grants. Since CEPI is a non-governmental organization partly funded by a government and is acting in a way a government organization would, it was accounted for under IAS 20. In addition, the valuation of the various components requires management's judgment. 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, pursuant to which we and Instituto Butantan intend to collaborate to transfer our drug product technology to Instituto Butantan, to enable Instituto Butantan to develop, manufacture and commercialize our chikungunya vaccine in low and middle income countries and obtain World Health Organization prequalification. The agreement includes various performance obligations including: delivery of Drug substance for which revenue is recognized at date of delivery, certain clinical studies (included studies financed by CEPI) for which revenue is recognized over time, as well as a license performance obligation for which revenue was recognized at a point in time when Instituto Butantan can benefit and use the license, which occurred in the first quarter of 2021. Judgement and estimates were applied when determining the transaction price as well as at the allocation of the transaction price to the performance obligations. For the years ended December 31, 2022 and 2021 €5.6 million and €3.5 million, respectively were recognized as revenue from collaboration, licensing and services and included €3.9 million and €1.3 million, respectively from CEPI pursuant to the CEPI grant, where Instituto Butantan is the beneficiary.

In February 2022, we announced that Valneva Scotland had been awarded 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 candidate and our other vaccine candidates. The funds under these grants will be available over three years, beginning in March 2022. As of December 2022, we received €5.1 million (£4.3 million) under the first grant of up to £12.5 million, which would support development related to the manufacture of our COVID-19 vaccine. We did not receive any payments in 2022 relating to the second grant of up to £7.5 million, which will support development connected to our manufacturing processes for other vaccines. The funds received were classified as current liabilities as at December 31, 2022.

Valuation of Intangibles and Tangibles / Impairment tests

As of December 31, 2022, impairment tests were performed on the IXIARO, DUKORAL, chikungunya and clinical trial material cash-generating units (CGUs). The impairment tests resulted in impairment charges of €8.3 million being taken. In addition, COVID related assets which will be no longer used resulted in 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, 2022, for IXIARO and chikungunya, and in an additional impairment loss for DUKORAL (€4.0 million) and CTM (€0.9 million) in the year ended December 31, 2022. With regards to the years ended December 31, 2021 and 2020, a reduction in revenue of 10.0% would result in no additional impairment loss.

Valuation of Inventories / Impairment tests

In 2022, inventory-related COGS were €257.8 million (2021: €145.3 million), of which €157.7 million (2021: €127.1 million) related to inventory which cannot be used, failed batches which were written down and product which is not expected to be sold. In 2022, €159.4 million (2021: €121.4 million) of these expenses related to VLA2001 and stem from 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. The valuation of commercialized products resulted in a reversal of write-downs from prior periods of €2.8 million due to higher sales expectations. In 2021, €5.7 million of these expenses related to commercialized products and stem from write-downs due to lower sales expectations and limited shelf life of the products.

Deferred Tax Asset Recognition

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 tax assets of €199.5 million, €153.8 million and €126.3 million as of December 31, 2022, 2021 and 2020, respectively are 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. We assumed this or entities where there is no profitable history and/or a negative outlook in the following 5-years period of the long range business plan.

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 Management Board and Supervisory Board members 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. In 2020, we established a Phantom Share Program with terms and conditions similar to the Free Ordinary Shares for certain employees.

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 5.22 to our consolidated financial statements as of and for the years ended December 31, 2022 and 2021 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 2022 was €6.22, therefore the provision taken as at December 31, 2022 amounted to €3.3 million, whereas the latest share price in 2021 was €24.50, and the respective provision amounted to €26.5 million as at December 31, 2021. 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

We have a two-tier corporate governance system consisting of a Management Board (*Directoire*), which is responsible for managing the Company, and a Supervisory Board (*Conseil de Surveillance*), which oversees the Management Board.

The following table sets forth information concerning the members of our Management Board and Supervisory Board as of the date of this annual report.

Name	Age	Position
Management Board Members		
Thomas Lingelbach	59	Chairman of the Management Board, President, Chief Executive Officer
Franck Grimaud	56	*Directeur Général*, Chief Business Officer
Peter Bühler	53	Chief Financial Officer
Juan Carlos Jaramillo	52	Chief Medical Officer
Dipal Patel	49	Chief Commercial Officer
Frédéric Jacotot	59	General Counsel, Corporate Secretary
Supervisory Board Members		
Frédéric Grimaud	58	Chairman of the Supervisory Board
James Sulat	72	Vice Chairman of the Supervisory Board
James Connolly	58	Member of the Supervisory Board
Maïlys Ferrère	60	Representative of Bpifrance Participations SA, member of the Supervisory Board
Anne-Marie Graffin	61	Member of the Supervisory Board
Sharon Tetlow	62	Member of the Supervisory Board
Johanna Willemina Pattenier	63	Member of the Supervisory Board

Management Board

We are managed by a Management Board under the control of a Supervisory Board. The members of the Management Board determine, at a high level, our business activities and ensure their implementation. Without prejudice to the powers expressly vested in the shareholders' meetings, and insofar as our bylaws allow, the Management Board deals with all matters relating to the conduct of our business. The Management Board is vested with the broadest powers to act in all circumstances on our behalf, within the limits of our corporate purpose and subject to the powers granted to the shareholders' meeting and Supervisory Board.

Our Management Board must be composed of two to seven members. Pursuant to our bylaws, the Management Board is appointed by the Supervisory Board for a three-year term renewable by the Supervisory Board. Management Board members may be dismissed at the ordinary general meeting and by the Supervisory Board. In the case of a vacancy between annual meetings, the Supervisory Board must within a two-month period appoint a temporary member to fill the vacancy or must change the number of Management Board members.

Thomas Lingelbach has served as our President and Chief Executive Officer and Chairman of our Management Board since 2013. 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.

Franck Grimaud has served as our *Directeur Général* and Chief Business Officer and as a member of our Management Board 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.

Peter Bühler has served as our Chief Financial Officer and as a member of our Management Board 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.

Juan Carlos Jaramillo, M.D., has served as our Chief Medical Officer and as a member of our Management Board 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.

Dipal Patel has served as our Chief Commercial Offer and as a member of our Management Board member 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 Vice President of Legal & IP and General Counsel since 2013 and has served on our Management Board since April 2017. 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.

Supervisory Board

The Supervisory Board is composed of a minimum of three and a maximum of eighteen members. The members of the Supervisory Board 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 the members of the Supervisory Board at any time during the meeting by a simple majority vote. The appointees are selected by the shareholders and may be individuals or companies (represented by a designated individual).

The age limitation for Supervisory Board members is 80 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.

Frédéric Grimaud has served as Chairman of our Supervisory Board since December 2012. Mr. Grimaud has served as President and Chief Executive Officer of Groupe Grimaud La Corbière SA, a life sciences development company and our largest shareholder, since September 2001 and prior to that held various positions at Groupe Grimaud and its affiliates. We believe Mr. Grimaud's leadership experience in the life sciences industry qualifies him to serve on our Supervisory Board.

James Sulat has served on our Supervisory Board since 2013 and is currently Vice Chairman of our Supervisory Board. Prior to that, 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 Exicure, 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 Supervisory Board.

James Connolly has served on our Supervisory Board since June 2022. 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 Supervisory Board.

Maïlys Ferrère has served as representative of Bpifrance Participations, member of the Supervisory Board, since June 2022. 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 Supervisory Board.

Anne-Marie Graffin has served on our Supervisory Board since 2013. 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.

Sharon Tetlow has served on our Supervisory Board since June 2020. She founded and has served as Managing Partner of Potrero Hill Advisors, which provides strategic and operational financial support to life science companies, since January 2016. Prior to that, she served as CFO of public and private biotech companies. She has served as a member of the Board of Directors of DICE Therapeutics, Inc. (NASDAQ: DICE) since November 2020, where she serves as Chair of the Audit Committee and as a member of both the Nominating and Governance Committee and the Finance Committee. She has served as a member of the Board of Directors of Structure Therapeutics, Inc. (NASDAQ: GPCR), where she is chair of the Audit Committee, and member of the Nominating and Governance Committee and the finance and pricing committee. Ms. Tetlow served as a member of the Board of Directors of Catalyst Biosciences, Inc. (NASDAQ: CBIO) from January 2020 through December 2022, where she chaired the Audit Committee and was a member of the Transaction Committee. Ms. Tetlow received her M.B.A. from Stanford University and her B.A. in Psychology from the University of Delaware. We believe Ms. Tetlow's expertise in corporate finance and strategic planning in the biotechnology and pharmaceutical industries and her public company board experience qualifies her to serve on our Supervisory Board.

Johanna Willemina Pattenier, M.D., has served on our Supervisory Board since June 2020. Dr. Pattenier served in a variety of positions at Novartis AG from 2012 through January 2017, most recently as General Manager of Novartis Vaccines and Diagnostics in Basel, Switzerland. Prior to this, Dr. Pattenier held a variety of commercial and medical positions at pharmaceutical companies GlaxoSmithKline plc, Organon & Co. and Byk Gulden Lomberg Chemische Fabrik GmbH. Dr. Pattenier received her Ph.D (Dr. Med.) in experimental surgery, cryopreservation of islets of Langerhans from University of Homburg/Saar and her M.D. from Erasmus University. We believe Dr. Pattenier's experience in the pharmaceutical and biotechnology industries qualifies her to serve on our Supervisory Board.

Diversity of the Supervisory Board

Supervisory Board Diversity Matrix (as of December 31, 2022)

Country of Principal Executive Offices:				France
Foreign Private Issuer:				Yes
Disclosure Prohibited under Home Country Law:				No
Total Number of Directors:				7
Part I: Gender Identity				
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Directors	4	3	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction				0
LGBTQ+				0
Did Not Disclose Demographic Background				1

Supervisory Board Diversity Matrix (as of December 31, 2021)

Country of Principal Executive Offices:				France
Foreign Private Issuer:				Yes
Disclosure Prohibited under Home Country Law:				No
Total Number of Directors:				5
Part I: Gender Identity				
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Directors	3	2	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction				0
LGBTQ+				0
Did Not Disclose Demographic Background				1

Family Relationships

Frédéric Grimaud, who is a member of our Supervisory Board, is a second cousin of Franck Grimaud, who is a member of our Management Board. There are no other family relationships among any of the members of our Management Board and Supervisory Board.

B. Compensation

Compensation of Members of the Supervisory Board

Attendance Fees

We pay attendance fees to the members of the Supervisory Board. At our general meeting of shareholders held on June 29, 2017, shareholders set the total attendance fees to be distributed among the members of the Supervisory Board at €350,000 for each 12-month period starting on June 1, 2017 and each anniversary thereof. The attendance fees are fixed. However, fees may be reduced if meeting attendance is under 75%. The following table shows the framework for the maximum allowable attendance fees for the 12-month period starting on January 1, 2022:

Member Role	**Maximum Allowable Attendance Fee**
Supervisory Board Chairman	€90,000
Supervisory Board Vice-Chairman	€60,000
Supervisory Board Committee Chairman	€60,000
Member of two Supervisory Board Committees	€60,000
Member of one Supervisory Board Committee	€52,500
Supervisory Board Member	€45,000

The following table sets forth information regarding the attendance fees earned by members of the Supervisory Board during the year ended December 31, 2022:

Member	Compensation
Frédéric Grimaud	€88,750
James Sulat	€59,583
James Connolly	€23,042
Anne-Marie Graffin	€59,583
Sharon Tetlow	€59,583
Johanna Willemina Pattenier	€52,903

Ms. Maïlys Ferrère did not receive any fees in connection with her representation of Bpifrance Participations on the Supervisory Board.

Compensation of Members of the Management Board—2022

Our Management Board is currently comprised of six members:

- Thomas Lingelbach, Chair of the Board, President & CEO, with a current term ending at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2024;
- Franck Grimaud, *Directeur Général* & Chief Business Officer, with a current term ending at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2024;
- Peter Bühler, Chief Financial Officer, with a current term ending at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2024;
- Frédéric Jacotot, General Counsel & Corporate Secretary, with a current term ending at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2024;
- Juan Carlos Jaramillo, Chief Medical Officer, with a current term ending at the 2025 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2024;
- Dipal Patel, Chief Commercial Officer, with a current term ending 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 each member of the Management Board is determined by the Supervisory Board, after recommendation by the nomination and compensation committee.

The following tables set forth compensation earned by members of the Management Board with respect to the year ended December 31, 2022.

Mr. Thomas Lingelbach – Chair of the Management Board, President & CEO

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 decisions, as applicable.

Type of Compensation	**Amount of compensation earned**	**Description**
Fixed compensation	€525,000	As per Supervisory Board decision of March 15, 2022.
Annual variable compensation	€214,200	60% of 2022 gross annual salary set by the Supervisory Board of March 15, 2022. Validation by the Supervisory Board of 68% of the objectives set with respect to the year 2022, on March 9, 2023.
Fringe benefits :		
– Car rental	Lease fee: €14,400 Insurance: €3,703.88 Other car related expenses (except fuel) : €6,311.20	Maximum €1,200 per month for the lease fee as per Mr. Lingelbach's Management Agreement (or €14,400 per year).
– Death and endowment insurance policy	€15,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement of home workplace journeys made by flights, and associated costs	€5,069.45	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	**€783,684.53**	

Mr. Franck Grimaud – Management Board member, Directeur Général & CBO

Mr. Grimaud's compensation is set in accordance with (a) the provisions of the Management Agreement 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	€275,000	As per Supervisory Board decision of March 15, 2022.
Annual variable compensation	€93,500	50% of 2022 gross annual salary set by the Supervisory Board of March 15, 2022. Validation by the Supervisory Board of 68% of the objectives set with respect to the year 2022, on March 9, 2023.
Fringe benefits :		
– Car rental	Lease fee: €11,123.60 Insurance: €1,659.52	Maximum €1,200 per month for the lease fee as per Mr. Grimaud's Management Agreement (or €14,400 per year).
– Garantie Sociale des Chefs et Dirigeants d'Entreprises	€8,004	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 Board of Directors of October 26, 2000.
Total compensation	**€389,287.12**	

Mr. Peter Bühler – Management Board member, Chief Financial Officer

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	€366,000	As per Supervisory Board decision of March 15, 2022.
Annual variable compensation	€124,440	50% of 2022 gross annual salary set by the Supervisory Board of March 15, 2022. Validation by the Supervisory Board of 68% of the objectives set with respect to the year 2022, on March 9, 2023.
Fringe benefits :		
– Car allowance	€13,800.00	Maximum €1,200 per month as per Mr. Bühler's Management Agreement (or €14,400 per year).
– Death and endowment insurance policy	€15,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement costs	€738.80	
Total compensation	**€519,978.80**	

Mr. Frédéric Jacotot – Management Board member, General Counsel & Corporate Secretary

Mr. Jacotot's compensation is set in accordance with (a) the provisions of the Management Agreement 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	€215,000	As per Supervisory Board decision of March 15, 2022.
Annual variable compensation	€73,100	50% of 2022 gross annual salary set by the Supervisory Board of March 15, 2022. Validation by the Supervisory Board of 68% of the objectives set with respect to the year 2022, on March 9, 2023.
Fringe benefits :		
– Garantie Sociale des Chefs et Dirigeants d'Entreprises	€10,379.57	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	**€298,479.57**	

Dr. Juan Carlos Jaramillo – Management Board member, Chief Medical Officer

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	€317,000	As per Supervisory Board decision of March 15, 2022.
Annual variable compensation	€107,780	50% of 2022 gross annual salary set by the Supervisory Board of March 15, 2022. Validation by the Supervisory Board of 68% of the objectives set with respect to the year 2022, on 9 March, 2023.
Fringe benefits: – Car allowance	€13,800	€1,200 per month as per Dr. Jaramillo's Management Agreement.
– Death and endowment insurance policy	€15,000	€1,500 per month as per Dr. Jaramillo's Management Agreement.
– Reimbursement of home workplace journeys made by flights, and associated costs	€8,704.39 plus rent of apartment €10,243.37	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	**€472,527.76**	

Ms. Dipal Patel – Management Board member, Chief Commercial Officer

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	£126,396	As per Supervisory Board decision of August 10, 2022.
Fringe benefits: – Car allowance	£1,015	€1,015 for the year 2022
– Death and endowment insurance policy	Covered by insurance policy	Long-term life insurance policy as a retirement savings product.
– Reimbursement of home workplace journeys made by flights, and associated costs	£0	
Total compensation	**£127,411**	

Compensation of Members of the Management Board—2022

The Supervisory Board has determined the following base salaries for the current members of our Management Board with respect to the year ended December 31, 2022:

Management Board Member	2022 Base Salary
Thomas Lingelbach	€525,000
Franck Grimaud	€275,000
Peter Bühler	€380,000
Frédéric Jacotot	€215,000
Juan Carlos Jaramillo	€317,000
Dipal Patel	£305,000

Limitations on Liability and Indemnification Matters

Under French law, provisions of bylaws that limit the liability of the members of Management and Supervisory Boards are prohibited. However, French law allows *sociétés européennes* to contract for and maintain liability insurance against civil liabilities incurred by members of Management and Supervisory Boards involved in a third-party action, provided that they acted in good faith and within their capacities as members of such board 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 Management and Supervisory Board members and have obtained insurance coverage for liability under the Securities Act. We also have entered into agreements with our Management and Supervisory Board members 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 Management and Supervisory Board members.

These agreements may discourage shareholders from bringing a lawsuit against our Management and Supervisory Board members for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our Management and Supervisory Board members, 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 Management and Supervisory Board members 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. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our Management Board and Supervisory Board members and our employees, including stock options, Free Convertible Preferred Shares (or FCPS), Free ordinary shares and BSAs (defined below).

Our Management Board's authority to grant these stock options, BSAs, FCPS 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 Management Board can continue to grant such awards for a specified period upon prior authorization of the Supervisory Board.

We have various compensation plans for our Management Board members, Supervisory Board members 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, FCPS and equity warrants.

Equity Warrants (BSAs)

Equity warrants (*bons de souscription d'actions*, or BSAs) are granted at a *de minimis* price and entitle the holder of one BSA to exercise the warrant for one underlying share, at an exercise price per share determined by our Management Board at the time of grant by reference to the then prevailing market price per share. We have granted BSAs to our Supervisory Board members.

Our current 2017 equity warrants plan (BSA 27) provides four exercise periods, with the following opening and closing dates (subject to suspension cases provided for by the plan):

- 1st exercise period: from December 15, 2018 to December 14, 2019 inclusive
- 2nd exercise period: from December 15, 2019 to December 14, 2020 inclusive
- 3rd exercise period: from December 15, 2020 to December 14, 2021 inclusive
- 4th exercise period: from December 15, 2021 to December 14, 2022 inclusive

During each exercise period, the beneficiaries are entitled to exercise up to 25% of the BSA 27 equity warrants they received. BSAs that are not validly exercised during a given exercise period lapse by operation of law at the end of the last day of such period. Any such lapsed BSAs lose all their value and in this respect, the relevant beneficiary is not entitled to any right of indemnification.

Our equity warrants cannot be sold on a regulated market.

The following table shows the BSAs outstanding as of December 31, 2022:

Plan name	**BSA 27**
General Meeting date	June 30, 2016
Grant decision date	December 15, 2017
BSAs issued by the Management Board	87,500
Subscription price per share	€2.574
BSAs lapsed as of December 31, 2022	15,625
BSAs exercised as of December 31, 2022	71,875
Outstanding BSAs as of December 31, 2022	—
Valneva SE ordinary shares potentially resulting from exercise of the warrants remaining as of December 31, 2022	—

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 (or formerly "Executive 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, as described below).

The beneficiaries receive a number of options, depending on their job functions, that they can convert into ordinary shares during specific exercise periods that are announced by the Management Board 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 provides 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, 2022:

Plan name	ESOP 2013	ESOP 2015	ESOP 2016	ESOP 2017	ESOP 2019	SLG SOP 2022	ESOP 2022
General Meeting date	June 28, 2013	June 26, 2014	June 30, 2016	June 30, 2016	June 28, 2018	June 23, 2022	June 23, 2022
Grant date	October 2, 2013	July 28, 2015	October 7, 2016	December 7, 2017	September 30, 2019	October 10, 2022	October 10, 2022
Subscription price	€2.919	€3.92	€2.71	€2.85	€3.05	€6.47	€6.47
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
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
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 09, 2023 (for 1/3 of the options) October 09, 2024 (for another 1/3 of the options) October 09, 2025 (for the remainder)	October 09, 2023 (for 1/3 of the options) October 09, 2024 (for another 1/3 of the options) October 09, 2025 (for the remainder)
Stock options exercised as of December 31, 2022	615,918	478,845	383,250	427,025	0	0	0
Shares resulting from exercise of stock options	677,346	478,845	383,250	427,025	0	0	0
Outstanding stock options as of December 31, 2022	17,782	43,655	14,500	551,475	1,994,176	1,159,751	2,154,500
Of which outstanding stock options held by corporate officers	*210,000*	*100,000*	*0*	*0*	*0*	*0*	*0*
Shares potentially resulting from stock option exercise after December 31, 2022	19,557	43,655	14,500	551,475	1,994,176	1,159,751	1,996,500
Stock options having lapsed as of December 31, 2022	419,250	189,500	186,500	291,000	675,834	0	158,000

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, 2022, the number of unvested outstanding free shares that have been granted by the Company to the members of the Management Board is 288,382 shares for the Chair of the Management Board (CEO) and 479,679 for all other members of the Management Board.

The following table shows the free ordinary shares outstanding as of December 31, 2022:

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 first tranche was vested and delivered (*a été définitivement acquise*) to the participants in March 2022, the second tranche will vest three (3) years as from December 19, 2019 and the third tranche will vest four (4) years as from December 19, 2019. The vesting (*attribution définitive*) of each tranche therefore occurs upon completion of each vesting period mentioned above, subject to employment and performance conditions.
Date of availability	Following free shares vesting, no compulsory holding period is applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (4th paragraph) of Article L. 225-197-1 of the French Commercial Code, the Supervisory Board decided that the Management Board members 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, 2022	636,648
Free ordinary shares being vested as of December 31, 2022	1,085,756 (including 856,807 by corporate officers)
Free ordinary shares lapsed as of December 31, 2022	469,543

Performance and employment conditions	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. 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, 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. 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. Additionally, each of the beneficiaries must continuously remain a Management Board 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, subject to the retirement exception below.
Provisions relating to retirement	Beneficiaries who will retire in accordance with the age requirements of their applicable retirement regime before complete vesting will remain entitled to a prorated amount of shares, for each unvested tranche, based on the period from the initial grant date until retirement, as compared to the total duration of the tranche in question (2, 3 or 4 years); provided, however, that the performance condition stated above was met in the performance appraisal immediately preceding the retirement. For Management Board members (including the CEO), the level of performance will also affect the amount of shares kept.
Provisions relating to a change of control	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 Management Board members (including the CEO), their level of performance will also affect the amount of shares that will be the subject of accelerated vesting. If a Change of Control takes place before December 19, 2021, 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 to the above-mentioned performance conditions, and for the Management Board (including the CEO), to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free ordinary 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 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.

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 first and second tranches shall vest and be delivered (seront définitivement acquises) to the participants two (2) years as from October 10, 2022, the third tranche will vest three (3) years as from October 10, 2022. The vesting (attribution définitive) of each tranche therefore occurs upon completion of each vesting period mentioned above, subject to employment conditions.
Date of availability	Following free shares vesting, no compulsory holding period is applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (4th paragraph) of Article L. 225-197-1 of the French Commercial Code, the Supervisory Board has decided that the Management Board members 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, 2022	0
Free ordinary shares being vested as of December 31, 2022	374,390
Free ordinary shares lapsed as of December 31, 2022	0
Performance and employment conditions	No performance condition. Same employment condition as the 2019 plan.
Provisions relating to retirement	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 Management Board members (including the CEO), the level of performance will also affect the æ of ordinary shares kept.
Provisions relating to a change of control	If a Change of Control takes place before October 9, 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 to the above-mentioned performance conditions, and for the Management Board (including the Chair), 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	Special free ordinary share plan 2022-2024
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 (*attribution définitive*) 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, the Supervisory Board has decided that the Management Board member concerned should keep not less than 10% of the vested free shares until termination of his office as Management Board member or corporate officer.
Free ordinary shares fully vested as of December 31, 2022	0
Free ordinary shares being vested as of December 31, 2022	27,521
Free ordinary shares lapsed as of December 31, 2022	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	If (a) a Change of Control takes place before December 6, 2024, and 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 above-mentioned performance conditions, and for the Management Board (including the Chair), 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. "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. 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 entry price at the grant date. The Phantom Shares Program does not have any dilutive effect on our shareholders, as the phantom shares do not constitute or qualify for our ordinary shares.

The overall objectives of the Phantom Stock Option Programs are (i) to retain certain employees who are U.S. citizens, (ii) to create long-term incentive for the participants and (iii) to align the interests of our employees who are U.S. citizens and our employees eligible for the ESOPs. 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 entry 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 entry prices are set in a range from €2.71 to €3.92. The phantom shares will be settled in cash between 2023 and 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 entry 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, 2022, the Phantom Stock Option Programs and Phantom Free Share plan consisted of an aggregate of 670,500 phantom shares.

The liability for the phantom plans is measured (at the end of each reporting period) at the fair value of the share options rights (determined using the Black Scholes valuation model), 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

The Supervisory Board is composed of a minimum of three and a maximum of eighteen members. The members of the Supervisory Board are appointed for a renewable term of three years at the general meeting of shareholders. The terms of Ms. Tetlow and Dr. Pattenier will expire at the end of the Annual General Meeting of shareholders in June 2023. The terms of Mr. Connolly, Ms. Graffin, Mr. Grimaud, and Mr. Sulat will expire at the end of the Annual General Meeting of shareholders in June 2025. The term of Bpifrance Participations, represented as of the date of this annual report by Ms. Maïlys Ferrère, will expire at the end of the Annual General Meeting of shareholders in June 2025. The general meeting of shareholders may revoke the appointments of the members of the Supervisory Board at any time during the meeting by a simple majority vote. The appointees are selected by the shareholders and may be individuals or companies (represented by a designated individual).

The age limit for the members of the Supervisory Board is 80. The limitations on holding such an appointment concurrently with an appointment in another company are subject to the applicable legal and regulatory provisions.

Role of the Supervisory Board in Risk Oversight

Our Supervisory Board is primarily responsible for the oversight of our risk management activities and has delegated to the audit and governance committee the responsibility to assist our Supervisory Board in this task. While our Supervisory Board oversees our risk management, our management, through the Management Board, is responsible for day-to-day risk management processes. Our Supervisory 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 Supervisory Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Supervisory Board Committees

The Supervisory Board has established an audit and governance committee and a nomination and compensation committee, which operate pursuant to rules of procedure adopted by our Supervisory Board.

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 Supervisory Board will only have an advisory role and can only make recommendations to our Supervisory Board. As a result, decisions will be made by our Supervisory Board taking into account non-binding recommendations of the relevant Supervisory Board committee.

Audit and Governance Committee

Our audit and governance committee assists our Supervisory 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 Supervisory Board informed on control systems, key processes and procedures, security and risks. The members of our audit and governance committee are James Connolly, James Sulat, and Sharon Tetlow. Ms. Tetlow is the chair of the committee.

Our Supervisory Board has determined that Mr. Connolly, Mr. Sulat and Ms. Tetlow are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Supervisory Board has further determined that Ms. Tetlow 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 and governance committee is to monitor the existence and efficacy of our financial audit and risk control procedures on an ongoing basis.

Our Supervisory Board has specifically assigned the following duties to the audit and governance 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

Our nomination and compensation committee assists our Supervisory Board in reviewing and making recommendations to our Supervisory Board with respect to the appointment and the compensation of the members of our Management Board and Supervisory Board. In accordance with operating rules adopted by the Supervisory Board, the nomination and compensation committee is composed of at least three members or their permanent representatives appointed by the Supervisory Board. The members of our nomination and compensation committee are Anne-Marie Graffin, Johanna Willemina Pattenier and James Sulat, all of whom are independent. Ms. Graffin is the chair of the committee.

Our Supervisory Board has specifically assigned the following duties to the nomination and compensation 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), reviewing the compensation of the members of our Management Board, examine and make proposals with respect to the various components of corporate officer's (including Management Board members) 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 the Supervisory Board and the committees members, assisting the Supervisory Board in the selection of the members of the Management Board and committees and making recommendations with respect to the independence of the members of the Supervisory Board and committees.

D. Employees

As of December 31, 2022, we had a total of 719 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	**266**
Valneva Canada Inc.	**5**
Valneva France SAS	**7**
Valneva Scotland Ltd	**175**
Valneva SE	**52**
Valneva Sweden AB	**183**
Valneva UK Ltd	**8**
Valneva USA, Inc.	**23**
Total	**719**

Of these employees, approximately 34% were primarily engaged in manufacturing, 33% in research and development, 25% in general and administrative functions and 7% 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."

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table and accompanying footnotes sets forth, as of December 31, 2022, 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 our Management Board and Supervisory Board members individually; and
- all of our Management Board and Supervisory Board members 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 and free convertible preferred shares (FCPS) that vest within 60 days of December 31, 2022 and options and equity warrants (BSAs) that are currently exercisable or exercisable within 60 days of December 31, 2022. Ordinary shares subject to free ordinary shares and FCPS that vest within 60 days of December 31, 2022, and options and BSAs currently exercisable or exercisable within 60 days of December 31, 2022 are deemed to be outstanding for computing the percentage ownership of the person holding these free ordinary shares, FCPS, options or BSAs 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, 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)]	13,704,831	9.90
Bpifrance Participations SA[(2)]	9,521,701	6.88
Deep Track Capital[(3)]	10,513,265	7.60
Pfizer Inc.[(4)]	9,549,761	6.90
Management Board and Supervisory Board Members:		
Thomas Lingelbach	219,347	*
Franck Grimaud	513,055	*
Peter Bühler	—	—
Juan Carlos Jaramillo	—	—
Frédéric Jacotot	153,995	*
Dipal Patel	—	—
Frédéric Grimaud[(5)]	276,746	*
James Sulat	30,367	*
James Connolly	—	—
Maïlys Ferrère for Bpifrance	—	—
Anne-Marie Graffin	14,250	*
Sharon Tetlow	—	—
Johanna Willemina Pattenier	—	—
All members of our Management Board and Supervisory Board as a group	**1,207,760**	**0.87**

* Represents beneficial ownership of less than 1%.

(1) Consists of 13,704,831 ordinary shares held by Groupe Grimaud La Corbière SAS (“Groupe Grimaud”). The majority shareholder of Groupe Grimaud is La Financiere 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 Mulle), 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 Sevremoine, France. Frédéric Grimaud, a member of our Supervisory Board, is the President and Chief Executive Officer of Groupe Grimaud.

(2) As reported in a Schedule 13D filed with the SEC on November 16, 2022. 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 ("EPIC") 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 November 15, 2022, (i) Bpifrance Participations SA held directly 9,547,269 ordinary shares and 17,004,054 voting rights, and (ii) CDC Croissance S.A., a wholly-owned subsidiary of CDC ("CDC Croissance"), held directly 2,069,552 ordinary shares and 2,069,552 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 9,547,269 ordinary shares and 17,004,054 voting rights indirectly through its 99.99% ownership of Bpifrance. EPIC may be deemed to be the beneficial owner of 9,547,269 ordinary shares and 17,004,054 voting rights indirectly through its joint ownership and control of Bpifrance S.A. CDC may be deemed to be the beneficial owner of (x) 11,616,821 ordinary shares and 19,073,606 voting rights, indirectly through its joint ownership and control of Bpifrance S.A. and (y) 2,069,552 ordinary shares and 2,069,552 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.

(3) As reported in a Schedule 13G filed with the SEC on October 7, 2022. 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.

(4) 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.

(5) Mr. Frédéric Grimaud's holdings consists of (i) 276,746 ordinary shares and (ii) the securities held by Groupe Grimaud described in footnote (1) above. Mr. Grimaud is the President & Chief Executive Officer of Groupe Grimaud.

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2020 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 and (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. Any of our principal shareholders who have held our ordinary shares in registered form for at least two years have this double voting right.

Shareholders in the United States

To our knowledge, as of December 31, 2022, approximately 35,298,848 shares, or 26% of our ordinary shares outstanding at that date, were held of record by 46 residents of the United States.

B. Related Party Transactions

Since January 1, 2022, 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.

Participation in our Nasdaq Offerings

In our October 2022 global offering, Bpifrance Participations SA purchased 1,020,408 of our ordinary shares at the public offering price of €4.90 per share, for an aggregate purchase price of €5.0 million.

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 did not make any payments under this agreement in 2022.

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.

Arrangements with the Members of our Management and Supervisory Boards

Management and Supervisory Board Compensation

See Item 6B of this Annual Report for information regarding compensation of the members of our Supervisory and Management Boards. We executed new management agreements with each member of our Management Board in 2022.

Indemnification Agreements

In connection with our global offerings in 2021 and 2022, we have entered into indemnification agreements with each of our Management Board and Supervisory Board members. We have liability insurance for 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 believe that this insurance and these agreements are necessary to attract qualified Management Board and Supervisory Board members.

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 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 Management Board or Supervisory Board 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 Supervisory Board 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 Management Board and Supervisory Board 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 Management and Supervisory Board members 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 Supervisory Board, 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 Management Board or Supervisory Board in the event that the related person is a member of the Management Board or Supervisory Board, immediate family member of a member of the Management Board or Supervisory Board or an entity with which a member of Management Board or Supervisory Board 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 Supervisory Board 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 Supervisory Board determines in the good faith exercise of its discretion.

All of the transactions described above were entered into prior to the adoption of the written policy, but 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 our prospectus dated October 28, 2021, filed with the SEC pursuant to Rule 424(b), under the headings “Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares,” “Description of Share Capital—Differences in Corporate Law,” and “Limitations Affecting Shareholders of a French Company” 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 (€4.9 million) recognized as of December 31, 2022.

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.

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 BN Distribution Agreements commenced on January 1, 2022 and shall continue until December 31, 2024. Unless terminated earlier this initial term will automatically extend by two years to terminate on December 31, 2026.

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 majeur 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 our Product Candidates

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 2022 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 3 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 2 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 2 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 Fundacao 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 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.

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 breakdown of expenses and commitments has been submitted to the EC in accordance with the requirements of the contract.

The EC APA remained in effect until all quantities of the Product ordered under the EC APA, as amended, were delivered.

As a result of the amendment and the reduction in the volume of orders from Member States, we have suspended production of VLA2001 and, as of December 31, 2022, have fully provided for €176.9 million of our remaining COVID-related inventory. For further information, please refer to Note 5.18 to our financial statements for the year ended December 31, 2022, included elsewhere in this Annual Report.

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 will continue until Dynavax has delivered all of the Product ordered by Valneva, unless terminated earlier in accordance with the terms of the agreement. Either party may terminate the agreement upon an uncured material breach of the agreement by or insolvency of the other party.

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, 2022, 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, 2022. 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.

This discussion applies only to investors that are entitled to Treaty benefits under the "Limitation on Benefits" provisions contained in 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 benefices 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, 2022, our market capitalization did not exceed 1 billion euros, pursuant to BOI-ANNX-000467-21/12/2022.

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.

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 abovementioned registration duties. As a result, transfer of ADSs should remain outside of the scope of such registration duties.

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-20-20-20-20-12/09/2012 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.

In any case, individual taxpayers who are not fiscally domiciled in France should not have to comply with these procedures if the French withholding tax applying to them is lower than 15%.

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 under those requirements will 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 will 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 required.

J. Annual Report to Security Holders.

Not required.

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 thousands	**Year ended December 31,**	
	2022	**2021**
EUR/USD +10%	13,873	6,818
EUR/USD -10%	(16,956)	(8,334)
EUR/GBP +10%	(6,605)	(11,986)
EUR/GBP -10%	8,073	14,650
EUR/SEK +10%	(2,761)	(2,884)
EUR/SEK -10%	3,374	3,525
EUR/CAD +10%	(616)	(557)
EUR/CAD -10%	753	681

As at December 31, 2022, the increase in the foreign currency exchange risk in USD was mainly caused by a significant increase in intercompany receivables denominated in USD in Valneva Austria GmbH.

As at December 31, 2022, the decrease in the foreign currency exchange risk in GBP was caused by lower refund liabilities denominated in GBP in Valneva Austria GmbH relating to the COVID-19 vaccine program.

As at December 31, 2022, there are no material changes in the foreign currency exchange risk in SEK, which is in line with the stable level of intercompany receivables within the group denominated in SEK.

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 2022, as well as 2021 and 2020, 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, 2022 and December 31, 2021, 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. Most of the trade receivables are receivables from governmental institutions with high credit rating (AAA-country or AA-country).

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 €6.7 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, 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, 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 €6.9 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, 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

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, 2022. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2022, as a result of the material weaknesses described below.

After giving full consideration to these material weaknesses, and the additional analyses and other procedures that we performed to ensure that our consolidated financial statements included in this Annual Report on Form 20-F were prepared in accordance with IFRS, our management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with IFRS.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls 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 GAAP.

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, and as a result of the material weaknesses described below, management has concluded that our internal control over financial reporting was not effective as of December 31, 2022.

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.

We 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 material weaknesses in these components of the COSO framework resulted from the lack of resources within Valneva, commensurate with the nature, growth and complexity of its business.

We have 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. Management identified a deficiency in one of the principles associated with the Risk Assessment component of the COSO framework as we 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. We 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. We identified a deficiency in one of the principles associated with the Information and Communication component of the COSO framework as we did not establish a process to identify, maintain, and develop all control activities over the financial consolidation and reporting system. Further, we 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.

The above control deficiencies constitute material weaknesses, either individually or in the aggregate, are pervasive in nature and impact all significant accounts and disclosures.

PricewaterhouseCoopers Audit and Deloitte & Associés, independent registered accounting firms, have issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2022, which expressed an adverse opinion thereon.

Remediation Progress and Plan

We have taken steps to address these material weaknesses and expect to continue to implement the remediation plan, which we believe will address the underlying causes.

We continue to monitor and adjust the longer-term resource needs of our various functions and reallocate responsibilities across the organization to ensure that the appropriate level of knowledge and experience is applied based on risk and complexity of transactions and tasks under review.

We will be supported by external advisors with subject matter expertise and additional resources to provide assistance with all elements of the internal control over financial reporting program, including reinforcement of our risk assessment; documentation of process flows; design and remediation of control deficiencies; and evaluation of the design and operational effectiveness of our internal controls.

We will continue to establish policies and procedures to support deployment of management's directives and control activities and to establish responsibility and accountability for executing policies and procedures in a timely manner.

We will continue to design and implement a set of controls over the financial consolidation and reporting system.

We strengthened our team and hired advisors with experience in internal controls over financial reporting. We will continue to deploy an annual testing plan that includes monitoring and operation of internal controls and addressing control deficiencies in order to assist with the monitoring of control activities.

We are continuing to develop and implement remediation plans; however, we cannot assure you that our efforts will be effective, that we will be able to remedy these material weaknesses or that we will be able to prevent any future material weaknesses in our internal control over financial reporting. We will not be able to conclude that we have remediated the material weaknesses until all relevant controls are fully implemented and have operated effectively for a sufficient period of time. See also "Item 3. Key Information—D. Risk factors— There are 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."

Changes in Internal Control Over Financial Reporting

Other than as noted above in "Management's Annual Report on Internal Control over Financial Reporting", 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.

Attestation Report of the Registered Public Accounting Firm

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Shareholders and Management Board of Valneva

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Valneva and its subsidiaries (together the "Company") as of December 31, 2022, 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, because of the effect of the material weaknesses identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2022, 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 balance sheet of the Company as of December 31, 2022 and the related consolidated statement of income (loss), comprehensive income (loss), statement of changes in equity and statement of cash flows for the year ended December 31, 2022 (collectively the "consolidated financial statements"). Our report dated March 30, 2023 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.

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 financial statements will not be prevented or detected on a timely basis.

The following material weaknesses have been identified and included in management's assessment. As described in Management's Annual Report on Internal Control over Financial Reporting, management 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 the Company's system of internal control over financial reporting in the remaining COSO framework components. Management identified a deficiency in one of the principles associated with the Risk Assessment component of the COSO framework as management did not design and implement an effective risk assessment to identify and assess all changes in the business that could impact the Company's system of internal control. Management also identified deficiencies in 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. Management identified a deficiency in one of the principles associated with the Information and Communication component of the COSO framework as management did not establish a process to identify, maintain, and develop all control activities over the financial consolidation and reporting system. Further, management 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. The above control deficiencies constitute material weaknesses, either individually or in the aggregate, are pervasive in nature and impact all significant accounts and disclosures.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2022 of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte & Associés /s/ PricewaterhouseCoopers Audit

Bordeaux and Neuilly-sur-Seine, France

March 30, 2023

Deloitte & Associés and PricewaterhouseCoopers Audit have served as the Company's auditors since 2007 and 2012, respectively.

Item 16. [Reserved]

A. Audit Committee Financial Expert

Our Supervisory Board has determined that Ms. Tetlow, Mr. Sulat, and Mr. Connolly are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Supervisory Board has further determined that Ms. Tetlow 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 Management Board and Supervisory Board. 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, 2022 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, 2022 and 2021.

Principal Accountant Fees and Services:

€ in thousand	**Year ended December 31,**							
	PricewaterhouseCoopers				**Deloitte & Associés**			
	2022	**%**	**2021**	**%**	**2022**	**%**	**2021**	**%**
Audit fees	**1,891**	**99 %**	**1,122**	**91 %**	**1,678**	**99 %**	**1,113**	**93 %**
provided by the statutory auditor	**1,386**	**—**	**937**	**—**	**1,376**	**—**	**939**	**—**
provided by the statutory auditor's network	**505**	**—**	**185**	**—**	**302**	**—**	**174**	**—**
Audit-related Fees	**0**	**—**	**90**	**7 %**	**13**	**1 %**	**85**	**7 %**
provided by the statutory auditor	**0**	**—**	**85**	**—**	**13**	**—**	**85**	**—**
provided by the statutory auditor's network	**0**	**—**	**5**	**—**	**0**	**—**	**0**	**—**
Tax Fees	**25**	**1 %**	**25**	**2 %**	**0**	**—**	**0**	**—**
provided by the statutory auditor's network	**25**	**—**	**25**	**—**	**0**	**—**	**0**	**—**
All Other Fees	**0**	**—**	**0**	**—**	**0**	**—**	**0**	**—**
Total	**1,916**	**100 %**	**1,238**	**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. In 2021, audit-related fees comprised mainly fees for the IPO project.

"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 Middlenext code, which recommends that a majority of the members of the Supervisory Board 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 Supervisory Board, (ii) each committee of the Supervisory Board have a formal written charter or (iii) our independent members of the Supervisory Board hold regularly scheduled meetings at which only independent members of the Supervisory Board 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 33 1/3% 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.

H. Mine Safety Disclosure.

Not applicable.

I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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†	SARS-CoV-2 Vaccine Supply Agreement, dated September 13, 2020, by and among the Secretary of State for Business, Energy and Industrial Strategy, Valneva SE and Valneva Austria GmbH, as amended on December 17, 2020 and January 30, 2021.	F-1	333-255155	10.2	April 9, 2021
4.3 †	Advance Purchase Agreement, dated January 12, 2021, by and between the European Commission and Valneva Austria GmbH.	20-F	001-40377	10.3	March 24, 2022
4.4†	Supply Agreement, dated September 12, 2020, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.	F-1	333-255155	10.3	April 9, 2021
4.5 †	Amendment to Supply Agreement, dated October 28, 2021, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.	20-F	001-40377	10.5	March 24, 2022
4.6†*	Amendment to Supply Agreement, dated March 8, 2022, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.				
4.7†	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
4.8†	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
4.9†*	Product Schedule, dated December 16, 2022, by and between IDT Biologika GmbH and Valneva Austria GmbH.				
4.10†	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
4.11†	Distribution Agreement, dated December 9, 2015, by and between GlaxoSmithKline GmbH & Co. KG and Valneva Austria GmbH.	F-1	333-255155	10.5	April 9, 2021
4.12†	Sublicense Agreement, dated April 14, 2003, by and between VaccGen International LLC and Intercell AG, as assigned to the Registrant and as amended.	F-1	333-255155	10.6	April 9, 2021

4.13†	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
4.14†	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
4.15†	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
4.16#†	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.	F-1	333-255155	10.9	April 9, 2021
4.17†	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
4.18†	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
4.19	Terms and Conditions Applicable to BSA 27 Equity Warrants and Form of Exercise Notice	F-1	333-255155	10.2	April 9, 2021
4.20†	Settlement Agreement, dated June 15, 2022, by and between Valneva Austria GMBH, Valneva S.E., The Secretary of State for Business, Energy and Industrial Strategy, and The Secretary of State for Health and Social Care.	6-K	001-40377	10.1	August 15, 2022
4.21	Fourth Amendment to Credit Agreement dated January 3, 2022, by and between Valneva Austria GmbH, the Lenders party thereto and Wilmington Trust, National Association	6-K	001-40377	10.2	August 15, 2022
4.22	Fifth Amendment to Credit Agreement dated April 25, 2022 by and between Valneva SE, Valneva Austria GmbH, the Lenders party thereto and Wilmington Trust, National Association	6-K	001-40377	10.3	August 15, 2022
4.23†	Amendment to the Advanced Purchase Agreement dated August 1, 2022, by and between Valneva Austria GmbH and the European Commission	6-K	001-40377	10.4	August 15, 2022
4.24†	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
4.25†	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
4.26†	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
4.27†*	Amendment No. 4 to Research Collaboration and License Agreement dated November 22, 2022, by and between Valneva Austria GmbH and Pfizer Inc.				

4.28†*	**Distribution Agreement, dated December 15, 2022, by and between Valneva SE and VBI Vaccines Inc.**				
4.29+	**Employee Stock Option Plan 2013**	**F-1**	**333-255155**	**10.1**	**April 9, 2021**
4.30+	**Employee Stock Option Plan 2015**	**F-1**	**333-255155**	**10.1**	**April 9, 2021**
4.31+	**Employee Stock Option Plan 2016**	**F-1**	**333-255155**	**10.1**	**April 9, 2021**
4.32+	**Employee Stock Option Plan 2017**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.33+	**Employee Stock Option Plan 2019**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.35+	**Free Convertible Preferred Share Plan 2017-2021**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.36+	**Free Share Plan 2019-2023**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.37+*	**Free Ordinary Share Plan 2022-2025**				
4.38+*	**Special Free Ordinary Share Plan 2022-2025 N°2**				
4.39+	**Phantom Stock Option Plan 2017 and Form of Exercise Notice**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.40+	**Phantom Stock Option Plan 2019**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.41+	**Phantom Stock Plan 2020**	**F-1**	**333-255155**	**10.2**	**April 9, 2021**
4.42	**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**
8.1	**Subsidiaries of the Registrant**	**F-1**	**333-255155**	**21.1**	**April 9, 2021**
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**				
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 30, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Shareholders and Management Board of Valneva

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Valneva and its subsidiaries (together the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of income (loss), comprehensive income (loss), statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 30, 2023 expressed an adverse opinion on the Company's internal control over financial reporting because material weaknesses existed.

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 Matter

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 separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Other Revenues — Significant agreements modifications — Notes 5.3.1 Critical judgements in applying the Group's accounting policies, 5.3.2 Key sources of estimation uncertainty, 5.5.2 Other revenues, 5.28 Contract liabilities and 5.29 Refund liabilities to the consolidated financial statements

Critical Audit Matter Description

The Company recognized other revenues or reversed previously recognized other revenues with customers, specifically the UK Authority ("UK"), the European Commission ("EC") and Pfizer, for agreements which have either been terminated or modified. During the twelve months period ended December 31, 2022, other revenues recognized for these modifications to agreements were € 234.1 million, including €169.2 million and €110.8 million related to the Covid-19 Vaccine Supply Agreement with the UK and Covid-19 Advance Purchase Agreement with the EC, respectively, and a reversal of €45.9 million related to the Lyme - Pfizer Collaboration and License Agreement.

The Company previously received advance or milestone payments, which were recognized as contract liabilities or refund liabilities in the prior year's financial statements. Other revenue is only recognized when it is highly probable that it will not

reverse in the future. The accounting for these modifications involves a higher level of judgment, particularly as it relates to the interpretation of contractual clauses and remaining performance obligations.

As at December 31, 2022, management assessed that :

- Valneva's risk of repayment due to residual obligations to the UK was remote;
- Valneva's risk of reimbursement of the down payments received from the EC was remote.

In addition, as a result of the Lyme-Pfizer Collaboration and License Agreement amendments which occurred in 2022, Management updated the estimated transaction price and assessed it was no longer highly probable that a significant reversal in the amount of revenue recognized would not occur. Therefore, the Company recorded a reversal of the cumulated other revenues previously recognized accordingly.

We identified other revenues on significant agreements modifications as a critical audit matter because of the significant judgments management made to evaluate remaining performance obligations and contractual clauses used to recognize other revenue for modified or terminated agreements. This required extensive audit effort due to the complexity of modified and terminated contracts and a high degree of auditor judgment when performing audit procedures to audit management's analysis and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

The audit procedures related to management's evaluation of remaining performance obligations and contractual clauses used to recognize revenue for modified or terminated contracts included the following, among others:

- evaluating, with professionals with specialized skill and knowledge, the Company's analysis of the agreements, amendments and termination agreements entered between Valneva and Pfizer, the UK and the EC, including their interpretation of the terms and conditions and their assessment of the accounting treatments for these modifications of agreements.
- assessing the reasonableness of the significant judgments made by management by:
    - Making inquiries of management, and of the Company's internal legal counsel, to understand the implications of the settlement agreement signed with the UK Government, in relation to the risk of Valneva's potential repayment obligation;
    - Making inquiries of management and review of Steering Committee minutes, to understand the implications of the Lyme-Pfizer Agreement amendments on the estimate of the transaction price;
    - Involving our legal professionals, who possess the specialized skills and knowledge, to assist in evaluating the Company's assessment of the legal implications of the use of the down payment made by the Company in connection with the Advance Purchase Agreement between the EC and Valneva and of the termination agreement of the Covid-19 Vaccine Supply Agreement with the UK;
    - Obtaining and analyzing correspondence between the Company and EC and UK, to evaluate management's assessment in relation to the risk of Valneva's potential repayment obligation.
- testing the mathematical accuracy of the calculation of the change in transaction price of the Lyme - Pfizer Collaboration and License Agreement.

/s/ Deloitte & Associés /s/ PricewaterhouseCoopers Audit

Bordeaux and Neuilly-sur-Seine, France
March 30, 2023

Deloitte & Associés and PricewaterhouseCoopers Audit have served as the Company's auditors since 2007 and 2012, respectively.

CONSOLIDATED FINANCIAL STATEMENTS 2022

VALNEVA

A European Company (*Societas Europaea*) with a Management and a Supervisory Board
Registered offices:
6 rue Alain Bombard, 44800 SAINT-HERBLAIN - France
Nantes Companies Register (RCS) No. 422 497 560

Consolidated financial statements

as at December 31, 2022

TABLE OF CONTENTS

1. CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

1.1 Consolidated Statements of Income (Loss)

(In € thousand) (Except per share amounts)	Note	Year ended December 31,		
		2022	2021	2020
Product sales	5.4/5.5	114,797	62,984	65,938
Other revenues	5.4/5.5	246,506	285,101	44,383
REVENUES		**361,303**	**348,086**	**110,321**
Cost of goods and services	5.4/5.6	(324,441)	(187,920)	(54,302)
Research and development expenses	5.4/5.6	(104,922)	(173,283)	(84,454)
Marketing and distribution expenses	5.4/5.6	(23,509)	(23,643)	(18,264)
General and administrative expenses	5.4/5.6	(34,073)	(47,606)	(27,539)
Other income and expenses, net	5.4/5.8	12,199	22,976	19,117
OPERATING LOSS		**(113,443)**	**(61,390)**	**(55,120)**
Finance income	5.9	260	249	516
Finance expenses	5.9	(19,054)	(16,964)	(10,738)
Foreign exchange gain/(loss), net	5.9	(12,587)	8,130	173
Result from investments in associates	5.16	9	(5)	(133)
LOSS BEFORE INCOME TAX		**(144,815)**	**(69,979)**	**(65,302)**
Income tax benefit/(expense)	5.10	1,536	(3,446)	909
LOSS FOR THE PERIOD		**(143,279)**	**(73,425)**	**(64,393)**
Losses per share for loss for the period attributable to the equity holders of the Company (expressed in € per share)	5.11			
Basic		**(1.24)**	**(0.75)**	**(0.71)**
Diluted		**(1.24)**	**(0.75)**	**(0.71)**

The accompanying Notes form an integral part of these financial statements.

“Foreign exchange gain/(loss), net” was reclassified from the categories “Finance income” and "Finance expenses" for period starting January 1, 2022. The comparable periods were adjusted accordingly to maintain the comparability.

1.2 Comprehensive Income (Loss)

€ in thousand	Note	Year ended December 31,		
		2022	2021	2020
Loss for the period		**(143,279)**	**(73,425)**	**(64,393)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit or loss				
Currency translation differences	5.22.1	(73)	(2,877)	2,438
Items that will not be reclassified to profit or loss				
Defined benefit plan actuarial gains/(losses)	5.30.1	178	205	(78)
Other comprehensive income/(loss) for the year, net of tax		**105**	**(2,672)**	**2,360**
TOTAL COMPREHENSIVE LOSS FOR THE YEAR ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(143,174)**	**(76,097)**	**(62,033)**

The accompanying Notes form an integral part of these financial statements.

2 CONSOLIDATED BALANCE SHEETS

(In € thousand)	Note	As at December 31,	
		2022	2021
ASSETS			
Non-current assets		**196,685**	**231,520**
Intangible assets	5.12	28,711	32,700
Right of use assets	5.13	41,603	48,285
Property, plant and equipment	5.14	112,435	125,545
Investments in associates	5.16	—	2,124
Deferred tax assets	5.10.2	5,637	3,582
Other non-current assets	5.20	8,299	19,282
Current assets		**424,660**	**585,832**
Inventories	5.18	35,104	124,098
Trade receivables	5.19	23,912	44,013
Other current assets	5.20	74,079	71,036
Cash and cash equivalents	5.21	289,430	346,686
Assets classified as held for sale	5.16	2,134	—
TOTAL ASSETS		**621,344**	**817,352**
EQUITY			
Capital and reserves attributable to the Company's equity holders		**219,797**	**170,581**
Share capital	5.22	20,755	15,786
Share premium	5.22	594,043	409,258
Other reserves	5.22.1	55,252	52,512
Retained earnings/(Accumulated deficit)	5.22	(306,974)	(233,549)
Loss for the period		(143,279)	(73,425)
LIABILITIES			
Non-current liabilities		**124,156**	**277,791**
Borrowings	5.24	87,227	50,726
Lease liabilities	5.13/5.27	28,163	53,687
Contract liabilities	5.28	—	4,741
Refund liabilities	5.29	6,635	158,970
Provisions	5.30	1,320	8,308
Deferred tax liabilities	5.10.2	694	1,290
Other liabilities	5.31	116	69
Current liabilities		**277,392**	**368,979**
Borrowings	5.24	11,580	7,107
Trade payables and accruals	5.25	41,491	68,119
Income tax liability		532	83
Tax and Employee-related liabilities	5.26	15,738	17,249
Lease liabilities	5.13/5.27	25,411	3,135
Contract liabilities	5.28	9,411	124,017
Refund liabilities	5.29	136,450	95,611
Provisions	5.30	31,257	48,708
Other liabilities	5.31	5,523	4,950
TOTAL LIABILITIES		**401,547**	**646,771**
TOTAL EQUITY AND LIABILITIES		**621,344**	**817,352**

The accompanying Notes form an integral part of these financial statements.

3 CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Year ended December 31,		
		2022	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss for the year		(143,279)	(73,425)	(64,393)
Adjustments for non-cash transactions	5.32	44,070	56,476	37,941
Changes in non-current operating assets and liabilities	5.32	(147,713)	59,353	88,472
Changes in working capital	5.32	1,732	36,127	77,740
Cash generated from operations	5.32	**(245,189)**	**78,532**	**139,759**
Income tax paid		(154)	(1,631)	(2,021)
NET CASH GENERATED FROM OPERATING ACTIVITIES		**(245,343)**	**76,901**	**137,738**
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property, plant and equipment	5.14	(29,246)	(92,229)	(18,936)
Proceeds from sale of property, plant and equipment	5.32	8	—	—
Purchases of intangible assets	5.12	(76)	(942)	(535)
Proceeds from sale of intangible assets	5.32	—	—	24
Interest received		260	54	107
NET CASH USED IN INVESTING ACTIVITIES		**(29,054)**	**(93,116)**	**(19,340)**
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from issuance of common stock, net of costs of equity transactions	5.23	189,837	166,614	75
Disposal of treasury shares	5.22.1	—	209	215
Proceeds from borrowings, net of transaction costs	5.24/5.32.2	39,331	859	50,266
Repayment of borrowings	5.24/5.32.2	(1,793)	(1,956)	(21,995)
Payment of lease liabilities	5.13/5.27	(3,048)	(2,805)	(2,111)
Interest paid		(9,211)	(8,417)	(4,711)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES		**215,116**	**154,504**	**21,740**
NET CHANGE IN CASH AND CASH EQUIVALENTS		**(59,282)**	**138,288**	**140,138**
Cash and cash equivalents at beginning of the year		346,642	204,394	64,439
Exchange gains/(losses) on cash		(828)	3,960	(183)
Restricted cash	5.21	2,898	44	41
CASH AND CASH EQUIVALENTS AT END OF THE YEAR		**289,430**	**346,686**	**204,435**

The accompanying Notes form an integral part of these financial statements.

4 CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(In € thousand) (except number of shares)	Note	Number of shares issued	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2020		**90,943,812**	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Total comprehensive income/(loss)		—	—	—	2,360	—	(64,393)	(62,033)
Income appropriation		—	—	—	—	(1,744)	1,744	—
Share-based compensation expense:	5.23							
Value of services		—	—	—	4,012	—	—	4,012
Exercises		*26,750*	4	71	—	—	—	75
Treasury shares		—	—	—	215	—	—	215
BALANCE AS AT DECEMBER 31, 2020		**90,970,562**	**13,646**	**244,984**	**52,342**	**(169,156)**	**(64,393)**	**77,422**
BALANCE AS AT JANUARY 1, 2021		**90,970,562**	**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:	5.23							
Value of services		—	—	—	2,632	—	—	2,632
Exercises		952,372	143	2,114	—	—	—	2,257
Treasury shares	5.22	(4,025)	(1)	—	209	—	—	209
Issuance of ordinary shares, May 2021	5.22	8,145,176	1,222	88,375	—	—	—	89,597
Issuance of ordinary shares, November 2021	5.22	5,175,000	776	87,199	—	—	—	87,975
Cost of equity transactions, net of tax	5.22	—	—	(13,414)	—	—	—	(13,414)
BALANCE AS AT DECEMBER 31, 2021		**105,239,085**	**15,786**	**409,258**	**52,512**	**(233,549)**	**(73,425)**	**170,581**

(In € thousand) (except number of shares)	Note	Number of shares issued	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2022		**105,239,085**	**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:	5.23							
Value of services		—	—	—	2,635	—	—	2,635
Exercises		2,578,636	387	3,371	—	—	—	3,758
Treasury shares	5.22	—	—	—	—	—	—	—
Issuance of ordinary shares, June 2022	5.22	9,549,761	1,432	89,195	—	—	—	90,627
Issuance of ordinary shares, October 2022	5.22	21,000,000	3,150	99,750	—	—	—	102,900
Cost of equity transactions, net of tax	5.22	—	—	(7,531)	—	—	—	(7,531)
BALANCE AS AT DECEMBER 31, 2022		**138,367,482**	**20,755**	**594,043**	**55,252**	**(306,974)**	**(143,279)**	**219,797**

The accompanying Notes form an integral part of these financial statements.

5 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

5.1 General information and significant events of the period

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 to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against chikungunya virus and Lyme disease.

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
- VLA2001, the only inactivated whole-virus COVID-19 vaccine approved in Europe.

Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the United States and over 700 employees.

Valneva SE is a public company listed on the Euronext Paris (symbol: VLA) and on the Nasdaq Global Select Market (symbol: VALN) since May 2021.

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	Interest held as at December 31,	
			2022	2021
BliNK Biomedical SAS[1]	FR	Equity method[2]	48.9%	48.9%
Vaccines Holdings Sweden AB	SE	Consolidation	100%	100%
Valneva Austria GmbH	AT	Consolidation	100%	100%
Valneva Canada Inc.	CA	Consolidation	100%	100%
Valneva France SAS	FR	Consolidation	100%	100%
Valneva Scotland Ltd.	UK	Consolidation	100%	100%
Valneva Sweden AB	SE	Consolidation	100%	100%
Valneva UK Ltd.	UK	Consolidation	100%	100%
Valneva USA, Inc.	US	Consolidation	100%	100%

[1]See Note 5.16
[2]The investment in BliNK Biomedical SAS was reclassified from “Investments in associates” to “Assets classified as held for sale” as at June 30, 2022.

The closing date for the consolidated financial statements is December 31st of each year.

The Company is registered at 6 rue Alain Bombard, 44800 Saint-Herblain, France.

The Company’s site in Saint-Herblain (Nantes, France) includes general and administrative functions and research and development (R&D) facilities. The Valneva SE site in Lyon operates commercial activities.

Vaccines Holdings Sweden AB is the holding company of Valneva Sweden AB.

Valneva Austria GmbH (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 and ENCEPUR.

Valneva Canada Inc. (Montreal, Quebec) commercializes IXIARO, DUKORAL and third-party products such as KAMRAB and RABIPUR .

Valneva France SAS (Lyon, France) commercializes IXIARO, DUKORAL and third-party products such as RABIPUR and ENCEPUR.

Valneva Scotland Ltd. (Livingston, Scotland) is primarily involved in the production of IXIARO and Valneva's chikungunya vaccine candidate VLA1553, which is currently in the development phase. Valneva Scotland Ltd. was also involved in the production of VLA2001 prior to suspension of its manufacturing.

Valneva Sweden AB (Solna, Sweden) manufactures DUKORAL and commercializes DUKORAL, IXIARO and third-party products such as Moskito Guard and other vaccines in the Nordic countries. In addition, Valneva Sweden AB provided R&D services and filling services for VLA2001.

Valneva UK Ltd. (based nearby London, United Kingdom) commercializes DUKORAL, IXIARO and third-party products such as RABIPUR in the United Kingdom.

Valneva USA, Inc. focuses on the commercialization of IXIARO to the U.S. military and the U.S. private market.

SIGNIFICANT EVENTS OF THE PERIOD

Impact of COVID-19

The Group has been and could continue to be materially adversely affected by the current COVID-19 pandemic in regions where Valneva has significant manufacturing facilities, concentrations of clinical trial sites, or other business operations. COVID-19 adversely impacted sales of travel vaccines, with travel to endemic areas significantly reduced compared to 2019 (pre-pandemic). DUKORAL and IXIARO are aimed at diseases that primarily threaten travelers to particular regions (e.g. Asia). As a result, sales of these vaccines decreased significantly in 2020 and 2021, adversely impacting the Group's financial results. Throughout 2022, the COVID emergency rules were relaxed in most parts of the world, resulting in a significant resumption of international travel, albeit not reaching pre-COVID levels. This trend of growing international travel is expected to continue in the new year. The Group's product sales will continue to be affected by the amount of international travel, and Valneva may not be able to complete the development of its vaccine candidates without additional financing if the travel industry does not recover as expected. Valneva continues to closely monitor how the pandemic and related response measures are affecting the Company's business. Valneva reported cash and cash equivalents of €289.4 million as at December 31, 2022. Although it is difficult to predict future liquidity requirements, the Group's management considered that the existing cash and cash equivalents as at December 31, 2022 will be sufficient to fund its operations for at least the next 12 months from the authorization of publication of these consolidated financial statements. For details on liquidity risk, see Note 5.2.5.

Impact from COVID-19, including the COVID segment (VLA2001 vaccine development), is described in the following Notes as at December 31, 2022 and for the year ended December 31, 2022:

Impact from COVID-19	Note	
COVID segment	5.1/5.28/5.29	The Company developed VLA2001, a vaccine against the SARS-CoV-2 virus causing COVID-19, which was approved with Emergency Use Authorization from Bahrain in February 2022, with Conditional Marketing Authorization from UK MHRA and received a full Marketing Authorization by EMA in June 2022. Valneva sold 1.25 million doses of VLA2001 to certain countries in the European Commission. In 2022, Valneva sold 0.5 million doses of VLA2001 to the Kingdom of Bahrain and will sell 0.5 million doses in 2023. For further information, see Note 5.5. Capital investments for the manufacturing of VLA2001 were made. Due to the reduced demand for VLA2001, related equipment of €11.9 million, right of use assets of €1.0 million, leasehold improvements of €1.9 million and remaining inventory of €176.9 million were written off as at December 31, 2022. Of the impaired VLA2001 inventory, €159.4 million was written off in 2022. All other COVID equipment will be used within other segments from 2022 onwards. From 2022 onward COVID is no longer a CGU for the purpose of the impairment test. For more information see Note 5.15.
Revenues from contracts with customers	5.5	Valneva's total product sales reached €114.8 million in 2022 compared to €63.0 million in 2021, an increase of 82.3%. This was driven by a continued recovery of travel vaccine sales that surpassed expectations, complemented by COVID-19 vaccine sales in Europe and Bahrain (€29.6 million). IXIARO/JESPECT sales were €41.4 million in 2022 compared to €45.1 million in 2021, a decrease of 8.4%, 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 IXIARO/JESPECT private sales reaching €28.8 million in 2022 compared to €7.1 million in 2021. DUKORAL sales were €17.3 million in 2022 compared to €2.4 million in 2021, an increase of 610.3%, also benefitting from the significant recovery in the private travel markets. Third Party product sales grew to €26.5 million in 2022 compared to €15.4 million in 2021, an increase of 72.1%.
Inventories	5.18	While the write-down for IXIARO and DUKORAL which is expected not to be sold before the expiry date was reduced to €2.9 million, COVID-related inventory of €176.9 million was written down as of December 31, 2022.
Trade receivables	5.19	An assessment of expected credit loss resulted in only a minor impact on the Group's figures.

Effects of climate change on the consolidated financial statements

In preparing the consolidated financial statements, Valneva's management has considered the impact of climate change. These considerations did not have a material impact on the financial reporting judgements and estimates in 2022, 2021 and 2020.

Significant agreements signed in the periods presented

COVID-19

Authorizations and Emergency Use granted by Health Authorities for Valneva's inactivated, adjuvanted COVID-19 vaccine, VLA2001 in 2022

In February 2022, the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain granted an Emergency Use Authorization for VLA2001.

In April 2022, Valneva announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) had granted a Conditional Marketing Authorization for VLA2001, for primary immunization in adults 18 to 50 years of age.

In May 2022, Valneva announced that the United Arab Emirates had granted Emergency Use Authorization for VLA2001.

In June 2022, Valneva announced that the European Commission (EC) had granted a marketing authorization for VLA2001 in Europe, for use as primary vaccination in people from 18 to 50 years of age. With this approval, VLA2001 became the first COVID-19 vaccine to receive a standard marketing authorization in Europe. The marketing authorization covers all 28 European Union Member States as well as Iceland, Liechtenstein, and Norway.

Vaccine Supply Agreement with the UK Authority from 2020, its termination in 2021 and Settlement Agreement of 2022

In September 2020, Valneva entered into a supply agreement (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.

In June 2022, Valneva 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. The Company continues to have certain other obligations pursuant to provisions of the UK Supply Agreement that survive its termination. For more information see Note 5.29.

Advance Purchase Agreement with the European Commission in 2021 and amendment in 2022

In November 2021, Valneva signed an Advance Purchase Agreement (APA) with the European Commission (the 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.

Kingdom of Bahrain and supply of VLA2001

In November 2021, Valneva and the Kingdom of Bahrain signed an APA for the supply of one million doses of VLA2001. In 2022, 0.5 million doses of VLA2001 were sold and €9.5 million of product sales revenue were recognized accordingly. As at December 31, 2022, accounts receivable and contract liabilities related to this agreement comprised €3.4 million and €3.8 million, respectively (December 31, 2021: accounts receivable: €3.8 million and contract liabilities: €3.8 million).

IDT Biologika GmbH (IDT) – Collaboration for the production of VLA2001

In November 2021, Valneva and IDT Biologika GmbH (IDT) announced their collaboration for the production of VLA2001. Under the collaboration, IDT was to produce VLA2001's drug substance at its Biosafety Level 3 facilities in Dessau-Roßlau, Germany, in addition to production taking place at Valneva's manufacturing site in Livingston, Scotland.

In September 2022, Valneva announced the decision to suspend manufacturing of the vaccine and wind-down of VLA2001-related activities in light of the reduced EC order.

In September 2022, Valneva Austria GmbH, Valneva SE (together referred to as Valneva) and IDT agreed to sign a settlement agreement under which they agreed to terminate their VLA2001 collaboration following the delivery of bulk vaccines to Valneva and taking into consideration existing order levels and inventories. Valneva agreed to pay IDT compensation in cash and in kind, in the form of specified equipment purchased by Valneva. As at December 31, 2022, a provision of €0.1 million related to the agreement with IDT (December 31, 2021: advance payments related to the agreement: €16.4 million).

LYME

In April 2020, Valneva signed an agreement with Pfizer (the Collaboration and License Agreement) 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. The Collaboration and License Agreement included a €116.9 million ($130 million) upfront payment to Valneva received in June 2020. Valneva is obligated to reimburse certain development costs incurred by Pfizer, through completion of the development program, which is expected to finish in 2024. The transaction price according to IFRS 15 was determined taking into consideration Valneva's expected refund obligation relating to its share of the development costs. The agreement includes research and development and service performance obligations for which revenue is recognized over time as well as a license performance obligation for which revenue is recognized at a point in time when Pfizer can benefit and use the license without Valneva's further involvement. The upfront payments, net of estimated refunds have been allocated to the performance obligations in proportion to their standalone selling prices. In addition, Valneva is entitled to receive partial reimbursement of research and development and service costs incurred. In the year ended December 31, 2021, €14.3 million was recognized as other revenues and was primarily related to the services performed. Additionally, as at December 31, 2021, €3.0 million of costs to obtain a contract was included in other non-current assets, and €79.6 million was recognized as discounted refund liabilities.

In June 2022 and in November 2022, Valneva and Pfizer updated the terms of their Collaboration and License Agreement. From May 1, 2022 onward, Valneva will fund 40% of the remaining shared development costs compared to 30% in the initial agreement. Pfizer will pay Valneva tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement. In addition, Valneva is eligible for up to

$100 million on the achievement of cumulative sales targets. The payment terms of the development cost reimbursements were also amended. Other future development and early commercialization milestones are $168 million. A development milestone due upon Pfizer's initiation of the Phase 3 study of $25 million was paid to Valneva in October 2022. In the year ended December 31, 2022, a reversal of €45.9 million was recognized as other revenues and primarily reflects the impact of the reduction in the highly probable portion of the transaction price. As at December 31, 2022, the discounted refund liability amounted to €135.5 million (December 31, 2021: €79.6 million), of which nil (December 31, 2021: €75.2 million) was recognized as a non-current refund liability. €3.7 million of costs to obtain a contract were included in other non-current assets as at December 31, 2022 (December 31, 2021: €3.0 million). For more details, see Note 5.5.2 and Note 5.29.

IXIARO

US Department of Defense (DoD)

In September 2020, the U.S. Department of Defense (DoD) awarded Valneva a new contract for the supply of IXIARO. The terms of the agreement, as subsequently amended in September 2021, included an initial base year followed by two option years, each with a range of minimum and maximum potential orders. The base year had a minimum value of approximately $53 million for 370,000 doses, and the first option year, which the DoD exercised in September 2021, had a minimum value of approximately $28.8 million for 200,000 doses. Valneva also agreed to provide additional inventory to the DoD 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 (€4.9 million) recognized as at December 31, 2022 (December 31, 2021: $5.4 million; €4.7 million). In August 2022, Valneva announced that DoD had decided not to exercise the second option year of the contract, as DoD considered its existing IXIARO supply adequate to meet current needs.

CHIKUNGUNYA

Coalition for Epidemic Preparedness Innovations (CEPI)

In July 2019, Valneva and Coalition for Epidemic Preparedness Innovations (CEPI) announced a new partnering agreement pursuant to which CEPI will provide Valneva up to $23.4 million for vaccine manufacturing and late-stage clinical development of Valneva's single-dose, live-attenuated vaccine (VLA1553) against chikungunya. In the fourth quarter of 2022, CEPI awarded Valneva an additional amount of $1.2 million.

In January 2021, Valneva and Instituto Butantan, a producer of immunobiological products, announced the signing of definitive agreements for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine candidate, VLA1553, in Low- and Middle-Income Countries (LMICs). This finalization follows the signing of a binding term sheet in May 2020. The collaboration falls within the framework of the $23.4 million funding agreement Valneva signed with CEPI in July 2019. Under the collaboration, Valneva transferred its chikungunya vaccine technology to Instituto Butantan, who will develop, manufacture, and commercialize the vaccine in LMICs. In addition, Instituto Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. The agreement includes small upfront and technology transfer milestones. As at December 31, 2022, €3.9 million was recognized as other revenues and €0.7 million was included in contract liabilities (December 31, 2021: €0.8 million included in contract liabilities, and €2.1 million recognised in other revenues in 2021).

FINANCING

In February 2022, Valneva announced that its subsidiary Valneva Scotland was awarded research and development funding of up to £20 million by Scottish Enterprise, Scotland's national economic development agency. The investment is comprised of two grants which build on the agency's longstanding engagement with Valneva and will benefit the Company's manufacturing site in Livingston. The grants were expected to be received over the next three years. In 2022, Valneva received €5.1 million (£4.3 million) under the first grant of

up to £12.5 million, which would support development related to the manufacture of Valneva's COVID-19 vaccine. Valneva did not receive any payments in 2022 relating to the second grant of up to £7.5 million, which will support development connected to Valneva's manufacturing processes for other vaccines. The funds received were classified as current liabilities as at December 31, 2022. Pursuant to the terms of the grants, Valneva could have to repay the funds received if it fails to comply with certain conditions, including conditions relating to employees at the Livingston site. Additionally, in 2020 Scottish Enterprise awarded Valneva Scotland funding of up to £0.9 million for development of the chikungunya vaccine. Of this total amount, €0.5 million (£0.4 million) was received in 2022. The funds received have been classified as current liabilities as at December 31, 2022.

In April 2022, Valneva signed an amendment to increase the principal amount of its existing €54.1 million ($60 million) debt financing agreement with funds managed by leading U.S.-based healthcare investment firms Deerfield and OrbiMed. The original loan agreement was signed in February 2020. The April 2022 amendment provided Valneva immediate access to €18.2 million ($20 million), with an additional $20 million available upon potential approval of VLA2001 by the EMA. This additional $20 million was drawn in September 2022 in the amount of €19.9 million. The increased funding will be used to further invest in research and development projects, including market access preparations for VLA1553. The loan interest rate 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, €92.3 million ($100.0 million) was drawn down and the carrying amount was €89.2 million ($95.0 million). As at December 31, 2021, €54.1 million ($60.0 million) was drawn down and the carrying amount was €49.7 million ($56.3 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.

In June 2022, Valneva signed an Equity Subscription Agreement with Pfizer. Pursuant to the Equity Subscription Agreement, Pfizer invested €90.6 million ($95 million) in Valneva, representing 8.1% of Valneva's then-existing 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. The equity investment closed on June 22, 2022.

In October 2022, Valneva announced the closing of a global offering to specified categories of investors of an aggregate of 21,000,000 new ordinary shares. The net proceeds from the global offering amounted to €95.5 million.

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 2022 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 by the Management Board on March 21, 2023 and authorized for issuance by the Supervisory Board on March 22, 2023.

5.2.2 Impact of new, revised or amended Standards and Interpretations

(a) ***New and amended standards adopted by the Group***

Standard - Interpretation – Amendment		Effective Date	Effects
Amendments to IFRS 3, IAS 16, and IAS 37	Reference to the Conceptual Framework, Proceeds before Intended use and Onerous Contracts - Cost of Fulfilling a Contract	January 1, 2022	None
Amendments to IFRS1, IFRS 9, IFRS 16 and IAS 41	Annual Improvements to IFRSs 2018-2020 Cycle	January 1, 2022	None

No IFRS Interpretations Committee's agenda decisions had any material impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

(b) ***New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2022, and not early adopted.***

The Group did not elect for early application of the following new standards, amendments and interpretations which were issued by the IASB but not mandatory as at January 1, 2022:

- IFRS 17 including Amendments to IFRS 17 – Insurance contracts
- Amendments to IAS 1 and IFRS Practice Statement 2 – Disclosure of Accounting Policies
- Amendments to IAS 8 – Definition of Accounting Policies
- Amendments to IAS 12 – Deferred Tax related to Assets and Liabilities arising from a Single Transaction

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.

Associates

Associates are entities over which the Company has significant influence.

5.2.4 Foreign currency translation

(a) ***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.

(b) ***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.

(c) ***Subsidiaries***

The results and financial position of all subsidiaries (none of which having 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;
- from 2021 onward, 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). In 2020, income and expenses for each income statement were converted using exchange rates applicable 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 and is closely supervised by the Management Board. The Group's risk management systems identify, evaluate and manage financial risks. The Management Board submits regular reports on its risk management systems, including the management of financial risks, to the Audit Committee of the Supervisory Board.

(a) ***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 ($). 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.

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.

The following table details the Group's sensitivity 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:

	Year ended December 31,	
(In € thousand)	**2022**	**2021**
EUR/$ +10%	13,873	6,818
EUR/$ -10%	(16,956)	(8,334)
EUR/GBP +10%	(6,605)	(11,986)
EUR/GBP -10%	8,073	14,650
EUR/SEK +10%	(2,761)	(2,884)
EUR/SEK -10%	3,374	3,525
EUR/CAD +10%	(616)	(557)
EUR/CAD -10%	753	681

As at December 31, 2022, the increase in the foreign currency exchange risk in $ were mainly caused by a significant increase in intercompany (IC) receivables denominated in $ in Valneva Austria GmbH.

As at December 31, 2022, the decrease in the foreign currency exchange risk in GBP was caused by lower refund liabilities denominated in GBP in Valneva Austria GmbH relating to the COVID-19 vaccine program (see Note 5.1).

As at December 31, 2022, there are no material changes in the foreign currency exchange risk in SEK, which is in line with the stable level of IC receivables within the group denominated in SEK.

While the Group utilized a hedging strategy to lower its exposure to non-Euro currencies, there is a business need to keep a certain level of non-Euro funds available in its accounts at any time in order to cover payment obligations denominated in GBP or $. In addition, revaluation of certain non-Euro cash balances is offset by revaluation of non-Euro denominated refund liabilities on the Group's balance sheet (see Note 5.29).

Interest rate risks

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 2022, as well as 2021 and 2020, the Group's investments at variable rates, as well as the borrowings at variable rates, were denominated in €, SEK, $, 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, 2022 and December 31, 2021, 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 risks***

The Group is exposed to credit risk. 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 as set by the Management Board. Most of the trade receivables are receivables from governmental institutions with high credit rating (AAA-country or AA-country). The credit quality of financial assets is described in Note 5.17.3.

(c) ***Liquidity risks***

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, 2022 will be sufficient to fund the operations for at least the 12 months from the date of authorization for issuance of these consolidated financial statements. For the existing 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.

AS AT 31 DECEMBER, 2021 (In € thousand)	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,121	48,560	20,534	1,765	—	—	77,980
Lease liabilities	4,060	29,011	5,761	12,798	9,928	1,905	63,464
Refund liabilities	101,070	132,355	55,000	12,720	—	—	301,145
Trade payables and accruals	68,119	—	—	—	—	—	68,119
Tax and employee-related liabilities[3]	10,101	—	—	—	—	—	10,101
Other liabilities	27	25	—	—	—	—	52
	190,499	**209,952**	**81,295**	**27,282**	**9,928**	**1,905**	**520,861**

[3]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.

AS AT 31 DECEMBER, 2022 (In € thousand)	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	11,629	74,815	44,859	939	—	—	132,242
Lease liabilities	26,674	5,915	5,706	11,620	9,568	80	59,563
Refund liabilities	140,098	—	7,000	—	—	—	147,098
Trade payables and accruals	41,491	—	—	—	—	—	41,491
Tax and employee-related liabilities[3]	10,778	—	—	—	—	—	10,778
Other liabilities	87	—	—	—	—	—	87
	230,756	**80,731**	**57,565**	**12,559**	**9,568**	**80**	**391,260**

[3]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 sufficient 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-sustainable 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 and Note 5.29: Revenue recognition of other revenues/refund liabilities: management’s judgement is required to determine the identification and separation 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 for the first three items in the context of the terminations of:
  - the UK Supply Agreement;
  - the EC APA;
  - the strategic alliance agreements (SAA) with GlaxoSmithKline (GSK) terminated in 2019; and
  - the Research Collaboration and License Agreement with Pfizer and several amendments thereto;
- Notes 5.8 and 5.31: Other income/Other liabilities: The Group receives funding from CEPI, which includes performance obligations and refund obligations. Management’s judgement is required to determine whether such components of an agreement are revenues from customers or fall within the standard of accounting for government grants. CEPI is a global partnership between public, private, philanthropic, and civil society organizations. Because CEPI is a non-governmental organization and acts in the way a government organization would, it was accounted for under IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance). In addition, the valuation of the various components required Management’s judgement;

- Note 5.13: Lease term: When determining lease terms, the Group makes judgements regarding whether it is reasonably certain that it will exercise renewal or early termination options.

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 5.5.1: 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 and 5.31: Other income/other liabilities: estimates of income recognized and repayments from grants, measured according to cost incurred compared to the budget;
- Note 5.10: 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 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 Management Board. 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 5.18: 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 2023 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. Given the significant changes to the ordered volumes of VLA2001 and the expected future demand, the related inventory which is not expected to be used before expiry date was written off;
- Note 5.23: 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: (1) As at December 31, 2022, for the royalty obligation under the UK Supply Agreement, the likelihood for this future obligation was assessed as remote. (2) As at December 31, 2022, management has assessed the likelihood of the repayment obligation under the UK Supply Agreement from the UK Authority for funding of certain capital expenditures as remote. (3) In 2022, the recognition and classification of the refund obligation related to Pfizer following the amendments of the

Research Collaboration and License Agreement were reassessed. (4) As at December 31, 2022, management has assessed the likelihood of the repayment of advance payments received under the Advance Purchase Agreement with the European Commission as remote;

- Notes 5.30 and 5.33: 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.

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 5.17: financial instruments; and
- Note 5.23: share-based payment arrangements.

5.4 Segment information

The Company's Management Board, as its chief operating decision maker, considers the operational business from a product rather than geographic perspective and has identified four reportable segments. Key performance indicators include revenue and operating profitability.

The individual segments consist of the following:

- "Commercialized products" (marketed vaccines, currently the Group's vaccines IXIARO and DUKORAL as well as third-party products)
- "COVID" (development, manufacturing, and distribution related to VLA2001)
- "Vaccine candidates" (proprietary research and development programs aiming to generate new products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding the COVID-19 vaccine candidate, which is presented separately). With the transfer of the license of Valneva's Lyme vaccine candidate VLA15 to Pfizer in December 2020, all related revenues and costs were moved from the "Vaccine candidates" segment to the "Technologies and services" segment.
- "Technologies and services" (services and inventions at the commercialization stage, i.e. revenue generated through collaborations, service, and licensing agreements). With the transfer of the license of

Valneva's VLA15 Lyme vaccine candidate to Pfizer in December 2020, all related revenues and costs were moved from the "Vaccine candidates" segment to the "Technologies and services" segment.

5.4.1 Income statement by segment

Income statement by segment for the year ended December 31, 2020

(In € thousand)	Commer-cialized products	COVID	Vaccine candidates	Techno-logies and services	Corporate Overhead	Total
Product sales	65,938	—	—	—	—	65,938
Other revenues	1	—	31,604	12,779	—	44,383
REVENUES	**65,939**	**—**	**31,604**	**12,779**	**—**	**110,321**
Cost of goods and services	(41,830)	—	(3,305)	(9,167)	—	(54,302)
Research and development expenses	(2,711)	(18,962)	(62,140)	(640)	—	(84,454)
Marketing and distribution expenses	(17,554)	—	(638)	(72)	—	(18,264)
General and administrative expenses	(13,412)	(2,374)	(7,781)	(2,274)	(1,697)	(27,539)
Other income and expenses, net	1,101	1,578	14,073	117	2,248	19,117
OPERATING PROFIT/(LOSS)	**(8,466)**	**(19,759)**	**(28,189)**	**743**	**551**	**(55,120)**

Income statement by segment for the year ended December 31, 2021

(In € thousand)	Commer-cialized products	COVID	Vaccine candidates	Techno-logies and services	Corporate Overhead	Total
Product sales	62,984	—	—	—	—	62,984
Other revenues	18	253,314	3,257	28,512	—	285,101
REVENUES	**63,002**	**253,314**	**3,257**	**28,512**	**—**	**348,086**
Cost of goods and services	(40,017)	(122,843)	—	(25,061)	—	(187,920)
Research and development expenses	(2,094)	(113,907)	(53,181)	(4,101)	—	(173,283)
Marketing and distribution expenses	(18,455)	(1,182)	(3,811)	(194)	—	(23,643)
General and administrative expenses	(6,102)	(23,003)	(8,323)	(5,495)	(4,684)	(47,606)
Other income and expenses, net	2,196	11,546	7,033	2,458	(257)	22,976
OPERATING PROFIT/(LOSS)	**(1,469)**	**3,927**	**(55,025)**	**(3,881)**	**(4,941)**	**(61,390)**

Income statement by segment for the year ended December 31, 2022

(In € thousand)	Commer-cialized products	COVID	Vaccine candidates	Techno-logies and services	Corporate Overhead	Total
Product sales	85,228	29,568	—	—	—	114,797
Other revenues	23	280,010	5,565	(39,091)	—	246,506
REVENUES	**85,251**	**309,578**	**5,565**	**(39,091)**	**—**	**361,303**
Cost of goods and services	(46,475)	(267,113)	(1,112)	(9,742)	—	(324,441)
Research and development expenses	(1,067)	(72,762)	(29,907)	(1,186)	—	(104,922)
Marketing and distribution expenses	(13,107)	(2,773)	(7,334)	(57)	(238)	(23,509)
General and administrative expenses	(5,137)	(19,392)	(3,910)	(1,919)	(3,715)	(34,073)
Other income and expenses, net	105	9,625	4,811	1,111	(3,454)	12,199
OPERATING PROFIT/(LOSS)	**19,570**	**(42,836)**	**(31,888)**	**(50,884)**	**(7,406)**	**(113,443)**

5.4.2 Geographical segments

In presenting information on the basis of geographical segments, segment revenue is based on the final location where Valneva's distribution partner sells the product or where the customer/partner is located. Segment assets are based on the geographical location of the assets.

Product sales per geographical segment

(In € thousand)	Year ended December 31,		
	2022	2021	2020
United States	21,992	40,339	36,414
Canada	18,904	4,226	8,965
Austria	13,749	9,341	3,333
United Kingdom	10,901	2,707	1,847
Nordics	8,560	2,436	2,866
Germany	20,341	726	7,060
France	2,625	999	734
Other Europe	6,245	2,076	1,334
Rest of World	11,480	134	3,384
PRODUCT SALES	**114,797**	**62,984**	**65,938**

Nordics includes Finland, Denmark, Norway and Sweden.

Non-current operating assets per geographical segment

(In € thousand)	As at December 31,	
	2022	2021
United States	64	66
Canada	183	239
Austria	52,199	61,237
Nordics	40,250	53,020
United Kingdom	84,843	87,387
Other Europe	5,211	4,582
NON-CURRENT ASSETS	**182,749**	**206,531**

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 are structured according to the location of the final customer. In some countries there are customers, but no assets.

5.4.3 Information about major customers

Product sales to the largest customer amounted to €16.0 million in 2022 (2021: €41.8 million, 2020: €33.8 million). Other revenues from the largest customer amounted to €169.2 million in 2022 (2021: €253.3 million, 2020: two largest customers with revenues €31.6 million and €7.5 million). There were no further customers with a contribution exceeding 10% of the annual revenue.

5.5 Revenues from contracts with customers

Within the Group the following revenue streams were identified:

a. Product Sales

b. Other revenues

5.5.1 Product sales

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, so 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 happen within few days. Sales contracts with retailers and with the Department of Defense (DoD) in the United States are shown as "direct product sales", whereas sales to distributors are reported as "indirect sales - sales through distributors".

Sales channels

Commercialized products (without VLA2001 product sales) are sold via the following sales channels:

(In € thousand)	Year ended December 31,		
	2022	2021	2020
Direct product sales	75,968	60,325	54,160
Indirect product sales (Sales through distributors)	9,260	2,678	11,778
TOTAL PRODUCT SALES	**85,228**	**63,002**	**65,938**

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

The UK Supply Agreement required the UK Authority to pay non-refundable advance payments to fund certain manufacturing-related expenses over the life of the project, and as at December 31, 2021, Valneva had received an aggregate of £369.7 million (€420.6 million) under the UK Supply Agreement. Valneva received no additional funds from the UK Authority in 2022.

For more information, see Note 5.1.

As at December 31, 2021, the impact of the termination of the UK Supply Agreement was assessed. 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 (refer to Note 5.1).

As at December 31, 2022,Valneva's repayment obligations to the UK Authority were assessed to be remote. Therefore, no refund liability was accounted for as at December 31, 2022, and 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) was recognized in 2022. Revenue was reported as other Revenues as it was due to the termination of the agreements.

Valneva will update this estimate of the refund liability in accordance with IFRS 15.55 on every balance sheet date going forward.

For more detailed information, see Notes 5.30.2 and 5.18.

Advance Purchase Agreement with the European Commission

The EC APA was amended in July 2022 to reduce the amount of doses of VLA2001 ordered. For more information, refer to Note 5.1. 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, 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.

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). For more information, refer to Note 5.1. 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 2020 the performance obligations (PO) in the agreement were identified and the constrained transaction price (highly probable consideration amount) was estimated and allocated to the PO. The identified three PO's were: a) License (including normal tech-transfer), b) Equipment, c) R&D works (for Phase 2 and additional Phase 2 studies) and additional support services. The upfront payment received, net of initial estimate of refunds, representing €34.1 million was allocated to those three PO in the proportion of 73.8%, 0.5% and 25.8%, respectively, in line with their stand-alone selling prices. Whereas the first two PO have been recognized as point in time, the R&D works and additional services is recognized over time. Valneva is entitled to receive partial reimbursement of research and development and support service costs incurred. These reimbursements are recognized as service revenue as research and development and support services work is performed. In 2021 and 2022 several amendments to the transaction price were made via amendments to the Collaboration and License Agreement as described in Note 5.1 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. The resulting reduction in transaction price was again allocated to the three PO's mentioned above and allocated in the same percentages as above.

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, the remaining cumulated revenue as of December 31, 2022 was reversed.

The following table summarizes revenue recognized on the Pfizer agreements:

(In € thousand)	2020	2021	2022	Total since inception
License incl. normal tech-transfer	25,173	(1,613)	(40,060)	(16,500)
Equipment for large scale	—	177	(277)	(100)
R&D work (for Phase 2 and additional phase 2 studies) and additional support services - including reimbursements received related directly to this PO	6,431	15,701	(5,532)	16,600
TOTAL revenue recognized	**31,604**	**14,265**	**(45,869)**	**—**

The revenue reversal of €45.9 million in 2022 is primarily caused by a change in transaction price, reflecting an increase in Valneva's expected contributions to funding of development costs to be incurred by Pfizer.

While the License and Equipment PO's were fulfilled in prior periods, the R&D works and additional services are ongoing until 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, 2022 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, 2022, the discounted refund liability amounted to €135.5 million (December 31, 2021: €79.6 million), of which nil (December 31, 2021: €75.2 million) was recognized as a non-current refund liability. €3.7 million of costs to obtain a contract were included in other non-current assets as at December 31, 2022 (December 31, 2021: €3.0 million). For more details, see Note 5.29.

5.5.3 Disaggregated revenue information

Revenues as presented in the Consolidated Income Statement and in the Segment Reporting (see Note 5.4) include both revenues from contracts with customers and other revenues (mainly subleases), which are out of scope from IFRS 15:

YEAR ENDED DECEMBER 31, 2020 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Product sales	65,938	—	—	—	65,938
Other revenue from contract with customers	—	—	31,604	11,814	43,419
Other non-IFRS 15 revenue	—	—	—	965	965
REVENUES	**65,938**	**—**	**31,604**	**12,779**	**110,321**

YEAR ENDED DECEMBER 31, 2021 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Product sales	62,984	—	—	—	62,984
Other revenue from contract with customers	18	253,314	3,257	27,613	284,202
Other non-IFRS 15 revenue	—	—	—	899	899
REVENUES	**63,002**	**253,314**	**3,257**	**28,512**	**348,086**

YEAR ENDED DECEMBER 31, 2022 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Product sales	85,228	29,568	—	—	114,797
Other revenue from contract with customers	23	280,010	5,565	(39,888)	245,709
Other non-IFRS 15 revenue	—	—	—	797	797
REVENUES	**85,251**	**309,578**	**5,565**	**(39,091)**	**361,303**

The Group's revenues from contracts with customers are disaggregated as follows:

Type of goods or service

YEAR ENDED DECEMBER 31, 2020 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO®	48,480	—	—	—	48,480
DUKORAL®	13,300	—	—	—	13,300
Third party products	4,158	—	—	—	4,158
Lyme VLA15	—	—	31,604	—	31,604
Services related to clinical trial material	—	—	—	7,997	7,997
Others	—	—	—	3,817	3,817
REVENUES FROM CONTRACTS WITH CUSTOMERS	**65,939**	**—**	**31,604**	**11,814**	**109,357**

YEAR ENDED DECEMBER 31, 2021 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO®	45,118	—	—	—	45,118
DUKORAL®	2,444	—	—	—	2,444
Third party products	15,440	—	—	—	15,440
COVID VLA2001	—	253,314	—	—	253,314
Chikungunya VLA1553	—	—	3,257	—	3,257
Lyme VLA15	—	—	—	14,265	14,265
Services related to clinical trial material	—	—	—	10,001	10,001
Others	—	—	—	3,346	3,346
REVENUES FROM CONTRACTS WITH CUSTOMERS	**63,002**	**253,314**	**3,257**	**27,613**	**347,186**

YEAR ENDED DECEMBER 31, 2022 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO®	41,371	—	—	—	41,371
DUKORAL®	17,335	—	—	—	17,335
Third party products	26,545	—	—	—	26,545
COVID VLA2001	—	309,578	—	—	309,578
Chikungunya VLA1553	—	—	5,565	—	5,565
Lyme VLA15	—	—	—	(45,869)	(45,869)
Services related to clinical trial material	—	—	—	3,205	3,205
Others	—	—	—	2,776	2,776
REVENUES FROM CONTRACTS WITH CUSTOMERS	**85,251**	**309,578**	**5,565**	**(39,888)**	**360,506**

The revenues within the vaccine candidates segment in 2020 related to the Lyme vaccine candidate and amounted to €31.6 million, whereas in 2021 the revenues amounted to €3.3 million related to the newly signed chikungunya vaccine collaboration with Instituto Butantan. As the Lyme vaccine candidate was outlicensed to Pfizer by the end of 2020, revenue from this vaccine candidate is included in the Technologies and Services segment from 2021 onward.

In 2021 revenues in the COVID segment of €253.3 million are related to the termination of the UK agreement. For more detail see further above within this Note. Revenues from technologies and services amounted to €27.6 million, compared to €11.8 million in 2020. In 2021 this revenue included €14.3 million from the collaboration with Pfizer related to the Lyme vaccine candidate.

In 2022, revenues in the COVID segment were €309.6 million. Thereof €29.6 million related to VLA2001 product sales, €169.2 million related to the termination of the UK agreement and €110.8 million related to the termination of the EC APA agreement. For more detail see further above within this Note. Negative revenues from technologies and services amounted to €39.9 million and included a reversal of revenue of €45.9 million from amendments of the Collaboration and License Agreement with Pfizer. For more details see Note 5.5.2.

Geographical markets

YEAR ENDED DECEMBER 31, 2020 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	36,414	—	31,604	341	68,359
Canada	8,965	—	—	—	8,965
Austria	3,333	—	—	6,928	10,261
United Kingdom	1,848	—	—	1,038	2,886
Nordics	2,866	—	—	5	2,871
Germany	7,060	—	—	200	7,260
France	712	—	—	907	1,620
Other Europe	1,356	—	—	1,465	2,821
Rest of World	3,384	—	—	930	4,314
REVENUES FROM CONTRACTS WITH CUSTOMERS	**65,939**	**—**	**31,604**	**11,814**	**109,357**

YEAR ENDED DECEMBER 31, 2021 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	40,339	—	—	14,452	54,791
Canada	4,226	—	—	—	4,226
Austria	9,341	—	—	8,376	17,718
United Kingdom	2,721	253,314	—	40	256,075
Nordics	2,440	—	—	—	2,440
Germany	726	—	—	240	966
France	999	—	—	280	1,279
Other Europe	2,076	—	—	2,930	5,006
Rest of World	134	—	3,257	1,294	4,684
REVENUES FROM CONTRACTS WITH CUSTOMERS	**63,002**	**253,314**	**3,257**	**27,613**	**347,186**

YEAR ENDED DECEMBER 31, 2022 (In € thousand)	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	21,992	—	—	(45,795)	(23,803)
Canada	18,904	—	—	—	18,904
Austria	11,330	7,347	—	2,433	21,109
United Kingdom	10,901	169,188	—	1,040	181,129
Nordics	7,096	4,916	—	—	12,012
Germany	4,328	64,031	—	170	68,529
France	2,644	42,617	—	1,263	46,525
Other Europe	6,084	11,923	—	733	18,740
Rest of World	1,972	9,556	5,565	268	17,360
REVENUES FROM CONTRACTS WITH CUSTOMERS	**85,251**	**309,578**	**5,565**	**(39,888)**	**360,506**

5.5.4 Assets and liabilities related to contracts with customers

See Note 5.19 for details on trade receivables, Note 5.20 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	**Notes**	**Year ended December 31,**		
		2022	**2021**	**2020**
Consulting and other purchased services		141,631	169,158	65,212
Cost of services and change in inventory		190,086	105,648	10,778
Employee benefit expense other than share-based compensation	5.7	56,393	85,334	58,264
Share-based compensation expense	5.7	(5,215)	14,678	6,328
Raw materials and consumables used		12,723	14,676	12,434
Depreciation and amortization and impairment	5.12/5.13/ 5.14	44,285	14,281	9,939
Building and energy costs		14,696	10,960	8,140
Supply, office and IT costs		11,739	7,409	3,333
License fees and royalties		6,830	4,865	4,384
Advertising costs		7,343	2,176	2,496
Warehousing and distribution costs		1,898	1,419	1,898
Travel and transportation costs		2,208	538	529
Other expenses		2,329	1,309	822
OPERATING EXPENSES		**486,945**	**432,452**	**184,558**

The increase in operating expenses of €54.5 million in 2022 compared to 2021 primarily resulted from the write-down of COVID-19 vaccine inventory as well as increased depreciation charges of fixed assets including the impairment of idle manufacturing equipment. 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 (see Note 5.5.2).

Principal Accountant Fees and Services:

€ in thousand	Year ended December 31,							
	PricewaterhouseCoopers				Deloitte & Associés			
	2022	%	2021	%	2022	%	2021	%
Audit fees	**1,891**	**99 %**	**1,122**	**91 %**	**1,678**	**99 %**	**1,113**	**93 %**
provided by the statutory auditor	1,386	—	937	—	1,376	—	939	—
provided by the statutory auditor's network	505	—	185	—	302	—	174	—
Audit-related Fees	**0**	**—**	**90**	**7 %**	**13**	**1 %**	**85**	**7 %**
provided by the statutory auditor	0	—	85	—	13	—	85	—
provided by the statutory auditor's network	0	—	5	—	0	—	0	—
Tax Fees	**25**	**1 %**	**25**	**2 %**	**0**	**—**	**0**	**—**
provided by the statutory auditor's network	25	—	25	—	0	—	0	—
All Other Fees	**0**	**—**	**0**	**—**	**0**	**—**	**0**	**—**
Total	**1,916**	**100 %**	**1,238**	**100 %**	**1,691**	**100 %**	**1,199**	**100 %**

In 2022 and 2021 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,		
	2022	2021	2020
Salaries	57,272	47,717	38,515
Social security contributions	(3,035)	35,923	18,555
Share-based compensation expense	(5,215)	14,678	6,328
Training and education	840	603	351
Other employee benefits	1,317	1,091	842
TOTAL EMPLOYEE BENEFIT EXPENSE	**51,178**	**100,012**	**64,592**

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. This provision changed from €26.5 million (2020: €7.4 million) for the year ended December 31, 2021 to €3.3 million for the year ended December 31, 2022.

During 2022, the Group had an average of 778 employees (2021: 722 employees, 2020: 532 employees).

5.8 Other income/(expenses), net

Other income and expenses, net include the following:

€ in thousand	Year ended December 31,		
	2022	2021	2020
Research and development tax credit	15,348	21,949	9,937
Grant income	191	1,684	7,680
Profit/(loss) on disposal of fixed assets and intangible assets, net	(38)	(42)	(10)
Profit/(loss) from revaluation of lease agreements	(32)	—	1,584
Taxes, duties, fees, charges, other than income tax	(217)	(212)	(168)
Miscellaneous income/(expenses), net	(3,054)	(403)	95
OTHER INCOME AND EXPENSES, NET	**12,199**	**22,976**	**19,117**

With regards to miscellaneous income/(expenses), net, see Note 5.30.2.

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.

Grant monies 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 grant monies 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 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 5.1). In 2022, €0.2 million of grant income related to CEPI (2021: negative €0.9 million, due to a change in estimate of the likelihood of repayment milestones) and €3.9 million of other revenue was related to CEPI. For more information see Note 5.24.

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.

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,		
	2022	2021	2020
FINANCE INCOME			
Interest income from other parties	260	249	119
Fair value gains on derivative financial instruments	—	—	397
TOTAL FINANCE INCOME	**260**	**249**	**516**
FINANCE EXPENSES			
Interest expense on loans	(8,238)	(7,273)	(6,162)
Interest expense on refund liabilities	(9,597)	(8,478)	(3,640)
Interest expenses on lease liabilities	(955)	(903)	(907)
Other interest expense	(264)	(309)	(30)
Fair value losses on derivative financial instruments	—	—	—
TOTAL FINANCE EXPENSES	**(19,054)**	**(16,964)**	**(10,738)**
FOREIGN EXCHANGE GAIN/(LOSSES), NET	**(12,587)**	**8,130**	**173**
FINANCE INCOME/(EXPENSES), NET	**(31,381)**	**(8,584)**	**(10,049)**

In 2022, the net finance result amounted to minus €31.4 million compared to minus €8.6 million in 2021 and minus €10.0 million in 2020. The foreign exchange gain/(losses), net are primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions.

In 2021, the decrease in net finance expense was mainly due to positive net foreign exchange gains which were partially offset by increased interest expenses on non-current refund liabilities. In 2020, the increase in net finance expenses was mainly due to higher borrowings and the increase in non-current refund liabilities.

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,**		
	2022	**2021**	**2020**
CURRENT TAX			
Current income tax charge	(1,029)	(32)	(69)
Adjustments in respect of current income tax of previous year	97	(19)	109
DEFERRED TAX			
Relating to origination and reversal of temporary differences	2,468	(3,395)	869
INCOME TAX BENEFIT/(EXPENSE)	**1,536**	**(3,446)**	**909**

The individual entities' reconciliations – 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,**		
	2022	**2021**	**2020**
Loss before tax	(144,815)	(69,979)	(65,302)
Tax calculated at domestic tax rates applicable to profits in the respective countries	37,203	18,824	16,675
Income not subject to tax (mainly R&D tax credit)	7,435	10,739	2,612
Expenses not deductible for tax purposes	(26)	(2,509)	(1,789)
Deferred tax asset not recognized	(45,955)	(26,902)	(15,852)
Utilization of previously unrecognized tax losses	2,628	—	—
Income tax credit/withholding tax/other adjustments	101	(459)	109
Effect of change in applicable tax rate	586	(3,291)	(771)
Exchange differences	(526)	296	(105)
Income tax of prior years	90	(64)	170
Minimum income tax	(2)	(80)	(141)
INCOME TAX BENEFIT/(EXPENSE)	**1,536**	**(3,446)**	**909**
Effective income tax rate	—	—	—

Although the Group operates at a loss overall, there are profitable jurisdictions.

5.10.2 Deferred tax

As at December 31, 2022, the deferred tax assets of €199.5 million (December 31, 2021: €153.8 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, 2022, the Group had tax losses carried forward of €821.6 million (December 31, 2021: €628.3 million), of which €272.1 million related to Valneva SE (December 31, 2021: €234.9 million), €521.7 million related to Valneva Austria GmbH (December 31, 2021: €380.0 million), €0.0 million related to Valneva USA, Inc. (December 31, 2021: €0.4 million), €19.6 million related to Valneva Scotland, Ltd. (December 31, 2021: €0.8 million) and €8.2 million related to Valneva Sweden AB (December 31, 2021: €12.6 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)	**2022**	**2021**	**2020**
Beginning of year	2,292	5,158	4,988
Exchange differences	171	529	(699)
Income statement charge / (credit)	2,480	(3,395)	869
END OF THE YEAR,	**4,943**	**2,292**	**5,158**

The deferred tax assets and liabilities are allocable to the various balance sheet items as follows:

€ in thousand	**As at December 31,**	
	2022	**2021**
DEFERRED TAX ASSET FROM		
Tax losses carried forward	203,852	156,470
Fixed assets	3,541	2,007
Inventory	3,306	1,837
Borrowings and accrued interest	1,526	1,284
Provision	1,659	1,611
Other items	2,502	2,891
Non-recognition of deferred tax assets	(199,493)	(153,836)
TOTAL DEFERRED TAX ASSETS	**16,893**	**12,264**
DEFERRED TAX LIABILITY FROM		
Fixed assets	(4,789)	(2,359)
Intangible assets	(6,229)	(6,855)
Other items	(932)	(758)
TOTAL DEFERRED TAX LIABILITY	**(11,950)**	**(9,972)**
DEFERRED TAX, NET	**4,943**	**2,292**

The corporate income tax rate in the United Kingdom was 19% and will be increased to 25% in 2023.

The corporate income tax rate in France was 26.5% in 2021 and was reduced to 25% from 2022 onward.

The deferred tax assets and liabilities presented above as at December 31, 2022 and December 31, 2021 have been adjusted for these changes in tax rates.

5.11 Earnings (Losses) per share

(a) 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,		
	2022	**2021**	**2020**
Net profit (loss) from continuing operations attributable to equity holders of the Company (in € thousand)	(143,279)	(73,425)	(64,393)
Weighted average number of outstanding shares	115,473,914	97,619,320	90,757,173
BASIC EARNINGS (LOSSES) FROM CONTINUING OPERATIONS PER SHARE (€ per share)	**(1.24)**	**(0.75)**	**(0.71)**

(b) 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,		
	2022	**2021**	**2020**
Profit used to determine diluted earnings per share (in € thousand)	(143,279)	(73,425)	(64,393)
Weighted average number of outstanding shares for diluted earnings (losses) per share[4]	115,473,914	97,619,320	90,757,173
DILUTED EARNINGS/(LOSSES) FROM CONTINUING OPERATIONS PER SHARE (€ per share)	**(1.24)**	**(0.75)**	**(0.71)**

[4]Potentially dilutive securities (2022: 1,504,892 diluted shares; 2021: 5,846,267; 2020: 5,481,763 diluted shares 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 2022 and 2021, no development costs have been 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 1-15 years
- Development costs 1-24 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 10 years) which is based on estimated period where Valneva benefits from the patent.

(In € thousand)	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
YEAR ENDED 31 DECEMBER, 2021					
Opening net book value	1,112	32,423	1,737	137	35,409
Additions	802	140	—	—	942
Amortization charge	(719)	(2,919)	(178)	—	(3,816)
Disposals	—	—	—	—	—
Exchange rate differences	22	123	21	(2)	165
CLOSING NET BOOK VALUE	**1,217**	**29,768**	**1,581**	**134**	**32,700**
AS AT DECEMBER 31, 2021					
Cost	6,254	80,724	9,895	134	97,007

Accumulated amortization and impairment	(5,037)	(50,956)	(8,314)	—	(64,307)
CLOSING NET BOOK VALUE	**1,217**	**29,768**	**1,581**	**134**	**32,700**

(In € thousand)	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
YEAR ENDED 31 DECEMBER, 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)
Impairment charge	—	—	—	—	—
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, 2022 and December 31, 2021, 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 €78.7 million (December 31, 2021: €79.0 million) and a net book value amounting to €27.7 million (December 31, 2021: €30.6 million).

For impairment test, see Note 5.15.

5.13 Leases (right of use assets and lease liabilities)

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 20 years) and Austria (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 Solna, Sweden include options to terminate the agreements earlier. The notice period is 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 0.013% and 6.523%, 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 Austria and 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 €5,000) 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 and lease liabilities

€ in thousand	**Right-of-use assets**				
	Land, buildings and leasehold improvements	**Manufacturing and laboratory equipment**	**Furniture, fittings and other**	**Total assets**	**Lease Liabilities**
YEAR ENDED 31 DECEMBER, 2021					
Opening net book value	43,121	37	216	43,374	52,088
Additions	7,642	—	231	7,874	7,873
Amortization	(2,628)	(22)	(135)	(2,784)	—
Revaluation due to variable payments	199	—	3	202	202
Termination of contracts	—	—	(41)	(41)	(44)
Lease payments	—	—	—	—	(3,601)
Interest expenses	—	—	—	—	802
Exchange rate differences	(341)	—	3	(339)	(496)
CLOSING NET BOOK VALUE	**47,993**	**15**	**278**	**48,285**	**56,822**

(In € thousand)	Right-of-use assets				
	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total assets	Lease Liabilities
YEAR ENDED 31 DECEMBER, 2022					
Opening net book value	47,993	15	278	48,285	56,822
Additions	1,482	—	147	1,629	1,629
Amortization	(2,944)	(15)	(145)	(3,103)	—
Impairment charge	(4,178)	—	—	(4,178)	—
Revaluation due to variable payments	859	—	—	859	859
Termination of contracts	—	—	(32)	(32)	—
Lease payments	—	—	—	—	(3,900)
Interest expenses	—	—	—	—	833
Exchange rate differences	(1,847)	—	(10)	(1,857)	(2,669)
CLOSING NET BOOK VALUE	**41,365**	**—**	**238**	**41,603**	**53,574**

Revaluation of right-of-use (RoU) assets for land, buildings and leasehold improvements and lease liabilities in 2020 mainly refers to the partial early termination of the rental contract in Sweden.

For impairment test, see Note 5.15.

As at December 31, 2022, RoU assets decreased to €41.6 million from €48.3 million as at December 31, 2021, mainly due to amortization, impairment charges, and exchange rate differences, but partly offset by a new lease contract for office space in France which amounted to €1.0 million. Major lease agreements were for the premises in Austria (December 31, 2022: €23.1 million, December 31, 2021: €24.0 million) and Sweden (December 31, 2022: €16.3 million, December 31, 2021: € 22.1 million).

For more details on lease liabilities, see Note 5.27. For more 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 2022, 2021 and 2020. Income relating to revaluation of lease liabilities was €1.6 million in 2020 related to the partial early termination of the rental contract in Sweden, while there have been no substantive revaluations in 2022 and 2021.

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, as appropriate, 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).

€ in thousand	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, 2021						
Opening net book value	10,651	12,041	726	257	11,105	34,779
Additions	664	14,360	912	16	79,897	95,848
Depreciation charge	(1,160)	(6,129)	(333)	(59)	—	(7,681)
Impairment charge	—	—	—	—	—	—
Disposals	—	(19)	(2)	(21)	(4)	(46)
Exchange rate differences	129	813	32	9	1,662	2,645
CLOSING NET BOOK VALUE	**10,284**	**21,066**	**1,335**	**202**	**92,659**	**125,545**
AS AT DECEMBER 31, 2021						
Cost	25,554	44,127	3,204	1,454	92,659	166,999
Accumulated depreciation and impairment	(15,269)	(23,062)	(1,870)	(1,252)	—	(41,453)
CLOSING NET BOOK VALUE	**10,284**	**21,066**	**1,335**	**202**	**92,659**	**125,545**

€ in thousand	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 and 2021 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.

From the total of €44.3 million (2021: €14.3 million; 2020: €9.9 million) of depreciation, amortization and impairment expenses, €39.5 million (2021: €8.9 million, 2020: €5.0 million) were charged to cost of goods and services, €3.6 million (2021: €4.7 million, 2020: €4.1 million) were charged to research and development expenses, €0.7 million (2021: €0.4 million, 2020: €0.5 million) were charged to marketing and distribution expenses and €0.6 million (2021: €0.3 million, 2020: €0.3 million) were charged to general and administrative expenses. The increase in depreciation and amortization charged to costs of goods and services was caused by investments in Scotland and Sweden in 2022 and 2021.

With regards to impairment charges recognized in 2022, see Note 5.15.

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). 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.

As at December 31, 2022, impairment tests were adapted to the changes resulting in de-recognition of COVID 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 chikungunya vaccine candidate 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 Chikungunya 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.

During 2021 and 2022, the Company invested in manufacturing facilities in both Scotland and Sweden in order to fulfill COVID-19 vaccine demand from contracts with the UK Government, the EC and the Kingdom of Bahrain. Given the significant changes to the volumes ordered under the EC APA and the assumed lack of future demand for VLA2001, no future COVID-19 cash-flows were considered in impairment tests as of December 31, 2022 for all assets acquired for the manufacturing of VLA2001.

- The new Almeida manufacturing facility in Scotland is ready for operations. However, to date no manufacturing of VLA2001 or other vaccines has taken place in this facility. Management intends to utilize the facility in future for manufacturing of IXIARO and the chikungunya vaccine. Future cash flows generated by utilizing this facility have been considered in calculating the value in use.
- As a result of suspending filling and packaging of VLA2001 in Sweden, the impairment test considered future cash flows from the utilization of the equipment for manufacturing of DUKORAL only.

Impairment testing procedures have been performed solely on the utilization of the established capacity through the Group's existing and future commercial stage vaccines.

An impairment test was also performed on the Clinical Trial Materials (CTM) Unit in Sweden, which is dedicated to small scale manufacturing of trial materials for customers. The CTM unit was operated as a separate CGU for several years and was primarily engaged in manufacturing of clinical trial materials for third party customers and more recently also provided services within the Valneva Group. A triggering event was identified as currently no active customer contracts are in place.

Impairment of manufacturing equipment:

During the year ended December 31, 2022, impairment charges amounting to €23.2 million were recorded that related to manufacturing equipment dedicated to the manufacturing of the Company's COVID vaccine VLA2001, which became idle after suspension of manufacturing of VLA2001. Estimates were made on future utilization of installed capacities including transfer of manufacturing processes taking expected future product sales from the Company's long-range business plan into consideration.

Almeida Manufacturing facility in Scotland:

The new manufacturing facility in Scotland is available for manufacturing operations. As at December 31, 2022, the total carrying value of all assets including right of use assets amounted to €83.2 million. The Company's long-range business model for IXIARO and the chikungunya vaccine candidate includes assumptions on market size/market share, product sales and resulting profitability over a five-year period as well as a terminal value for the period beyond 5 years. This business model has been used as a basis to calculate the value in use.

Cash flows are expected to be generated after transfer of manufacturing activities in 2024. Considerable value in use is expected to be generated over the planning horizon of five years as well as through the terminal value for the period beyond the 5-year planning horizon. In total, the value in use far exceeded the current carrying value of €83.7 million. The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 8.3% for IXIARO and 8.3% for chikungunya.

The discount rate of 8.3% for IXIARO was based on 2.2% risk-free rate, 7.8% market risk premium, minus 0.6% country risk premium, 0.3% currency risk, a levered beta of 1.20 and a peer group related equity-capital ratio.

The discount rate of 8.3% for chikungunya was based on 2.2% risk-free rate, 7.7% market risk premium, minus 0.6% country risk premium, 0.1% currency risk, a levered beta of 1.20 and a peer group related equity-capital ratio.

For the impairment tests for the manufacturing facility in Scotland all future cash flows from utilization of the facility by both the IXIARO and the chikungunya CGUs were considered in calculating the value in use. This

also included utilization of the newly built facility by these CGUs. The impairment test has resulted in no impairment losses.

Manufacturing equipment and a right of use asset have been determined to have no further utilization after the expected transfer of manufacturing activities into the Almeida facility. An impairment charge amounting to €11.5 million was posted in December 2022, which is addition to the impairment charges taken on manufacturing equipment at a CMO in the amount of €3.3 million in June 2022 resulted in total impairment charges for 2022 of €14.8 million.

Filling and Packaging facility and CTM unit in Sweden:

Manufacturing of VLA2001 has been suspended in the new filling and packaging facility in Sweden. The facility will be prepared for utilization within the DUKORAL manufacturing process. As at December 31, 2022, the carrying value of the related property, plant and equipment as well as right of use assets amounted to €48.6 million. The Company's long-range business model for DUKORAL includes assumptions on market size/market share, product sales and resulting profitability over a five-year period as well as a terminal value for the period beyond five years. Scenarios have been developed, and the impairment test used a weighted average across two scenarios for calculation of a value in use.

For the impairment test of the manufacturing facility in Sweden certain assets and liabilities that were not directly attributable to a specific CGU were allocated between the DUKORAL and CTM Unit Sweden CGUs on a basis that reasonably reflects the actual utilization of assets by specific CGU with space occupation and headcount being the main indicators applied.

For DUKORAL the carrying value exceeded the value in use by €8.3 million and an impairment charge for the same amount has been posted in December 2022 and resulted in an impairment loss amounting to €5.2 million related to property, plant & equipment and to €3.2 million related to right of use assets.

The impairment test for the CTM unit resulted in no impairment charges.

The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 8.3% for DUKORAL and 9.5% for the CTM Unit Sweden.

The discount rate of 8.3% for DUKORAL was based on 2.2% risk-free rate, 7.8% market risk premium, minus 0.7% country risk premium, 0.3% currency risk, a levered beta of 1.06 and a peer group related equity-capital ratio.

The discount rate of 9.5% for the CTM Unit Sweden was based on 2.2% risk-free rate, 9.1% market risk premium, minus 0.6% country risk premium, 0.7% currency risk, a levered beta of 1.21 and a peer group related equity-capital ratio.

Sensitivity to changes in assumptions

The net present value calculations are most sensitive to the following assumptions:

- discount rate
- reduction of expected revenues

The net present value calculation uses a discount rate of 8.3% for DUKORAL (2021: 7.2%), 8.3% for IXIARO (2021: 7.5%), 8.3% for Chikungunya and 9.5% for the CTM unit. The recoverable amounts of these CGUs would equal its carrying amount if the key assumptions were to change as follows: increase in the discount rate from 8.3% to 56.3% would trigger an impairment loss for IXIARO (2021: 4,560 basis points from 7.5% to 53.1%), increase by 100 basis points from 8.3% to 9.3% would trigger an impairment loss for DUKORAL of

€5.1 million (2021: increase of 590 basis points from 7.2% to 13.1% acceptable without triggering an impairment loss). Increase in the discount rate from 9.5% to 15.0% would trigger an impairment loss for the CTM unit.

	2022				2021	
Sensitivity analysis	IXIARO	DUKORAL	Chikungunya	CTM	IXIARO	DUKORAL
WACC	8.3%	8.3%	8.3%	9.5%	7.5%	7.2%
Break-even WACC	56.3%	7.6%	113.6%	15.0%	53.1%	13.1%
Impairment if WACC increases by 1%	NO	5.1	NO	NO	NO	NO
Impairment if sales reduce by 10%	NO	4.0	NO	0.9	NO	NO

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. A reduction in IXIARO, chikungunya and DUKORAL revenues of 10% would result in no impairment loss for IXIARO and chikungunya and an impairment loss of €4.0 million for DUKORAL (no impairment loss in 2021 and 2020). A reduction in revenues of the CTM unit of 10% would trigger an impairment loss of €0.9 million.

As at December 31, 2022 impairment charges amounted €23.1 million, of which €8.3 million related to DUKORAL assets (thereof €3.2 million right of use assets, €2.5 million of leasehold improvements and €2.7 million of manufacturing equipment) and €14.8 million related to COVID assets (of which €1.0 million right of use assets, €1.9 million leasehold improvements and €11.9 million manufacturing equipment) (see Note 5.13 and 5.14).

For the year ended December 31, 2021 no impairment charges were recorded.

For the year ended December 31, 2020, impairment charges amounted to €0.1 million and related to assets in the course of construction (see Note 5.14).

5.16 Investments in associates/Asset classified as held for sale

An associate is an entity over which the Company has significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the investee but is not control or joint control over those policies.

The results and assets and liabilities of associates are incorporated in these consolidated financial statements using the equity method of accounting, except when the investment, or a portion thereof, is classified as held for sale, in which case it is accounted for in accordance with IFRS 5. Under the equity method, an investment in an associate is initially recognized in the consolidated statement of financial position at cost and adjusted thereafter to recognize the Company's share of the profit or loss and other comprehensive income of the associate. When the Company's share of losses of an associate exceeds the Company's interest in that associate (which includes any long-term interests that, in substance, form part of the Company's net investment in the associate), the Company discontinues recognizing its share of further losses. Additional losses are recognized only to the extent that the Company has incurred legal or constructive obligations or made payments on behalf of the associate.

The requirements of IAS 28 are applied to determine whether there is any objective evidence that its net investment in the associate is impaired after the initial recognition of the net investment (a "loss event"). When, and only when, there is a loss event existing and the impact on the estimated future cash flows from the net investment can be reliably estimated, the entire carrying amount of the investment is tested for impairment in accordance with IAS 36 as a single asset by comparing its recoverable amount (higher of value in use and fair value less costs of disposal) with its carrying amount. Any impairment loss recognized forms part of the carrying

amount of the investment. Any reversal of that impairment loss is recognized in accordance with IAS 36 to the extent that the recoverable amount of the investment subsequently increases.

As at December 31, 2022, the investment in associate (BliNK) was reclassified to an asset held for sale in accordance with IFRS 5, whereas as at December 31, 2021 this investment was recognized as an investment in associates and accounted for by using the equity method in accordance with IAS 28. Management's intent to sell the equity interest by June 30, 2023 triggered the change in the classification. The book value of the investment amounted to €2.1 million as at December 31, 2021, and was increased by €9 thousand for the period ended June 30, 2022. There was no impact on the consolidated statement of income (loss) for the second semester of 2022, and no impairment indicators were identified during 2022.

Details of the Group's material associate are as follows:

Name of associate	Place of business	Measurement method	% of ownership interest as at December 31,	
			2022	2021
BliNK Biomedical SAS	FR	2021: Equity method 2022: lower of carrying amount and fair value less costs to sell	48.9%	48.9%

In January 2015, the Company and the UK Company BliNK Therapeutics Ltd founded BliNK Biomedical SAS ("BliNK"), a private company specialized in the discovery of innovative monoclonal antibodies. The Company contributed assets and liabilities in conjunction with the VIVA│Screen® technology. From 2018 onward BliNK reduced its research activities and has licensed out its technology.

BliNK is a private company and its shares are not listed on a stock exchange.

In 2022, the Company recorded a loss of €0.0 million related to its share of equity in BliNK (2021: loss of 0.0). The total equity of BliNK amounted to €4.6 million as at December 31, 2022 (December 31, 2021: €4.3 million), see Note 5.16.1.

5.16.1 Summarized financial information

The summarized financial information below represents amounts shown in the associate's financial statements prepared in accordance with IFRS (adjusted by the Group for equity accounting purposes).

€ in thousand	As at December 31,	
	2022	2021
BLINK BIOMEDICAL SAS		
Non-current assets	1	2
Current assets	4,903	4,782
Non-current liabilities	209	209
Current liabilities	28	93
Revenue	266	267
Profit/(Loss) from continuing operations	212	(16)
TOTAL COMPREHENSIVE INCOME/(LOSS)	212	(16)

5.16.2 Reconciliation to the carrying amount

€ in thousand	As at December 31,	
	2022	2021
Net assets of associate	4,557	4,344
Proportion of the Company's ownership interest in BliNK Biomedical SAS	48.9 %	48.9 %
BALANCE	**2,228**	**2,121**

5.17 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.

5.17.1 Financial instruments by category

AS AT DECEMBER 31, 2021 (In € thousand)	Assets at fair value through profit and loss	Assets at amortized costs	Total
ASSETS AS PER BALANCE SHEET			
Trade receivables	—	44,013	44,013
Other assets[5]	—	11,522	11,522
Cash and cash equivalents	—	346,686	346,686
ASSETS	**—**	**402,221**	**402,221**

[5]Prepayments and tax receivables and other non-financial assets are excluded from the other assets balances, as this analysis is required only for financial instruments.

AS AT DECEMBER 31, 2021 (In € thousand)	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
LIABILITIES AS PER BALANCE SHEET			
Borrowings	—	57,834	57,834
Trade payables and accruals	—	68,119	68,119
Tax and employee-related liabilities[6]	—	10,101	10,101
Lease liabilities	—	56,822	56,822
Refund liabilities	—	254,581	254,581
Other liabilities[7]	—	44	44
LIABILITIES	**—**	**447,502**	**447,502**

[6]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.
[7]Deferred income is excluded from the other liabilities balance, as this analysis is required only for financial instruments.

AS AT DECEMBER 31, 2022 (In € thousand)	Assets at fair value through profit and loss	Assets at amortized costs	Total
ASSETS AS PER BALANCE SHEET			
Trade receivables	—	23,912	23,912
Other assets[5]	—	11,988	11,988
Cash and cash equivalents	—	289,430	289,430
ASSETS	**—**	**325,330**	**325,330**

[5]Prepayments and tax receivables and other non-financial assets are excluded from the other assets balances, as this analysis is required only for financial instruments.

AS AT DECEMBER 31, 2022 (In € thousand)	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
LIABILITIES AS PER BALANCE SHEET			
Borrowings	—	98,806	98,806
Trade payables and accruals	—	41,491	41,491
Tax and employee-related liabilities[6]	—	10,778	10,778
Lease liabilities	—	53,574	53,574
Refund liabilities	—	143,085	143,085
Other liabilities[7]	—	32	32
LIABILITIES	**—**	**347,767**	**347,767**

[6]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.
[7]Deferred income is excluded from the other liabilities balance, as this analysis is required only for financial instruments.

5.17.2 Fair value measurements

As at December 31, 2022 and December 31, 2021, the Company did not have assets and liabilities measured though profit and loss.

In 2020, the Group entered into various foreign currency option and forward contracts to limit the risk of foreign currency losses on expected future cash flows. The underlying currency amount and the duration of the options depend on the amount and timing of the expected future cash flows.

As at December 31, 2022 and December 31, 2021, the Company did not have open foreign currency options nor foreign currency forwards.

5.17.3 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)	As at December 31,	
	2022	2021
TRADE RECEIVABLES		
Receivables from governmental institutions (AAA-country)	757	289
Receivables from governmental institutions (AA-country)	3,620	23,086
Receivables from governmental institutions (A-country)	—	606
AA	—	2
A	4,861	3,442
Counterparties without external credit rating or rating below A	14,674	16,589
TRADE RECEIVABLES	**23,912**	**44,013**
OTHER ASSETS		
A	11,296	11,296
Assets from governmental institutions (AA-country)	151	199
Counterparties without external credit rating or rating below A	541	27
OTHER ASSETS	**11,988**	**11,522**
CASH AND CASH EQUIVALENTS		
AA	11,557	3,457
A	272,719	332,361
Counterparties without external credit rating or rating below A	5,154	10,868
CASH AND CASH EQUIVALENTS	**289,430**	**346,686**

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.

5.17.4 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, 2022 and December 31, 2021 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, 2022 and December 31, 2021.

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, 2022 and December 31, 2021, the expected credit loss was calculated using the cumulative expected default rate based on the counterparties' ratings and was immaterial.

5.18 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)	**As at December 31,**	
	2022	**2021**
Raw materials	86,452	102,082
Work in progress	114,218	55,681
Finished goods	11,783	8,135
Purchased goods (third party products)	3,518	7,362
GROSS AMOUNT OF INVENTORIES BEFORE WRITE-DOWN	**215,970**	**173,260**
Less: write-down provision	(180,866)	(49,162)
INVENTORIES	**35,104**	**124,098**

The increase in gross amounts of work in progress and finished goods is primarily related to the production of VLA2001. Of the write-down provision on inventory of €180.9 million as of December 31, 2022 (December 31, 2021: €49.2 million), €176.9 million related to VLA2001 inventory (December 31, 2021: €41.6 million).

Inventory write-downs as a result of excess, obsolescence, scrap or other reasons are recorded as a component of Cost of goods and services in our consolidated statement of income.

In 2022, inventory-related COGS were €257.8 million (2021: €145.3 million), of which €157.7 million (2021: €127.1 million) related to inventory which cannot be used, failed batches which were written down and product which is not expected to be sold. In 2022, €159.4 million (2021: €121.4 million) of these expenses related to VLA2001 and stem from 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. The valuation of commercialized products (excluding VLA2001) resulted in a reversal of write-downs from prior periods of €2.8 million due to higher sales expectations. In 2021, €5.7 million of these expenses related to commercialized products and stem from write-downs due to lower sales expectations and limited shelf life of the products, In addition, in 2022, €66.6 million of COGS related to onerous agreements provision and settlement costs.

Write-down provisions related to the inventory categories as follows:

(In € thousand)	As at December 31,	
	2022	2021
Raw materials	79,939	29,751
Work in progress	99,089	15,096
Finished goods	1,417	3,974
Purchased goods (third party products)	421	342
TOTAL WRITE-DOWN PROVISION	**180,866**	**49,162**

In 2022, Valneva suspended the manufacturing of VLA2001. 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 the reduced expected sales volumes. As at December 31, 2022, €176.9 million of the inventory reserve related to VLA2001 (December 31, 2021: €41.6 million), of which €78.8 million was attributable to the raw materials (December 31, 2021: €29.8) and €98.1 million to work in progress (December 31, 2021: €11.8 million). In 2021 the write-down provision was related to faulty product or product with short expiry dates.

As at December 31, 2022, the remaining write-down provision related to Valneva's commercialized vaccines IXIARO and DUKORAL and to third-party products which are not expected to be sold. Commercial inventories not carrying a minimum residual shelf-life at the expected time of sale on the basis of the most current sales expectations have been written down. These write-downs totaled €2.9 million as at December 31, 2022 (December 31, 2021: €7.6 million), of which €1.4 million (December 31, 2021: €4.0 million) related to finished goods, €1.0 million (December 31, 2021: €3.3 million) related to work in progress and €0.4 million (December 31, 2021: €0.3 million) related to purchased goods.

5.19 Trade receivables

Trade receivables and other assets 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.

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise when the Group provides money, goods, or services directly to a debtor with no intention of trading the receivable.

They are included in current assets, except those with maturities beyond 12 months after the balance sheet date. These are classified as non-current assets. Loans and receivables are classified as “trade receivables and other assets” in the balance sheet.

Trade receivables include the following:

€ in thousand	As at December 31,	
	2022	2021
Trade receivables	23,997	44,030
Less: loss allowance of receivables	(84)	(17)
TRADE RECEIVABLES, NET	**23,912**	**44,013**

In 2022 and 2021, no material impairment losses were recognized. As at December 31, 2022, the amount of trade receivables past due amounted to €4.4 million (2021: €21.2 million). The trade receivables past due in 2021 mainly related to accounts receivable due from governmental authorities (with credit ratings of A+), mainly related to the APA with the EC.

In the month of January 2023 this amount of trade receivables past due of €4.4 million was lowered by €2.7 million due to payments received that month.

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, 2022, trade receivables included €23.9 million (December 31, 2021: €40.9 million) of receivables from contracts with customers.

5.20 Other assets

Other assets include the following:

€ in thousand	As at December 31,	
	2022	2021
R&D tax credit receivables	49,174	35,390
Advance payments	1,672	27,375
Tax receivables	9,066	6,145
Prepaid expenses	4,939	5,131
Contract costs	3,710	3,010
Consumables and supplies on stock	1,380	1,722
Miscellaneous current assets	451	23
OTHER NON-FINANCIAL ASSETS	70,391	78,796
Deposits	11,822	11,339
Miscellaneous financial assets	165	183
OTHER FINANCIAL ASSETS	11,988	11,522
OTHER ASSETS	**82,378**	**90,318**
Less non-current portion	(8,299)	(19,282)
CURRENT PORTION	**74,079**	**71,036**

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 increase in R&D tax credit receivables is mainly related to increased research and development expenditures primarily in connection with the COVID-19, chikungunya and Lyme vaccine candidates.

As at December 31, 2022, the deposits mainly related to a deposit associated with a lease agreement, which was reclassified from the non-current portion to the current portion due to the expiration of the agreement within one year compared to 2021.

As at December 31, 2021, advance payments amounting to €16.4 million related to the agreement with IDT Biologika to produce the COVID-19 vaccine. Advance payments amounting to €7.2 million related to the collaboration agreement with Dynavax, concluded for the supply of Dynavax's CpG 1018 adjuvant for use in VLA2001. These advance payments from 2021 were released in 2022 due to the wind-down of COVID activities.

Contract costs mainly relate to the collaboration with Pfizer (see Note 5.1) and refer to costs to obtain a contract. It will be amortized in line with the pattern of revenue recognition.

5.21 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 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 with a maximum maturity of three months.

€ in thousand	**As at December 31,**	
	2022	**2021**
Cash in hand	3	3
Cash at bank	286,530	346,639
Short-term bank deposits (maximum maturity of 3 months)	—	—
Restricted cash	2,898	44
CASH AND CASH EQUIVALENTS	**289,430**	**346,686**

As at December 31, 2022, the restricted cash mainly consisted of a locked bank account for a bank guarantee provided to IDT as security for a payment relating to the settlement agreement announced in September 2022. As a result of a payment made in February 2023, this restriction has been removed. As at December 31, 2021, the restricted cash was a Certificate of Deposit with restricted limited access to secure the credit limit for the Company's commercial card. In 2021 and for part of 2022, the minimum liquidity requirement for the Group according to the debt financing agreement with U.S. healthcare funds Deerfield and OrbiMed (see Note 5.24.1) was €50.0 million. Following an amendment to this agreement in April 2022, the minimum liquidity requirement is €35.0 million.

5.22 Equity

The ordinary shares and convertible preferred shares are classified as equity.

Number of shares	**As at December 31,**	
	2022	**2021**
Ordinary shares issued (€0.15 par value per share)	138,346,968	105,190,223
Convertible preferred shares registered	20,514	48,862
TOTAL SHARES ISSUED	**138,367,482**	**105,239,085**
Less Treasury shares	(124,322)	(124,322)
OUTSTANDING SHARES	**138,243,160**	**105,114,763**

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 Company has issued stock options to employees under various employee stock option plans (ESOPs) established in 2013, 2015, and 2016. In total, 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 the exercise period opened in January 2022, which resulted in an increase of 1,176,391 ordinary shares. Additionally, 28,348 preferred shares for the Group's Executive Managers from the free convertible preferred share (FCPS) plan 2017-2021 were converted into 772,070 ordinary shares. 636,648 free ordinary shares for the benefit of Management Board and Management Committee members from the free share plan 2019-2023 were fully vested and transferred to their beneficiaries on March 25, 2022.

In June 2022, Pfizer invested €90.6 ($95) million net representing 9,549,761 shares at a price of €9.49 per share through a reserved capital increase. The cost of equity transactions in the amount of €0.1 million, which were directly attributable to the issue of new shares, are shown in equity as a deduction, net of tax, from the proceeds. For more details see to Note 5.1.

In October 2022, the Company announced the closing of its global offering (the Global Offering) to specified categories of investors of an aggregate of 21,000,000 new ordinary shares, consisting of a public offering of 375,000 American Depositary Shares (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. Aggregate gross proceeds of the Global Offering, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately €102.9 million ($99.9 million). The cost of equity transactions in the amount of €7.4 million, which were directly attributable to the issue of new shares, are shown in equity as a deduction, net of tax, if any, from the proceeds.

Conditional and authorized capital

As at December 31, 2022, the Company had 7,267,281 shares of conditional capital in connection with (see Note 5.23):

- the possible exercise of existing stock options;
- the possible exercise of existing equity warrants (BSAs);
- the possible final grant of existing Free Ordinary Shares;
- the possible final grant and conversion of existing Free Convertible Preferred Shares;

Pursuant to resolution No. 28 of the Combined General Meeting held on June 23, 2022, the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future, under resolutions 20 to 27 of said Meeting, may not exceed €5,175,000, 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.

5.22.1 Other reserves

(In € thousand)	Other regulated reserves	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
BALANCE AS AT JANUARY 1, 2021	**52,820**	**(2,474)**	**(898)**	**12,368**	**(9,474)**	**52,342**
Currency translation differences	—	(2,877)	—	—	—	(2,877)
Defined benefit plan actuarial losses	—	205	—	—	—	205
Share-based compensation expense:						
Value of services	—	—	—	2,632	—	2,632
Purchase/sale of treasury shares	—	—	253	—	(43)	209
BALANCE AS AT DECEMBER 31, 2021	**52,820**	**(5,146)**	**(645)**	**15,000**	**(9,517)**	**52,512**

(In € thousand)	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:						
Value of services	—	—	—	2,635	—	2,635
Purchase/sale of treasury shares	—	—	—	—	—	—
BALANCE AS AT DECEMBER 31, 2022	**52,820**	**(5,041)**	**(645)**	**17,636**	**(9,517)**	**55,252**

Regulated non-distributable reserve relates to a mandatory legal reserve from the merger with Intercell AG.

The Company did not obtain a dividend from its subsidiaries or associates nor paid a dividend to its shareholders in 2022 and 2021.

5.23 Share-based compensation

The Company operates various share-based compensation plans, both equity-settled and cash-settled plans. The profit and loss statement includes the following expenses arising from share-based payments:

(In € thousand)	Year ended December 31,		
	2022	**2021**	**2020**
Stock option plans	1,916	646	1,182
Free convertible preferred share plans	—	652	1,266
Free ordinary shares program	719	1,334	1,563
Equity warrants	—	—	—
Phantom shares	(11,291)	11,877	2,317
SHARE-BASED COMPENSATION EXPENSE /(INCOME)	**(8,656)**	**14,509**	**6,328**

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 six 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:

	2022			2021		
	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	3,933,385	3,996,588	3.11	4,911,410	4,975,831	3.06
Granted	3,152,751	3,152,751	6.47	—	—	—
Forfeited	(196,834)	(196,834)	3.05	(187,950)	(189,168)	3.07
Exercised	(1,114,963)	(1,176,391)	3.32	(790,075)	(790,075)	2.79
OUTSTANDING AT YEAR END	**5,774,339**	**5,776,114**	**4.90**	**3,933,385**	**3,996,588**	**3.11**
Exercisable at year end	2,621,588	2,623,363	3.02	3,203,817	3,267,020	3.12

1,114,963 employee stock options (of which 615,918 were granted from ESOP 2013, 478,845 from ESOP 2015 and 20,200 were granted from ESOP 2016) were exercised in January 2022, whereas 790,075 employee stock

options (of which 363,050 were granted from ESOP 2016 and 427,025 from ESOP 2017) were exercised in January 2021.

Stock options outstanding at the end of the period have the following expiry dates and exercise prices:

	Exercise price	Number of options as at December 31, (presentation as number of convertible shares)	
Expiry date	**(in € per share)**	**2022**	**2021**
2023	2.92	19,557	696,903
2025	3.92	43,655	522,500
2026	2.71	14,500	36,200
2027	2.85	551,475	552,725
2029	3.05	1,994,176	2,188,260
2032	6.47	3,152,751	—
OUTSTANDING AT YEAR END		**5,776,114**	**3,996,588**

In 2022, 3,152,751 stock options were granted (2021: none).The weighted average grant date fair value of options granted during the year of 2022 was €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 Oct 10, 2022
Expected volatility (%)	70.36
Risk-free interest rate (%)	1.70– 1.75

5.23.2 Free ordinary shares

In 2022, Company's Management Board granted free ordinary shares for the benefit of Management Board and Management Committee members. The purpose of this free share plan 2022-2025 is to provide a long-term incentive program for the Company's senior management. In addition 27,521 free shares have been granted to one of the Management Board member, which will vest on December 6, 2024. No free ordinary shares were granted in 2021 and 2020.

In 2022, the number of free ordinary shares granted was as follows:

	Number of free ordinary shares granted
Management Board	196,855
Senior Leadership Group	205,056
FREE ORDINARY SHARES GRANTED	**401,911**

In accordance with the foregoing, changes in the outstanding free ordinary shares are as follows:

	Number of free shares	
	2022	**2021**
Outstanding as at January 1	1,842,404	1,842,404
Granted	401,911	—
Forfeited	(120,000)	—
Exercised	(636,648)	—
OUTSTANDING AT YEAR END	**1,487,667**	**1,842,404**

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 will vest on October 10, 2024, and the third tranche will vest on October 10, 2025.

Following the vesting of the free shares, no compulsory holding period will apply to the vested shares.

The plan further provides 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 October 10, 2024. 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. However, this is subject to meeting the performance conditions defined for the plan. Finally, the terms and conditions applicable to the free share plan state that if a Change of Control takes place before October 10, 2024, 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 on November 21, 2019, 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 Free convertible preferred share plan

In 2017, the FCPS Program 2017-2021, a long-term incentive plan for the Group's Executive Managers was implemented. As a prerequisite to the possibility of participating in the program, each potential beneficiary was required to make a cash investment in the Company, by purchasing the Company's ordinary shares.

The "Final Share Price" (volume-weighted average stock market price of the Company's ordinary shares over a period of six months immediately preceding the Conversion Date, as rounded to the second decimal place) was €18.21.

In 2022, 28,348 FCPS were converted into 772,070 Company's ordinary shares.

5.23.4 Phantom shares

In 2017 and 2019, phantom share plans were issued for employees who are US citizens, with the same conditions as the stock options program (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.

In 2021 and 2022, no new phantom shares were granted, but in 2022 a change from one phantom share program to another for one employee was agreed.

In accordance with the foregoing, changes in the outstanding free ordinary shares are as follows:

	Number of free shares	
	2022	**2021**
Outstanding as at January 1	841,450	932,200
Granted	117,000	—
Forfeited	(67,001)	(65,750)
Exercised	(220,949)	(25,000)
OUTSTANDING AT YEAR END	**670,500**	**841,450**

The carrying amount of the liability relating to the phantom shares as at December 31, 2022 was €3.0 million (December 31, 2021: €14.3 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:

	Exercise price	Number of phantom shares as at December 31,	
Expiry date	**in € per share**	**2022**	**2021**
2023	2.92	—	4,950
2025	3.92	—	6,000
2026	2.71	—	—
2027	2.85	6,250	6,250
2029	3.05	244,250	134,250
2030	—	420,000	690,000
OUTSTANDING AT YEAR END		**670,500**	**841,450**

The significant inputs into the models were:

	As at December 31,	
	2022	**2021**
Expected volatility (in %)	51.07 -86.95	72.97
Expected vesting period (term in years)	0.25 - 0.93	0.25 – 4.39
Risk-free interest rate (in %)	1.32 -2.37	(0.78) – (0.64)

5.23.5 Equity warrants

In 2017, the Company granted equity warrants to members of the Supervisory Board. The warrants granted in 2017 (BSA 27) were exercisable in four equal portions after 12, 24, 36 and 48 months. The subscription price for one new ordinary share under the 2017 plan (BSA 27) amounted to €2.574.

Changes in the equity warrants outstanding are as follows:

	Number of equity warrants	
	2022	**2021**
Outstanding as at January 1	21,875	43,750
Granted	—	—
Exercised	(21,875)	(21,875)
Forfeited	—	—
OUTSTANDING AT YEAR END	**—**	**21,875**

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 year-end include the following:

€ in thousand	**As at December 31,**	
	2022	**2021**
NON-CURRENT		
Other loans	87,227	50,726
NON-CURRENT BORROWINGS	**87,227**	**50,726**
CURRENT		
Other loans	11,580	7,107
CURRENT BORROWINGS	**11,580**	**7,107**
TOTAL BORROWINGS	**98,806**	**57,834**

The maturity of non-current borrowings is as follows:

(In € thousand)	**As at December 31,**	
	2022	**2021**
Between 1 and 2 years	29,452	21,102
Between 2 and 3 years	28,386	15,502
Between 3 and 4 years	23,377	12,306
Between 4 and 5 years	5,388	674
Over 5 years	624	1,143
NON-CURRENT BORROWINGS	**87,227**	**50,726**
Current borrowings	11,580	7,107
TOTAL BORROWINGS	**98,806**	**57,834**

The carrying amounts of the Group's borrowings are denominated in the following currencies:

(In € thousand)	As at December 31,	
	2022	2021
Borrowings denominated in EUR	4,433	4,708
Borrowings denominated in USD	94,373	53,126
TOTAL BORROWINGS	**98,806**	**57,834**

5.24.1 Other loans

In April 2022, Valneva signed an amendment to increase the principal amount of its existing €54.1 million ($60 million) debt financing agreement with funds managed by leading U.S.-based healthcare investment firms Deerfield and OrbiMed. The original loan agreement was signed in February 2020. The April 2022 amendment provided Valneva immediate access to €18.2 million ($20 million), with an additional $20 million available upon potential approval of VLA2001 by the European Medicines Agency. This additional $20 million was drawn in September 2022 in the amount of €19.9 million. The increased funding will be used to further invest in research and development projects, including market access preparations for VLA1553. The loan interest rate 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, €92.3 million ($100.0 million) was drawn down and the carrying amount was €89.2 million ($95.0 million). As at December 31, 2021, €54.1 million ($60.0 million) was drawn down and the carrying amount was €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.

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 OrbiMed agreed to modify this covenant for 2021 and 2022, replacing the twelve-month rolling €115 million minimum revenue requirement with quarterly minimum revenue requirements representing an annual total of €64 million in 2021 and €103.75 million in 2022. The parties also agreed to modify the minimum cash requirement to €50 million for 2021 and 2022. Following an amendment to this agreement in April 2022, the minimum liquidity requirement is €35.0 million.

The Group does not expect these limitations to affect its ability to meet its cash obligations. As at December 31, 2022, 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 loan agreement, which could result in additional costs (up to additional 10%-points of interest over the duration of the default) and an early repayment obligation (payment of the principal increased by 5% and of an indemnity representing the interests expected until December 2023). The Group does not expect these limitations to affect its ability to meet its cash obligations.

The loan was included in the balance sheet item “Borrowings”.

(In € thousand)	2022	2021
BALANCE AS AT JANUARY 1	**49,671**	**46,190**
Proceeds of issue	38,502	—
Transaction costs	(255)	—
Accrued interest	7,521	6,167
Payment of interest	(7,685)	(6,459)
Exchange rate difference	1,429	3,774
BALANCE AS AT DECEMBER 31	**89,182**	**49,671**
Less: non-current portion	(79,709)	(44,360)
CURRENT PORTION	**9,473**	**5,311**

As at December 31, 2022, Other loans also included borrowings related to financing of research and development expenses and CIR (R&D tax credit in France) of €4.4 million (December 31, 2021: €4.7 million) as well as an amount related to CEPI of €5.2 million December 31, 2021: €3.5 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, 2022, €93.6 million (December 31, 2021: €54.4 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

For the majority of the borrowings and other loans, the fair values are not materially different from their carrying amounts, since the interest payable on those borrowings is either close to current market rates or the borrowings are of a short-term nature.

As at December 31, 2022, material differences were identified only for guaranteed other loans. Based on an estimated arms’ length interest rate of 9.82%, the fair value is €3.9 million (carrying amounts is €4.4 million).

5.25 Trade payables and accruals

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less. Trade payables are recognized initially at fair value. Short-term trade payables are subsequently measured at the repayment amount.

Trade payables and accruals include the following:

In € thousand	As at December 31,	
	2022	2021
Trade payables	14,505	16,035
Accrued expenses	26,986	52,084
BALANCE AS AT DECEMBER 31	**41,491**	**68,119**
Less non-current portion	—	—
CURRENT PORTION	**41,491**	**68,119**

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

5.26 Tax and employee-related liabilities

The Group recognizes a liability and an expense for bonuses. The Group recognizes a liability when it has assumed a contractual obligation or when there is a past practice that has created a constructive obligation.

€ in thousand	As at December 31,	
	2022	2021
Employee-related liabilities	10,778	10,101
Social security and other taxes	4,960	7,148
BALANCE AS AT DECEMBER 31	**15,738**	**17,249**
Less non-current portion	—	—
CURRENT PORTION	**15,738**	**17,249**

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.

The development of lease liabilities is described in Note 5.13.

The maturity of non-current lease liabilities is as follows:

€ in thousand	As at December 31,	
	2022	2021
Between 1 and 2 years	2,341	25,301
Between 2 and 3 years	2,232	2,150
Between 3 and 4 years	2,286	2,214
Between 4 and 5 years	2,322	2,289
Between 5 and 10 years	9,905	10,733
Between 10 and 15 years	8,998	9,114
Over 15 years	80	1,886
NON-CURRENT LEASE LIABILITIES	**28,163**	**53,687**
Current lease liabilities	25,411	3,135
TOTAL LEASE LIABILITIES	**53,574**	**56,822**

The carrying amounts of the Group's lease liabilities are denominated in the following currencies:

€ in thousand	As at December 31,	
	2022	2021
EUR	24,694	24,650
SEK	27,314	30,657
Other	1,566	1,515
TOTAL LEASE LIABILITIES	**53,574**	**56,822**

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:

€ in thousand	2022	2021
BALANCE AS AT JANUARY 1	128,758	89,636
Revenue recognition	(130,678)	(89,364)
Exchange rate differences	498	7
Addition	10,833	128,479
BALANCE AS AT DECEMBER 31	**9,411**	**128,758**
Less non-current portion	—	(4,741)
CURRENT PORTION	**9,411**	**124,017**

In 2022, revenue recognized in the amount of €116.8 million related to the APA with the European Commission (see Note 5.1), €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.

In 2022, additions (amounts received for future performance obligations) 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.

With regards to additions in 2021, €116.9 million were related to the APA with the European Commission to supply up to 60 million doses of VLA2001, €3.8 million were related to the APA with the Kingdom of Bahrain, and €4.7 million were related to a payment received from the DoD for IXIARO. Of the changes to the position because of revenue recognized in 2021, €87.0 million related to the UK Supply Agreement (see Note 5.1).

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:

(In € thousand)	2022	2021
BALANCE AS AT JANUARY 1	254,581	111,426
Additions	52,012	159,179
Payments	(2,626)	(18,022)
Other releases	(879)	(15,198)
Revenue recognition	(169,242)	—
Interest expense capitalized	9,597	8,478
Exchange rate difference	(357)	8,718
BALANCE AS AT DECEMBER 31	**143,085**	**254,581**
Less non-current portion	(6,635)	(158,970)
CURRENT PORTION	**136,450**	**95,611**

As at December 31, 2022, €135.5 million (of which €135.5 million is current) related to the collaboration with Pfizer (see Note 5.1) and €6.6 million (of which €6.6 million is non-current) related to the expected payment to GSK related to 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 (£70.8) million. Additions included the milestone of $25 million (€24.5 million) related to the Collaboration and License Agreement with Pfizer as well as other payments received where we have a repayment obligation.

As at December 31, 2021, €79.6 million of which €75.2 million is non-current) related to the collaboration with Pfizer (see Note 5.1), €166.9 million (of which €77.3 million is non-current) related to the UK Supply Agreement (see Note 5.5.2), €6.4 million (of which €6.3 million non-current) related to the expected payment to GSK related to the termination of the SAA in 2019. Other releases related to reductions in refund liabilities in the wake of revaluations that increased contract liabilities.

Expected cash outflows for refund liabilities are disclosed under Note 5.2.5.

5.30 Provisions

5.30.1 Provisions for employee commitments

€ in thousand	As at December 31,	
	2022	2021
Employer contribution costs on share-based compensation plans	3,330	26,520
Phantom shares	2,976	14,267
Retirement termination benefits	330	422
Leaving indemnities	267	—
BALANCE AS AT DECEMBER 31	**6,903**	**41,210**
Less non-current portion	1,320	8,308
CURRENT PORTION	**5,583**	**32,901**

(a) 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, 2022: €6.22 (December 31, 2021: €24.5).

(b) 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

	As at December 31,	
	2022	**2021**
Discount rate	3.60 %	1.00 %
Salary increase rate	2.50 %	2.00 %
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)	20	22

Changes in defined benefit obligation

Present value of obligation development:

(In € thousand)	**2022**	**2021**
BALANCE AS AT JANUARY 1	**422**	**550**
Current service cost	86	77
Actuarial losses/(gains)	(178)	(205)
BALANCE AS AT DECEMBER 31	**330**	**422**

5.30.2 Other provisions

€ in thousand	**As at December 31,**	
	2022	**2021**
Non-current	960	—
Current	24,714	15,806
PROVISIONS	**25,674**	**15,806**

As at December 31, 2022, €18.8 million of the provision related mainly to onerous purchase agreements related to the wind-down of COVID activities (December 31, 2021: €13.5 million). Secondly, the position comprised €5.2 million from a provision for expected legal and settlement costs under a court proceeding related to the Intercell AG/Vivalis SA merger (December 31, 2021: €2.1 million).

5.31 Other liabilities

€ in thousand	**As at December 31,**	
	2022	**2021**
Deferred income	5,519	4,966
Other financial liabilities	32	44
Miscellaneous liabilities	88	8
OTHER LIABILITIES	**5,639**	**5,019**
Less non-current portion	(116)	(69)
CURRENT PORTION	**5,523**	**4,950**

As at December 31, 2022 deferred income mainly included conditional advances from government enterprise grants in Scotland, whereas as at December 31, 2021 deferred income mainly included a conditional advance payment from CEPI (see Note 5.8).

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	Note	Year ended December 31,		
		2022	2021	2020
LOSS FOR THE YEAR		(143,279)	(73,425)	(64,393)
Adjustments for :				
Depreciation and amortization	5.12/5.13/5.14	21,036	14,281	9,799
Write-off/impairment fixed assets/intangibles	5.12/5.13/5.14	23,249	—	140
Share-based compensation expense	5.23	(8,656)	14,509	6,328
Income tax expense/(income)	5.10	(1,536)	3,446	(909)
Dividends received from associated companies	5.16	—	—	—
(Profit)/loss from disposal of property, plant, equipment and intangible assets	5.8	38	46	10
Share of (profit)/loss from associates	5.16	(9)	5	133
Fair value losses on derivative financial instruments		—	—	—
Provision for employer contribution costs on share-based compensation plans	5.30.1	(22,933)	19,079	7,351
Other non-cash (income)/expense		14,088	(11,604)	4,470
Interest income	5.9	(260)	(249)	(119)
Interest expense	5.9	19,054	16,964	10,738
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and consolidation) :				
Other non-current assets		10,981	194	(2,303)
Long term contract liabilities	5.28	(5,241)	4,662	(674)
Long term refund liabilities	5.29	(154,833)	54,501	90,653
Other non-current liabilities and provisions		1,379	(3)	795
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):				
Inventory		84,224	(92,373)	(4,196)
Trade and other receivables		12,401	(21,349)	(24,023)
Contract liabilities	5.28	(114,603)	34,453	88,801
Refund liabilities	5.29	33,764	80,160	10,614
Trade and other payables and provisions		(14,053)	35,236	6,544
CASH GENERATED FROM OPERATIONS		(245,189)	78,532	139,759

In 2022, other non-cash (income)/expense mainly related to net foreign exchange losses. In 2021, other non-cash (income)/expense mainly related to net foreign exchange gains.

In 2020, other non-cash (income)/expense included €3.3 million of expenses from disposal of VLA15 (see Notes 5.1 and 5.12), €1.6 million of income from a revaluation of lease liabilities and right of use assets and €2.6 million of net foreign exchange losses.

The following table shows the adjustments to reconcile profit/loss from the disposal of property, plant, equipment and intangible assets to proceeds from the disposal of fixed assets:

€ in thousand	Year ended December 31,		
	2022	2021	2020
Net book value	46	46	34
Loss on disposal of fixed assets	(38)	(46)	(10)
PROCEEDS FROM DISPOSAL OF PROPERTY, PLANT, EQUIPMENT AND INTANGIBLE ASSETS	**8**	**—**	**24**

5.32.2 Reconciliation of liabilities arising from financing activities

The table below details changes in the Group's liabilities arising from financing activities, including both cash and non-cash changes. 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 lease liabilities, see Note 5.13.

(In € thousand)	Bank borrowings	Other loans	Total
BALANCE AS AT JANUARY 1, 2021	**—**	**53,363**	**53,363**
Repayments	—	(1,956)	(1,956)
Additions, net of transaction costs	—	859	859
Foreign exchange movements	—	3,998	3,998
Other changes[8]	—	1,570	1,570
BALANCE AS AT DECEMBER 31, 2021	**—**	**57,834**	**57,834**
BALANCE AS AT JANUARY 1, 2022	**—**	**57,834**	**57,834**
Repayments	—	(1,793)	(1,793)
Additions, net of transaction costs	—	39,331	39,331
Foreign exchange movements	—	2,073	2,073
Other changes[8]	—	1,362	1,362
BALANCE AS AT DECEMBER 31, 2022	**—**	**98,806**	**98,806**

[8]Other changes include interest accruals and payments.

5.33 Commitments and contingencies

As at December 31, 2022, there were €9.9 million of capital expenditure contracted, mainly related to manufacturing sites for the COVID-19 vaccine candidate (December 31, 2021: €23.6 million).

5.33.1 Other commitments, pledges and guarantees

The other commitments relate to minimum payments consist of:

€ in thousand	As at December 31,	
	2022	2021
Loans and grants	49	143
Royalties	8,262	8,941
OTHER COMMITMENTS	**8,311**	**9,084**

The pledges consist of:

€ in thousand	As at December 31,	
	2022	2021
Pledges on consolidated investments	28,247	19,901
Pledges on bank accounts	284,889	292,257
Pledges on receivable	219,494	344,519
GUARANTEES AND PLEDGES	**532,630**	**656,677**

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; however, the final outcome will depend on the court's position on a couple of 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, 2021: €2.1 million). €3.1 million of additional expenses related to this litigation was included in "other expenses" in the period ended December 31, 2022.

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 BliNK 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 is expected in the third quarter of 2023. After consultation with its external advisors the Company believes that this claim is unsubstantiated, and the filed litigation is not likely to succeed in court. Detailed information on the potential specific financial consequences, which might result from a successful claim could adversely affect the Company's ability to defend its interests in this case and therefore is not provided, in accordance with IAS 37.92.

5.34 Related-party transactions

5.34.1 Rendering of services

In € thousand	Year ended December 31,		
	2022	2021	2020
Provision of services:			
Operating activities	1,200	231	187
Financing activities	8	—	—
PROVISION OF SERVICES	**1,208**	**231**	**187**

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 amounting to €1.2 million included Valneva's agreement with Vital Meat SAS (an affiliate of Group Grimaud La Corbière SAS) according to which Valneva transferred certain assets (patent and cell lines) to Vital Meat SAS for a consideration of €1.0 million.

From June 2022 onward, Bpifrance qualifies as related party, as Bpifrance is a shareholder of Valneva with significant influence through membership on the Company's Supervisory Board. A financing of receivables from the French Tax Authorities relating to the Research Tax Credit 2021, previously domiciled and assigned to Bpifrance, amounting to 80% of the amount of the assigned receivables, was granted in November 2022 until July 31, 2023. The amount borrowed is €1.4 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 —% if it were to be negative) plus 1.7% per annum were charged for an amount of €8,000 at December 31, 2022.

5.34.2 Key management compensation

The aggregate compensation of the members of the Company's Management Board included the following:

€ in thousand	Year ended December 31,		
	2022	2021	2020
Salaries and other short-term employee benefits[9]	2,821	1,930	2,950
Other long-term benefits	45	24	18
Share-based payments (expense of the year)	722	856	1,786
KEY MANAGEMENT COMPENSATION	**3,588**	**2,809**	**4,755**

[9]In 2020 leaving indemnities of 0.9 million have been included.

5.34.3 Supervisory Board compensation

In 2022, the aggregate compensation of the members of the Company's Supervisory Board amounted to €0.4 million (2021: €0.3 million, 2020: €0.2 million). In the year 2017, the Company granted equity warrants to members of the Supervisory Board, which were fully exercised in 2022. For more information, see Note 5.23.

5.35 Events after the reporting period

No events that are expected to have a material effect on the financial statements occurred after the reporting period.

VALNEVA SE

European company with an Management Board and Supervisory Board
with a share capital of 20,752,045.20 Euros
Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain
Identification N° 422 497 560 RCS Nantes

ARTICLES OF ASSOCIATION

As amended by the *Directeur General* decisions of January 4, 2023[1]

[1] RCS – Trade and Companies Register

TITLE I

FORM - COMPANY NAME - COMPANY OBJECT -

REGISTERED OFFICE - DURATION

Article 1. Form

The company was incorporated in the form of a Limited Liability Company with a Board of Directors under the terms of a private deed of 24 March 1999.

The shareholders of the company modified the form of management and governance, adopting the formula of a Management Board and Supervisory Board, by decision of the Extraordinary General Meeting of 29 November 2002.

On May 28 2013, the Company was transformed into a European Company (Societas Europaea or SE) with a Management Board and Supervisory Board through a cross-border merger between Intercell AG, a company governed by Austrian law, with a share capital of 55,183,961 Euros, with registered office at Campus Vienna Biocenter 3, 1030 Vienna, Austria, formerly entered in the Trade and Companies Register of Vienna under number FN 166438m and Vivalis SA, a limited liability company governed by French law with a share capital of 3.224.379,30 Euros, with registered office at La Corbière - 49450 Roussay, and with the unique identification number 422 497 560 RCS Angers.

It is governed by the European Community and national regulations in effect, as well as by these Articles of Association (the ***Company***).

Article 2. Name

The company name is: Valneva.

In all of the instruments and documents deriving from the Company and intended for third parties, the name must be immediately preceded or followed by the words "European company" or the initials "SE" and a statement of the amount of the share capital.

Article 3. Object

The Company has as its object, within France and in every country:

- research and development within the field of biomedicine and pharmacology;
- the 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;
- the production, monitoring and marketing of all products, services and research programmes with applications to human and animal health, using the technologies of molecular and cellular biology and all of the associated techniques;
- the participation of the Company by all means, direct or indirect, in all operations which may be associated with its company object, through 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 favour its exploitation, realisation or development.

Article 4. Registered office

The registered office of the Company is located at 6 rue Alain Bombard, 44800 Saint-Herblain.

The registered office may be transferred to any location within France, upon simple decision by the Supervisory Board and subject to ratification by the shareholders at their next Ordinary General Meeting or by a decision of the Extraordinary General Meeting in accordance with applicable statutory provisions. The transfer of the registered office to another member State of the European Community is subject to ratification of the Special Meeting of the Shareholders in accordance with L. 229-2 of the French commercial code. In the case of a transfer decided in accordance with the law by the Supervisory Board, the latter is authorized to modify the Articles of Association in consequence.

Article 5. Duration - Financial year

The duration of the Company shall be ninety nine (99) years from its first registration in the Trade and Companies Register, except in cases of extension or early dissolution.

The financial year shall begin on 1 January and shall end on 31 December.

TITLE II

SHARE CAPITAL – SHARES

Article 6. Share Capital

The share capital is set at 20,752,045.20 Euros. It is divided into:

- 138,346,968 ordinary shares with nominal value of 0.15 Euro each, fully subscribed and paid up.

Article 7. Change in the share capital

The share capital shall be increased by any means and by all procedures provided by law. The Extraordinary General Meeting, on the report of the Management Board, has sole competence for deciding on the share capital increase and may delegate such competence as provided by law.

The shareholders shall have a preferential subscription right, in proportion to their shares, for subscribing to shares in the context of a share capital increase. Shareholders may waive their preferential subscription right in an individual capacity.

The right to the allocation of new shares to the shareholders, following the capitalisation of reserves, profits or issuance premiums, shall belong to the bare owner, subject to the rights of the usufructuary.

Pursuant to the Management Board meeting dated June 7, 2013, noting the exercise of stock options, the share capital has been increased up to 6,092,801.94 Euros through cash contributions of 174,571.20 Euros, including 14,547.60 Euros in nominal.

Pursuant to the Management Board meeting dated July 5, 2013, the share capital has been increased, through cash contributions, of 2,274,782.25 Euros in nominal, raising it from 6,092,801.94 Euros to 8,367,584.19 Euros.

Pursuant to the Management Board meeting dated July 24, 2013, noting the end of the four years vesting period with respect to free shares allocated to employees on July 23, 2009, the share capital has been increased up to 8,369,159.19 Euros through incorporation of issue premiums of 1,575 Euros.

Pursuant to the Management Board meeting dated October 9, 2013, noting the end of the two years vesting period with respect to free shares allocated to employees on September 6, 2011, the share capital has been increased up to 8,370,659.19 Euros through incorporation of issue premiums of 1,500 Euros.

Pursuant to the Management Board meeting dated January 21, 2014, noting the exercise of stock options, the share capital has been increased up to 8,384,717.19 Euros through cash contributions of 168,696 Euros, including 14,058 Euros in nominal.

Pursuant to the Management Board meeting dated January 21, 2014, noting the definitive allocation of free shares granted by the Company to employees and executive officers on February 22, 2010 (plan 2 - allotment 2), the share capital has been increased up to 8,389,717.14 Euros through incorporation of issue premiums of 4,999.95 Euros.

Pursuant to the Management Board meeting dated March 3, 2014, noting the end of the four years vesting period with respect to free shares allocated to employees on February 22, 2010, the share capital has been increased up to 8,390,317.14 Euros through incorporation of issue premiums of 600 Euros.

On May 21, 2014, the *Directeur Général*, acting by delegation of powers granted by the Management Board on May 12, 2014, noticed the exercise of share issuance rights. Consequently, the share capital of the company has been increased up to 8,465,317.14 Euros, through cash contributions of 2,770,000 Euros, including 75,000 Euros in nominal.

On June 3, 2014, the *Directeur Général*, acting by delegation of powers granted by the Management Board on May 12, 2014, noticed the exercise of share issuance rights. Consequently, the share capital of the company has been increased up to 8,555,317.14 Euros, through cash contributions of 3,486,000 Euros, including 90,000 Euros in nominal.

On June 25, 2014, the *Directeur Général*, acting by delegation of powers granted by the Management Board on May 12, 2014, noticed the exercise of share issuance rights.

Consequently, the share capital of the company has been increased up to 8,630,317.14 Euros, through cash contributions of 2,700,000 Euros, including 75,000 Euros in nominal.

Pursuant to the Management Board meeting dated October 2, 2014, noting the end of the four years vesting period with respect to free shares allocated to employees on October 1st, 2010, the share capital has been increased up to 8,631,142.14 Euros through incorporation of issue premiums of 825 Euros.

Pursuant to the Management Board meeting dated February 6, 2015, the share capital has been increased, through cash contributions, of 2,734,719.90 Euros in nominal, raising it from 8,631,142.14 Euros to 11,365,862.04 Euros.

As a result of the Management Board meeting held on April 30, 2015, acknowledging stock options subscriptions, the share capital has been raised to 11,377,832.04 Euros, through a cash contribution of 143,640 Euros, including 11,970 Euros as nominal value.

Pursuant to the Management Board meeting dated July 24, 2015, noting the end of the two years vesting period with respect to free shares allocated to employees on July 24, 2013, the share capital has been increased up to 11,382,407.04 Euros through incorporation of issue premiums of 4,575 Euros.

As a result of the Management Board meeting held on July 28, 2015, acknowledging the subscription of preferred share convertible into ordinary shares ("Convertible Preferred Shares"), the share capital has been raised to 11,382,568.14 Euros, through a cash contribution of 172,914 Euros, including 161.10 Euros as nominal value.

Pursuant to the Management Board meeting dated September 7, 2015, noting the end of the four years vesting period with respect to free shares allocated to employees on September 6, 2011, the share capital has been increased up to 11,383,243.14 Euros through incorporation of issue premiums of 675 Euros.

On December 14, 2016, pursuant to a decision of the Managing Director, acting by delegation of powers granted by the Management Board on November 30, 2016, the share capital has been increased up to 11,815,935.39 Euros through cash contributions of 7,499,999 Euros, including 432,692.25 Euros in nominal.

Pursuant to a decision of the Managing Director dated May 17, 2017, acting by delegation of powers granted by the Management Board on May 15, 2017, noticed the buy back and the cancellation of 285 Convertible Preferred Shares. Consequently, the share capital of the company has been decreased to 11,815,892.64 Euros, through cash reduction of 42.75 Euros in nominal.

Pursuant to the Management Board meeting dated July 24, 2017, noting the end of the four years vesting period with respect to free shares allocated to employees on July 24, 2013, the share capital has been increased up to 11,816,042.64 Euros through incorporation of issue premiums of 125 Euros.

On October 1, 2018, pursuant to a decision of the Chairman of the Management Board, acting by delegation of powers granted by the Management Board on September 26, 2018, the share capital has been increased up to 13,816,042.74 Euros through cash contributions of 50,000,002.50 Euros, including 2,000,000.10 Euros in nominal.

Pursuant to the Management Board meeting dated May 3, 2019, noting the exercise of equity warrants on April 24, 2019, the share capital has been increased to 13,816,511.49 Euros, through a cash contribution of 8,043.75 Euros, including 468.75 Euros as nominal value.

Pursuant to the Management Board meeting dated July 29, 2019, noting the end of the four years vesting period with respect to free convertible preferred shares allocated to employees or Management Board members on July 28, 2015, the share capital has been increased up to 13,819,470.24 Euros through incorporation of issue premiums of 2,958.75 Euros.

Pursuant to the Management Board meeting dated November 4, 2019, noting the exercise of equity warrants on October 25, 2019, the share capital has been increased to 13,819,938.99 Euros, through a cash contribution of 8,043.75 Euros, including 468.75 Euros as nominal value.

Pursuant to the Management Board meeting dated May 15, 2020, noting the exercise of equity warrants on May 12, 2020, the share capital has been increased to 13,820,407.74 Euros, through a cash contribution of 8,043.75 Euros, including 468.75 Euros as nominal value.

Pursuant to the Management Board meeting dated May 29, 2020, deciding to cancel all of the 17,836,719 preferred shares redeemed by the Company, the share capital was decreased at 13,642,040.55 Euros through cancellation of 17,836,719 preference shares with a par value of 0.01 Euros each, *i.e*. a share capital decrease for the total nominal amount of 178,367.19 Euros.

Pursuant to the Management Board meeting dated July 29, 2020, noting the exercise of equity warrants on July 27, 2020, the share capital has been increased to 13,642,771.80 Euros, through a cash contribution of 19,110 Euros, including 731.25 Euros as par value.

Pursuant to the Management Board meeting dated August 31, 2020, noting the exercise of equity warrants on August 25, 2020, the share capital has been increased to 13,643,240.55 Euros, through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the Management Board meeting dated December 1, 2020, noting the exercise of equity warrants on November 26, 2020, the share capital has been increased to 13,643,709.30 Euros, through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the Management Board meeting dated December 10, 2020, noting the exercise of equity warrants on December 4, December 7 and December 9, 2020, the share capital has been increased to 13,645,584.30 Euros, through a cash contribution of 32,175 Euros, including 1,875 Euros as par value.

On January 27, 2021, the *Directeur Général* noting (i) the exercise of equity warrants on January 22, 2021 (representing a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value), and (ii) the exercise of stock options between January 18 and January 25, 2021 inclusive (representing a total cash contribution of 2,200,886.75 Euros, including 118,511.25 Euros as par value). Consequently, the share capital of the company has been increased up to 13,764,564.30 Euros.

Pursuant to the Management Board meeting dated May 6, 2021, the share capital has been increased, through cash contributions, by 1,062,414.30 Euros in nominal value, raising it from 13,764,564.30 Euros to 14,826,978.60 Euros.

Pursuant to the Management Board meeting dated May 7, 2021, the share capital has been increased, through cash contributions, by 159,362.10 Euros in nominal value, raising it from 14,826,978.60 Euros to 14,986,340.70 Euros.

Pursuant to the decisions of the *Directeur Général* dated August 26, 2021 (acting by delegation of powers granted by the Management Board on January 25, 2021), noting the exercise of equity warrants on August 19, 2021, the share capital has been increased to 14,986,809.45 Euros through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the decisions of the *Directeur Général* dated September 3, 2021 (acting by delegation of powers granted by the Management Board on January 25, 2021), noting the exercise of equity warrants on September 2, 2021, the share capital has been increased to 14,987,278.20 Euros through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the Management Board meeting dated October 4, 2021, deciding to cancel all of the 4,025 Ordinary Shares held as treasury shares by the Company following termination of its liquidity agreement, the share capital was decreased to 14,986,674.45 Euros through cancellation of 4,025 Ordinary Shares with a par value of 0.15 Euros each, i.e., a share capital decrease for the total nominal amount of 603.75 Euros.

Pursuant to the Management Board meeting dated October 28, 2021, the share capital has been increased, through cash contributions, by 675,000 Euros in nominal value, raising it from 14,986,674.45 Euros to 15,661,674.45 Euros.

Pursuant to the Management Board meeting dated October 30, 2021, the share capital has been increased, through cash contributions, by 101,250 Euros in nominal value, raising it from 15,661,674.45 Euros to 15,762,924.45 Euros.

Pursuant to the decisions of the *Directeur Général* dated December 9, 2021 (acting by delegation of powers granted by the Management Board on January 25, 2021), noting the exercise of equity warrants on December 6, December 7 and December 8, 2021, the share capital has been increased to 15,764,799.45 Euros through a cash contribution of 32,175 Euros, including 1,875 Euros as par value.

Pursuant to the Management Board meeting dated December 15, 2021, noting the end of the four years vesting period with respect to free convertible preferred shares allocated to employees or Management Board members on December 15, 2017, the share capital has been increased up to 15,769,668.90 Euros through incorporation of issue premiums of 4,869.45 Euros.

Pursuant to the decisions of the *Directeur Général* dated December 22, 2021 (acting by delegation of powers granted by the Management Board on December 15, 2021), noting the conversion, with effect on December 16, 2021, of Convertible Preferred Shares definitively allotted by the Management Board on December 15, 2021, the share capital has been

increased to 15,785,862.75 Euros as a result of the conversion of 4,115 Convertible Preferred Shares with a par value of 0.15 euro each into 112,074 new Ordinary Shares, also with a par value of 0.15 euro each (representing a net share capital increase of 16,193.85 Euros, paid up by debiting the special blocked reserve account).

Pursuant to the decisions of the *Directeur Général* dated January 11, 2022 (acting by delegation of powers granted by the Management Board on December 15, 2021), noting the conversion, with effect on January 3 and 4, 2022, of Convertible Preferred Shares definitively allotted by the Management Board on December 15, 2021, the share capital has been increased to 15,897,421.05 Euros as a result of the conversion of 28,348 Convertible Preferred Shares with a par value of 0.15 euro each into 772,070 new Ordinary Shares, also with a par value of 0.15 euro each (representing a net share capital increase of 111,558.30 Euros, paid up by debiting the special blocked reserve account).

Pursuant to the decisions of the *Directeur Général* dated January 26, 2022 (acting by delegation of powers granted by the Management Board on January 17, 2022), noting (i) the exercise of equity warrants on January 21, 2022 (representing a total cash contribution of 8,043.75 Euros, including 468.75 Euros as par value), and (ii) the exercise of stock options between January 4 and January 11, 2022 inclusive (representing a total cash contribution of 3,908,987.37 Euros, including 176,458.65 Euros as par value), the share capital of the company has been increased up to 16,074,348.45 Euros.

Pursuant to the decisions of the *Directeur Général* dated February 25, 2022 (acting by delegation of powers granted by the Management Board on January 17, 2022), noting the exercise of equity warrants on February 4, 2022, the share capital of the company has been increased up to 16,074,817.20 Euros through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the Management Board meeting dated March 25, 2022, noting the end of the vesting period in respect of a portion of the free Ordinary Shares initially granted on December 19, 2019 to employees or corporate officers, the share capital has been increased to 16,170,314.40 Euros through incorporation of issue premium of 95,497.20 Euros.

Pursuant to the Management Board meeting dated June 19, 2022, the share capital has been increased, through cash contributions, by 1,432,464.15 euros in nominal value, raising it from 16,170,314.40 euros to 17,602,778.55 euros.

Pursuant to the Management Board meeting dated September 29, 2022, the share capital has been increased, through cash contributions, by 3,150,000 euros in nominal value, raising it from 17,602,778.55 euros to 20,752,778.55 euros.

Pursuant to the decisions of the *Directeur Général* dated October 31, 2022 (acting by delegation of powers granted by the Management Board on January 17, 2022), noting the exercise of equity warrants on October 21, 2022, the share capital of the company has been increased up to 20,753,247.30 Euros through a cash contribution of 8,043.75 Euros, including 468.75 Euros as par value.

Pursuant to the decisions of the *Directeur Général* dated December 1, 2022 (acting by delegation of powers granted by the Management Board on January 17, 2022), noting the exercise of equity warrants on November 30, 2022, the share capital of the company has been increased up to 20,754,184.80 Euros through a cash contribution of 16,087.50 Euros, including 937.50 Euros as par value.

Pursuant to the decisions of the *Directeur Général* dated December 23, 2022 (acting by delegation of powers granted by the Management Board on January 17, 2022), noting the exercise of equity warrants on December 8 and 10, 2022, the share capital of the company has been increased up to 20,755,122.30 Euros through a cash contribution of 16,087.50 Euros, including 937.50 Euros as par value.

Pursuant to the Management Board meeting dated January 4, 2023, the share capital was decreased to 20,752,045.20 Euros through cancellation of 20,514 preferred shares convertible with nominal value of 0.15 Euro each, i.e., a share capital decrease for the total nominal amount of 3,077.10 Euros.

Article 8. Paying up of the shares

Shares subscribed in cash shall mandatorily be paid up for at least a quarter of their nominal value on subscription and if necessary, for the entire issuance premium.

The paying in of the surplus shall take place on one or several occasions, at the decision of the Management Board, within five years of the date on which the share capital increase has become final.

Calls for funds shall be brought to the attention of subscribers by registered letter with notice of receipt, sent at least fifteen days before the date set for each payment. Payments shall be made either to the registered office or to any other place indicated for this purpose.

Any delay in the payment of amounts due on the unpaid amount of the shares shall entail, *ipso jure* and without any formality being necessary, the payment of interest at the legal rate, starting from the due date, without prejudice to the personal action that the Company may take against the defaulting shareholder and the enforcement measures provided by law.

Article 9. Reduction - amortisation of the share capital

The reduction of the share capital shall be authorised or decided by the Extraordinary General Meeting, which may delegate all of the powers to the Management Board for the execution of the same. In no case may it infringe the equal standing of shareholders.

The reduction of the share capital to an amount less than the legal minimum may only be decided under the condition precedent of a share capital increase intended to bring it to an amount at least equal to this minimum, unless the Company is transformed into a company of another form.

In the event of failure to comply with these provisions, any interested party may apply to a court for the dissolution of the Company.

At the same time, the court cannot pronounce the dissolution if the adjustment has taken place on the day on which it rules on the merits.

The share capital may be amortised in accordance with the law.

Article 10. Form of the shares

1. The fully paid up shares may take nominative or bearer form, at the choice of the shareholder, subject to the legal and regulatory provisions in effect.

   The shares are recorded in the shareholders' accounts under the conditions and pursuant to the procedures provided by law. The securities recorded in the account are transferred by transfer from account to account. Records in the accounts, payments and transfers are carried out in accordance with legal and regulatory requirements.

2. For the purposes of identifying the holders of bearer shares, the Company is entitled, according to legal and regulatory requirements, to ask at its own expense the central depository responsible for maintaining the securities issuance account (the ***Central Depositary***), as per the case, for the name or company name, nationality, year of birth or year of incorporation and the addresses of the holders of securities conferring immediate or future voting rights at its meetings and the number of shares held by each of them, as well as, if applicable, the restrictions which may affect the securities.

   With regard to the list provided to the Company by the Central Depositary, the Company has the right to request either from the Central Depository, or directly from the persons on this list and which the Company believes may be registered as an intermediary and on behalf of third party owners of securities, the information provided in the preceding paragraph regarding the owners of the securities.

   These persons shall be required, if they have the capacity of intermediary, to disclose the identity of the owners of these securities. The information shall be provided directly to the authorised financial intermediary which holds the account, with the obligation of this latter party to notify it, as appropriate, to the Issuer or to the Central Depository.

   The Company is also entitled, with regard to the securities in the nominative form, to ask, at any time, the intermediary registered on behalf of third party owners of the securities to disclose the identity of the owners of these securities.

   For as long as the Company considers that certain holders of securities, in bearer or nominative form, whose identity has been disclosed to it are acting as holders on behalf of third party owners of the shares, it shall be entitled to ask these owners to reveal the identity of the owners of the securities, under the conditions provided above.

   Following the requests for information cited above, the Company shall be entitled to request that any legal person owning shares of the Company representing more than 2% of its share capital or voting rights reveals the identity of persons holding directly or indirectly more than one third of the share capital of this legal person or of the voting rights which are exercised at the general meetings of the same person.

   When the person forming the object of a request pursuant to the stipulations of this Article has not submitted the information so requested within the legal and regulatory deadlines or has transmitted incomplete or erroneous information regarding either its capacity or the owners of the securities, the shares or the securities giving immediate or future access to the share capital for which the person has been entered in the account shall be deprived of voting rights for all General Meetings to be held until the

date of regularisation of identification, with the payment of dividends deferred until that date.

Article 11. Indivisibility of shares

Shares are indivisible with respect to the Company. The undivided joint owners of shares shall be represented at General Meetings by one of their number or by a joint representative of their choice. In the absence of agreement among them on the choice of a representative, the latter shall be designated by order of the President of the Commercial Court ruling in summary proceedings at the request of the first joint owner to take action.

The bare owner and the usufructuary have the right to participate in collective decisions. The voting right attached to the share belongs to the usufructuary for the Ordinary General Meetings and to the bare owner for the Extraordinary General Meetings. Shareholders may nevertheless agree among themselves on any other allocation for the exercise of the voting right at General Meetings. In this event, they shall bring their agreement to the attention of the Company by registered letter addressed to the registered office, with the Company obliged to observe this agreement for any General Meeting to be convened after the expiry of a one-month deadline after sending the registered letter, with the postmark serving as evidence of the date of dispatch.

The right of the shareholder to obtain notification of the company documents or to consult them may also be exercised by each of the joint owners of the undivided shares, by the usufructuary and the bare owner of shares.

Article 12. Transfer and Transmission of shares - Crossing of Threshold

The transfer of shares shall be made by transfer from account to account, pursuant to the law.

In the event of a share capital increase, the shares shall be negotiable as of its final conclusion.

Movements of securities for which due payments have not been made shall not be authorised.

In addition to the legal obligation to inform the Company of holdings of certain fractions of the share capital and to make any resulting declaration of intent, each natural or legal person, acting alone or in concert, who comes to hold or ceases to hold a fraction equal to 2% of the share capital or voting rights, or any multiple of this percentage, shall be obliged to notify the Company of the same within four stock exchange trading days, as soon as one of these thresholds is crossed, by registered letter with notice of receipt, addressed to the registered office of the Company, specifying the number of shares, corresponding voting rights and securities giving access to the share capital that it holds alone or in concert.

In order to determine the stipulated thresholds, account shall also be taken of the shares held indirectly and of shares regarded as owned shares, as defined by the provisions of Articles L. 233-7 *et seq.* of the French Commercial Code.

In each of the declarations cited above, the declaring party shall certify that the declaration made includes all shares held or possessed pursuant to the provisions of Articles L. 233-*7 et seq.* of the French Commercial Code. It shall also indicate the date or dates of acquisition.

This disclosure obligation applies in all cases of crossing thresholds stipulated above, including the thresholds prescribed by law.

Failure to observe the notification obligation cited above shall be sanctioned, at the demand (recorded in the minutes of the Meeting) of one or several shareholders who together hold a fraction of at least 2% of the share capital or voting rights of the Company, by suspension of voting rights attached to the shares which exceed the fraction that has not been regularly declared for each General Meeting of Shareholders held until the date of regularisation of the notification.

Furthermore, in the event that the registered shareholder knowingly disregards the notification obligation for threshold crossing with regard to the Company, the Commercial Court within the jurisdiction of which the Company has its registered office may, at the request of the Company or of a shareholder, pronounce the complete or partial suspension of voting rights, for a total period not exceeding five years, against any shareholder who has not made the declarations cited above or who has not observed the content of the declaration of intent provided in Article L. 233-7 VII of the French Commercial Code within six (6) months of the publication of the said declaration.

Article 13. Rights and obligations attached to the shares

1. Each share gives the right to participate in collective decisions, as well as the right to be informed of the progress of the Company and to receive certain documents at times and under the conditions provided by law and these Articles of Association.

2. Shareholders shall only bear losses up to the limit of their contributions.

Subject to the provisions of the law and of these Articles of Association, no majority may impose an increase in their commitments. The rights and obligations attached to the share shall follow the security regardless of its holder.

3. The ownership of a share shall entail the *ipso jure* adhesion to the decisions of the General Meeting and to these Articles of Association.

   The assignment shall include all dividends fallen due and falling due, as well as any portion of the reserve fund, unless otherwise notified to the Company.

   The heirs, creditors, assignees or other representatives of a shareholder may not, under any pretext, require the sealing of the property and company documents, demand the division or the sale by auction of these assets or interfere in the administration of the Company. In order to exercise their rights, they shall refer to the company inventories and to the decisions of the General Meeting.

4. Whenever it is necessary to possess a certain number of shares in order to exercise any right, in the event of an exchange, consolidation or attribution of securities or for an increase or reduction in the share capital, a merger or any other transaction, shareholders holding a number of shares less than that required shall only be able to exercise these rights provided that they personally ensure that they obtain the required number of shares.

5. Each share confers a right of ownership of the Company's assets, to profit-sharing and to the liquidation surplus, to a share proportional to the stake in the share capital which it represents, taking into account, where appropriate, amortised and unamortised, paid up and unpaid share capital, for the nominal amount of the shares and the rights of the different classes of shares.

6. Except in cases where the law provides otherwise and with the exception of the double voting right provided below, each shareholder shall have as many voting rights and express as many votes at Meetings as he has shares fully paid up for all of the due payments. For the same nominal value, each capital or participating share shall confer one vote.

7. A double voting right, considering the proportion of the share capital which they represent, shall be attributed to all fully paid up shares, which shall be documented by a registration in the nominative form for at least two years, starting from the registration of the Company in the form of a European company, in the name of the same shareholder. This right is also granted on issuance, in the event of a share capital increase through incorporation of reserves, profits or issue premiums, to the shares attributed as a bonus to a shareholder by virtue of former shares for which it has already benefited from this right.

TITLE III

ADMINISTRATION AND CONTROL OF THE COMPANY

Article 14. Management Board

1. The Company is directed by a Management Board which carries out its duties under the control of the Supervisory Board.

   The Management Board shall be composed of two to at most seven members, appointed by the Supervisory Board.

2. On penalty of nullity of appointment, the members of the Management Board shall be natural persons. They may be chosen from outside the shareholders.

   If a member of the Supervisory Board is appointed to the Management Board, his mandate on the former Board shall end as soon as he takes up his position.

3. The members of the Management Board shall be appointed by the Supervisory Board; they shall be dismissed by the Ordinary General Meeting of shareholders or by the Supervisory Board.

   If the dismissal is decided without just cause, it may give rise to damages.

   In the event that the concerned party has concluded an employment agreement with the Company, the revoking of his functions as a member of the Management Board shall not have the effect of terminating this agreement.

4. The Management Board shall be appointed for a period of three (3) years, ending on the date of the General Meeting convened to decide on the financial statements for the past financial year and held during the year in which the mandate expires, on expiry of which, it shall be entirely renewed. In the event of a vacancy, the Supervisory Board shall make provision within two months for the filling of the vacant

position. A member of the Supervisory Board may be appointed by the Supervisory Board to exercise the duties of a member of the Management Board for the remaining period until the renewal of the Management Board and up to six months. During this period, the duties of the party in question on the Supervisory Board shall be suspended.

The members of the Management Board shall all be re-electable.

5. The age limit for the exercise of duties of the members of the Management Board shall be set at seventy (70). A member of the Management Board in office shall be considered to have resigned at the end of the financial year during which he reaches this age. A member of the Management Board who has been put under guardianship shall also be deemed to have resigned automatically.

   Compulsory retirement in accordance with the preceding paragraph shall not invalidate the discussions and decisions in which the member of the Management Board deemed to have resigned automatically took part.

   The procedure for and amount of remuneration of each of the members of the Management Board shall be set by the Supervisory Board.

6. The Supervisory Board shall appoint one of the members of the Management Board as chairman. The chairman of the Management Board shall carry out his duties for the duration of his mandate as a member of the Management Board.

   The chairman of the Management Board may be dismissed by decision of the General Meeting of shareholders or by the decision of the Supervisory Board, with a majority of the members of the Supervisory Board.

7. The Management Board shall meet as often as the interests of the Company demand, on convening by its Chairman, its *Directeur Général* or by at least half of its members, at the registered office of the company or at any other location indicated in the convening notice; it may be convened by any means, including by e-mail or even verbally. The agenda must appear in the convening notice but may be supplemented at the time of the meeting.

   The Chairman of the Management Board shall chair the sessions and appoint a secretary, who may be chosen from outside of its members. In the absence of the Chairman of the Management Board, the sessions shall be chaired by the *Directeur Général*, or failing that by the member of the Management Board whom the Management Board has appointed for this purpose.

   For decisions to be valid, at least half of the members must be present. If the Management Board includes two members, the decisions shall be taken unanimously. If it includes more than two members, decisions shall be taken by a majority of members present. Each member of the Management Board shall have one voting right; in the event of a tied vote, the Chairman of the Management Board shall have a casting vote.

   For the purposes of calculating the quorum and majority, members of the Management Board who take part in its meeting via conference call or telecommunications media, which permit their identification and guarantee their effective participation, the nature and conditions of application of which are determined by legislative and regulatory provisions in effect shall be considered to be present.

   However, this procedure may not be used to establish the annual financial statements and management report, or to establish the consolidated accounts and management report for the group, if it is not included in the annual report.

8. The Statutory Auditors shall be convened to all of the meetings of the Management Board which examine or draw up the annual or interim financial statements.

9. The decisions are confirmed by minutes drawn up in a special register and signed by the Chairman of the Management Board and another member of the Management Board who has taken part in the session. The special register may be kept, and the minutes may be drawn up and signed, in electronic format, in accordance with applicable laws and regulations.

   The minutes shall mention the name of the present or represented members and those of the absent members. Copies or extracts of these minutes shall be certified the Chairman of the Management Board, one of its members or any other person designated by the Management Board and during the liquidation period, by the liquidator, possibly in electronic format, in accordance with applicable laws and regulations.

10. The members of the Management Board may allocate the executive tasks among themselves with the authorisation of the Supervisory Board, pursuant to Article R. 225-39 of the French Commercial Code. This allocation may in no case dispense the Management Board from meeting and deciding on the most important management issues of the Company nor have the effect of depriving the Management Board of its character as a body which provides the general management of the Company in a collective manner.

Article 15. Attributions and powers of the Management Board

1. The Management Board shall be assigned the most extensive powers for acting in all circumstances in the name of the Company and shall exercise these within the limits of the company object and subject to those expressly attributed by law to the Supervisory Board and to the General Meetings of shareholders and those which require the prior authorisation of the Supervisory Board, as specified below.

   Any limitation on the powers of the Management Board shall be unenforceable against third parties.

   The Management Board shall convene the General Meetings of the shareholders, set their agenda and execute their decisions.

   At least once a quarter, the Management Board shall submit a report to the Supervisory Board which retraces the principal actions or events occurring in the management of the Company.

   After the closure of each financial year and within the following three (3) months, the Management Board shall submit the annual documents to the Supervisory Board, as well as all documents provided by law, for verification and control purposes. It shall propose the allocation of results for the past financial year.

2. The Chairman of the Management Board shall represent the Company in its relations with third parties. At the same time, the Supervisory Board shall be authorised to attribute the same power of representation to one or several members of the Management Board, for which each of them shall then have the title of *Directeur Général*. The Supervisory Board may abolish this power of representation by withdrawing the role of *Directeur Général* from the member of the Management Board. The Company shall even be committed by the actions of the Chairman or one of the *Directeurs Généraux* which do not relate to the Company object, unless it demonstrates that the third party was aware that this action exceeded this object or could not have been unaware of the same in view of the circumstances.

   The stipulations limiting this power of representation are unenforceable against third parties.

   The actions committing the Company with regard to third parties are validly executed with a single signature of any one of the members of the Management Board authorised to represent the Company, pursuant to the stipulations of this Article.

3. The Management Board may entrust special, permanent or temporary missions which it determines to one or several of its members or to any other person and delegate the powers to them which it judges necessary for one or several given objects, with or without the power of subdelegation.

4. The Management Board shall examine and present the quarterly and half-yearly accounts to the Supervisory Board.

5. The Management Board shall decide or authorise the issuance of bonds under the conditions of Article L. 228-40 of the French Commercial Code, unless the General Meeting decides to exercise this power. The Management Board may delegate to its Chairman and, with the agreement of the same, to one or several of its members, the powers necessary for realising the issuance of bonds, within a one-year deadline, and draw up the procedures for these.

6. The members of the Management Board, as well as any person convened on to attend its meetings shall be bound by secrecy with regard to information of a confidential character or which is presented as such.

7. The decision listed in Article 19 of these Articles of Association are subject to the prior approval of the Supervisory Board, ruling with a simple or enhanced majority or unanimously, as per the case, at the proposal of the Management Board.

   When an operation demands the authorisation of the Supervisory Board, pursuant to Article 19 of these Articles of Association and which this latter party refuses, the Management Board may submit the difference to the General Meeting of shareholders, which shall decide on the follow-up for the plan, pursuant to Article R. 225-40 of the French Commercial Code.

Article 16. Composition of the Supervisory Board

The Supervisory Board consists of at least three (3) members and at most eighteen (18) members, appointed by the Ordinary General Meeting of shareholders, subject to legal exemptions.

The members of the Supervisory Board who are natural persons, must be aged less than eighty (80), subject to the following stipulations.

A legal person may be appointed as member of the Supervisory Board but must, under the conditions provided by the law, designate a natural person who shall be its permanent representative on the Supervisory Board. The permanent representatives must be aged less than eighty (80), subject to the following stipulations.

Article 17. Duration of duties – Renewal – Co-opting

The term of office of the members of the Supervisory Board is set at three (3) years (with one year understood as the interval between two consecutive Ordinary General Meetings), subject to the following stipulations.

The term of office of any member of the Supervisory Board shall be limited to the remaining period until the annual Ordinary General Meeting, held in the year during which the member of the Supervisory Board in question reaches the age of eighty (80).

A member of the Supervisory Board put under guardianship shall be deemed to have resigned automatically. Such compulsory resignation shall not invalidate the discussions and decisions in which the member of the Supervisory Board deemed to have resigned automatically took part.

The members of the Supervisory Board shall be re-elected on one or several occasions, subject to the above stipulations concerning the age limit. They may be dismissed at any time by decision of the Ordinary General Meeting, under the conditions and pursuant to the procedures provided by law.

In the event of a vacancy, due to death or resignation, of one or several positions on the Supervisory Board, the Supervisory Board may make appointments in a provisional capacity between two General Meetings. These appointments shall be submitted for the ratification of the following Ordinary General Meeting. In the absence of ratification, the decisions taken and the acts previously carried out by the Board shall nevertheless remain valid.

When the number of members of the Supervisory Board has fallen below the legal minimum, the Management Board shall call the Ordinary General Meeting within the shortest possible period, with a view to establishing a full Board.

The member appointed as a replacement for another whose mandate has not expired, shall only remain in office during the remaining time of the mandate of his predecessor.

Furthermore, the Supervisory Board may include elected members representing employees, pursuant to the provisions of Article L. 225-79 and, as appropriate, L. 225-71 and L. 22-10-22 of the French Commercial Code.

Article 18. Bureau and resolutions of the Board

1. The Board shall, among its members, appoint a Chairman and a Deputy Chairman, who are responsible for convening Board meetings and, as the case may be, directing its discussions. The Chairman shall also designate a secretary, who may be selected outside the shareholders and, together with the Chairman and the Deputy Chairman, shall form the Board committee.

   They shall be appointed for the duration of their mandate for the Supervisory Board and shall always be re-electable.

   The Chairman and the Deputy Chairman shall be natural persons.

   In the event of absence or impediment of the Chairman, the session of the Supervisory Board shall be chaired by the Deputy Chairman.

2. Supervisory Board meetings shall be held as often as the interests of the Company require and at least once per quarter, at the request of the Chairman, the Deputy Chairman or a member of the Supervisory Board, made by any written means, including by email or even verbally.

   At the same time, the Chairman shall convene the Board on a date which must not be more than fifteen (15) days later, when at least one member of the Management Board or at least one third of the members of the Supervisory Board submit a grounded request in this sense. If the request has remained without response, its authors may themselves call the meeting, indicating the agenda of the session. Other than this case, the agenda shall be set by the Chairman and may only be set at the time of the meeting.

Supervisory 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.

In-person meetings shall take place at the registered office or at any other location indicated in the convening notice.

For resolutions to be valid, at least half of the members of the Supervisory Board must be present. Subject to the stipulations of Article 19, decisions shall be taken by a majority of votes of present or represented members; in the event of a tie vote, the chairman of the session shall have the deciding vote.

Moreover, for the purposes of calculating the quorum and majority, the members of the Supervisory Board who take part in the board meetings by videoconference or any other electronic means of telecommunications or remote transmission shall be considered to be present, except for the adoption of the decisions relating to verification and control of the annual financial statements and, as appropriate, of the consolidated accounts.

The members of the Supervisory Board may be represented at each session by one of their colleagues, but one member may only represent one of his colleagues as a proxy. These powers shall only be valid for a single session and may be granted by simple letter, e-mail or fax.

An attendance register shall be kept at the registered office, which shall be signed by the members of the Supervisory Board who take part in the board meeting. The attendance register may be kept in electronic format, in accordance with applicable laws and regulations.

The production of an extract or copy of the minutes shall serve as sufficient evidence for the number of members in office and their attendance or representation.

The decisions of the Board shall be noted in the minutes drawn up in a special register or on numbered and initialled loose sheets, possibly in electronic format, pursuant to the conditions set by the current legislation.

These minutes shall be signed by the chairman of the session and by another member of the Supervisory Board, possibly in electronic format, in accordance with applicable laws and regulations.

In the event of impediment of the chairman of the session, the minutes shall be signed by at least two members of the Supervisory Board.

The copies or extracts of these minutes shall be certified by the Chairman, the Deputy Chairman, a member of the Management Board or by a proxy authorised for this purpose, possibly in electronic format, in accordance with applicable laws and regulations.

The Supervisory Board shall draw up internal regulations which may provide that with the exception of decisions relating to the verification and inspection of the annual financial statements, as well as the verification and inspection of the consolidated financial statements, for the purposes of calculating the quorum and majority, the members of the Supervisory Board shall be considered to be present who attend the meeting via videoconference or telecommunications media which permit their identification and guarantee their effective participation, the nature and conditions of application of which are determined by the current legal and regulatory provisions.

The members of the Supervisory Board, as well as any person taking part in the meetings of the Supervisory Board, shall be bound to secrecy with regard to the resolutions of the Supervisory Board, as well as to the information presenting a confidential character or presented as such by the Chairman of the Supervisory Board or the Chairman of the Management Board.

The Statutory Auditors shall be convened to all of the meetings of the Supervisory Board which examine or draw up the annual or interim financial statements.

Article 19. Powers and attributions of the Supervisory Board

The Supervisory Board shall exercise permanent control of the management of the Company carried out by the Management Board.

It shall appoint the members of the Management Board and set their remuneration. It shall designate the Chairman of the Management Board and possibly the *Directeurs Généraux*. It may also pronounce their dismissal under the conditions provided by law and by the Articles of Association of the Company.

It shall convene the General Meeting of shareholders, in the absence of convening by the Management Board.

It shall carry out the verifications and inspections which it considers appropriate at any time of the year and may order the forwarding of documents which it considers necessary for carrying out its mission.

The Supervisory Board shall authorise the following agreements and operations, prior to their conclusion:

1. By a majority of present or represented members, pursuant to current legal and regulatory provisions:
   (i) any assignment of property in kind;
   (ii) any total or partial assignment of investments;
   (iii) any establishment of sureties, as well as securities, endorsements and guarantees; and
   (iv) any agreement referred to in Article 22 of these Articles of association and subject, according to Article L. 229-7 of the French Commercial Code, to the rules set forth in Articles L. 225-89 through L. 225-90 of the French Commercial Code, which relates to the Supervisory Board's approval of regulated agreements, to the exception of agreements related to standard transactions concluded under ordinary conditions.
2. With a majority representing more than half of its members in office (i.e. for the first Supervisory Board, by a majority of 4 out of the 7 members in office):
   (i) approval of the annual budget;
   (ii) approval of the business plan;
   (iii) appointment and revocation of the members of the Management Board (*directoire*) and *Directeurs Généraux*, decision on their remuneration and leaving terms;
   (iv) submission of draft resolutions to the shareholders' meeting relating to any distribution (including distribution of dividends or reserves) to the shareholders;
   (v) approval of material changes in accounting policies;
   (vi) submission of draft resolutions to the extraordinary shareholders' meeting and exercise of delegations of authority or delegations of powers granted by the shareholders' meeting and relating to the issue of shares or securities granting access, immediately and/or in the future, to the share capital of the Company;
   (vii) share capital reductions and share buy back programs;
   (viii) submission of draft resolutions to the shareholders' meeting relating to any amendment of the Articles of Association;
   (ix) acquisition and disposal of business branches, equity interests or assets for an amount exceeding EUR 2 million as well as any lease management (*location-gérance*) of all or part of the *fonds de commerce*, except for the transactions previously submitted and approved as part of the annual budget or business plan;
   (x) assignments of rights relating to, and the licensing of antibodies, vaccines or related products for an amount exceeding EUR 3 million;
   (xi) implementation of any capital expenditure for an amount exceeding EUR 2 million not previously submitted and approved as part of the annual budget;
   (xii) implementation of any expense for recruiting a team for a total annual gross compensation (including social charges and withholding taxes) of EUR 3 million in the first year, and not previously submitted and approved as part of the annual budget;
   (xiii) any implementation, refinancing or amendment to the terms of any borrowings (including any bonds) for an amount exceeding EUR 2 million, and not previously submitted and approved as part of the annual budget;
   (xiv) allocation of options entitling their holders to subscribe to newly issued shares (*options de souscription d'actions*) or to acquire existing shares (*options d'acquisition d'actions*), allocation of free shares or other plans in favour of the Management Board members and key employees (i.e employees with an annual gross compensation in excess of EUR 100,000);

(xv) any merger, demerger, asset contribution, dissolution, liquidation or other restructurings;

(xvi) any settlement or compromise relating to any litigation of an amount exceeding EUR 1 million, provided that any settlement or compromise relating to a litigation of an amount exceeding EUR 500,000 will be reviewed by the audit committee of the Supervisory Board;

(xvii) any material change in the business; and

(xviii) any agreement or undertaking to do any of the foregoing.

Any decision to transfer out of France the registered office and/or the research & development centre(s) operated by the Company in France shall be subject, as from the date hereof, to the prior authorisation of the Supervisory Board resolving unanimously.

The Supervisory Board shall receive a report from the Management Board on the progress of the company's affairs whenever it considers it necessary and at least once a quarter.

Within the deadline of three months from the end of the financial year, the Management Board shall present the annual financial statements and its draft management report for the General Meeting to the Supervisory Board, for verification and control purposes.

It shall present its observations on the report by the Management Board, as well as on the annual financial statements to the Annual Ordinary General Meeting of shareholders.

The Supervisory Board may grant all of the special mandates or specific missions to one or several of its members, for one or several given objects.

The Supervisory Board may also appoint, from among its members, one or several specialised committees, the composition and attributions of which it shall set and which shall carry out their activities at its liability, without the said attributions having the object of delegating to the committees the powers exclusively attributed to the Supervisory Board by the law or these Articles of Association, or the effect of reducing limiting the powers of the Supervisory Board.

Article 20. Allocation of the Supervisory Board

The members of the Supervisory Board may receive by way of remuneration of their activity a fixed annual amount, the amount of which, determined by the Ordinary General Meeting of shareholders, shall be maintained until a decision to the contrary and shall be charged to the general expenses of the Company.

The Board shall share these benefits among its members in a manner which it considers appropriate.

The Supervisory Board may also allocate exceptional remuneration to certain of its members for missions or mandates entrusted to them in the cases and under the conditions provided by law.

No remuneration, permanent or otherwise, may be paid to the members of the Supervisory Board, other than what is allocated to the Chairman and possibly to the Deputy Chairman, or that due by way of an employment contract corresponding to an effective job.

Article 21. Observers

The Supervisory Board may appoint one or several observers who only take part in meetings of the Supervisory Board and its committees in an advisory capacity.

The observer or observers are called to attend as observer the meetings of the Supervisory Board. The observer or observers must receive the same information as the members of the Supervisory Board.

The observers may be consulted by members of the Supervisory Board, as necessary, on all questions within their competences and for which they can deliver an opinion or an advice.

The observer(s) may not be remunerated.

Article 22. Agreements between the Company, a member of the Management Board or of the Supervisory Board, or a shareholder

All agreements entered into directly, or through an intermediary, between the Company and a member of its Management Board Supervisory Board, one of its shareholders holding more than 10% of the voting rights or in the case of an entity shareholder, its controlling company within the meaning of Article L. 233-3 of the French Commercial Code, shall be subject to the prior authorization of the Supervisory Board.

The same applies to agreements in which one of the persons mentioned in the preceding paragraph has an indirect interest, as well as agreements which take place between the Company and an entity, if one of the Management Board members or one of Supervisory

Board members of the Company is the owner, general partner having unlimited liability, manager, director, member of the supervisory board or, generally, an executive officer of such entity.

The prior authorization of the Supervisory Board is motivated by giving reasons indicating the interest of the agreement for the company, in particular, by specifying the financial conditions attached to it.

The party directly or indirectly interested shall inform the Supervisory Board as soon as he or she is aware of an agreement subject to authorization. If this party serves on the Supervisory Board, he or she shall not have the right to take part in the discussions and the vote on the requested authorization.

The Chairman of the Supervisory Board shall inform the Statutory Auditors of all authorized agreements entered into and shall submit them for approval to the General Meeting of the Shareholders. The Statutory Auditors submit a report on these agreements to the meeting of shareholders which must vote on this report. The party directly or indirectly interested in the agreement shall not have the right to take part in the vote and its shares shall not be taken into account for the calculation of the majority.

The agreements approved by the Shareholders' Meeting, together with those not approved, shall be effective with respect to third parties except when declared null and void in cases of fraud. However and even in the absence of fraud, any prejudicial consequences for the Company of agreements that have not been approved may be borne by the interested party.

Regardless of the liability of the interested party, all agreements for which the prior authorization by the Supervisory Board is required, which are concluded without such prior authorization by the Supervisory Board, may be declared null and void if the consequences thereof were prejudicial to the Company. An action to render the agreement null and void shall be time barred after three years as of the date of the agreement. However, if such agreement has been hidden, this period shall be calculated as of the date on which its existence was revealed. The nullity can be remedied by a vote by the Shareholders' Meeting held on a special report by the Statutory Auditors' stating the circumstances under which the authorization procedure was not followed. In such case, the interested party may not take part in the vote and his or her shares shall not be taken into account for the calculations of quorum and majority.

The foregoing provisions do not apply to agreements concerning current operations and entered under normal conditions or agreements entered into between two companies, one of which holds, directly or indirectly, all of the share capital of the other, if applicable, less the minimum number of shares required to satisfy the requirements of article 1832 of the French Civil Code, or articles L. 225-1 and L. 22-10-2 of the French Commercial Code.

The Supervisory Board must set up a procedure to regularly assess whether agreements relating to current operations and entered into on customary terms meet these criteria. The persons directly or indirectly interested in one of these agreements shall not take part in this assessment.

Article 23. Statutory auditors

One or several Statutory Auditors shall be appointed and shall carry out their monitoring mission pursuant to the law.

They shall have the permanent mission, to the exclusion of any interference in the management, of verifying the books and values of the Company and of monitoring the regularity and fairness of the Company accounts.

TITLE IV

SHAREHOLDERS' MEETINGS

Article 24. Nature of the Meetings

The decisions of the shareholders shall be taken at a General Meeting.

The Ordinary General Meetings shall be those which are convened on to take all of the decisions which do not modify the Articles of Association.

The Extraordinary General Meetings shall be those convened on to decide or authorise direct or indirect modifications of the Articles of Association.

The Special Meetings shall bring together the holders of shares of a given category to rule on a modification of the rights of the shares of this category and all other decisions provided by law or by these Articles of Association.

The resolutions of the General Meetings shall oblige all of the shareholders, even if absent, dissenting or incapable.

Article 25. Calling and convening of the General Meetings

The General Meetings shall be convened either by the Management Board or failing this, by the Supervisory Board or the Statutory Auditors or by a representative designated by the court, at the demand, either of any interested party or the Social and Economic Committee in the event of an emergency or by several shareholders representing at least 5% of the share capital.

During the liquidation period, the Meetings shall be convened by the liquidator(s).

The General Meetings shall be convened at the registered office or at any other location indicated in the notice of calling.

The Company shall be obliged, within the time limits set out in applicable laws, to publish a notice of meeting in the *Bulletin des Annonces Légales Obligatoires* (BALO) (Bulletin of Obligatory Legal Announcements containing the mentions provided by the laws in effect.

The convening of the General Meetings shall be realised by the inclusion in a newspaper authorised to receive legal announcements in the Department of the registered office and in addition, in the *Bulletin des Annonces Légales Obligatoires* (BALO), within the time limits set out in applicable laws.

When a Meeting has been unable to deliberate in regular fashion, due to failure to reach the necessary quorum, the second Meeting and as per the case, the second extended Meeting, shall be convened, in the same forms as the first, within the time limits set out in applicable laws and the notice of calling shall recall the date of the first calling and reproduce its agenda.

Article 26. Agenda

1. The agenda of the Meetings shall be drawn up by the author of the calling.
2. One or several shareholders, representing at least the required proportion of the share capital and acting under the conditions and pursuant to the deadlines set by the law, shall be entitled to request the inclusion of draft resolutions in the agenda of the Meeting by registered letter with a request for notice of receipt.
3. If a Social and Economic Committee exists, it may request the entering of draft resolutions on the agenda of a Meeting.

   These draft resolutions must be notified to the shareholders and be entered in the agenda and submitted to the vote of the Meeting.
4. The Meeting may not deliberate on an issue which is not entered on the agenda, which may not be modified at a second calling. It may nevertheless dismiss one or several members of the Supervisory Board under any circumstances and replace them.

Article 27. Admissions to Meetings - Powers

All of the shareholders shall be entitled to take part in the Meetings on providing proof of their identity, though subject to compliance with the following provisions:

- for holders of registered shares, their registration in the registered share account maintained by the Company no later than the second day preceding the Meeting date;

- for holders of ordinary bearer shares, issuance of a certificate of participation (attestation de participation) by an authorized intermediary confirming they are registered in a securities account no later than the second day preceding the Meeting date.

Any shareholder may vote by post through a form, the details of which are set forth by a decree of the *Conseil d'État*, and a copy of which may further be obtained under the conditions indicated by the notice of calling of the Meeting.

A shareholder may also vote by proxy, in accordance with the provisions of Articles L. 225-106 and L. 22-10-39 of the French Commercial Code, and thus be represented either by another shareholder who provides evidence of a power of attorney, by his/her spouse or partner with whom he/she has concluded a civil solidarity pact, or by any other natural or legal person of his/her choice (and this under the conditions provided in Articles L. 22-10-40, R. 225-79 and R. 22-10-24 of the French Commercial Code).

In the event of existence of a Social and Economic Committee within the Company, two of its members designated by the counsel, of which one belongs to the category of technical staff and supervisors and the other to the category of employees and workers, or where appropriate, the persons mentioned in Articles L. 2312-74 and L. 2312-75 of the Labour Code, may attend the General Meetings. They shall be heard at their request for all of the resolutions which require the unanimity of shareholders.

Shareholders may, upon decision of the Management Board, take part in the General Meetings by videoconference or by any other means of telecommunication, including the Internet, which allow their identification in accordance with the conditions and procedures set forth by the applicable regulations in force. Where applicable, this decision shall be communicated in the convening notice of the General Meeting.

Upon decision of the Management Board, the shareholders may access and use the proxy form or voting form in electronic format, under the conditions and in accordance with the conditions and procedures set forth by the applicable regulations in force.

Article 28. Holding of the Meeting - Bureau - Minutes

An attendance sheet shall be signed by the attending shareholders and representatives, to which shall be attached the powers granted to each representative and, as appropriate, the postal voting forms. It shall be certified as accurate by the bureau of the Meeting.

The Meetings shall be chaired by the Chairman of the Supervisory Board or, in his absence, by the Deputy Chairman or by a member of the Board especially appointed for this purpose. In the event of convening by a Statutory Auditor or court-appointed agent, the Meeting shall be chaired by the author of the convening notice. Failing this, the Meeting shall itself elect its Chairman.

The two present and accepting shareholders, representing the largest number of votes, both as themselves and as representatives, shall serve as scrutineers. The bureau so established shall designate a secretary, who may be selected from outside the members of the Meeting.

The deliberations of the meetings shall be recorded in minutes signed by the members of the bureau and drawn up in a special register, possibly in electronic format, in accordance with the applicable laws and regulations. Copies and extracts of these minutes shall be certified under the conditions set by applicable laws and regulations, possibly in electronic format.

Article 29. Quorum - Vote

1. The quorum shall be calculated on all of the shares comprising the share capital, except in the Special Meetings, where it shall be calculated on all of the shares for the category in question, all of which minus the shares deprived of the voting rights by virtue of the provisions of the law. In the event of a postal vote, for the calculation of the quorum, only forms duly completed and received by the Company at least three (3) days before the date of the Meeting shall be considered, *i.e.* no later than the fourth day before the date of the Meeting.
2. Subject to the double voting right cited in the Article 13, the voting rights attached to shares shall be proportional to the stake in the share capital which they represent.
3. The vote shall be expressed by a show of hands, by a roll-call or by a secret ballot, pursuant to what the bureau of the Meeting or the shareholders decide. The shareholders may also vote by post, or by proxy under the conditions of Article 27 of the Articles of association, including, upon decision of the Management Board, by videoconference or by any other means of telecommunication, including the Internet, which allow their identification in accordance with the conditions and procedures set forth by the applicable regulations in force.
4. For the purposes of calculating the quorum and majority, shareholders shall be considered to be present who take part in the Meeting via videoconference or telecommunications media, including the Internet, which permit their identification and guarantee their effective participation, the nature and conditions of application of which are determined by legislative and regulatory provisions in effect.

Article 30. Ordinary General Meeting

The Ordinary General Meeting shall take all of the decisions exceeding the powers of the Management Board, which do not have the object of modifying the Articles of Association.

The Ordinary General Meeting shall meet at least once a year, within six months of the end of the financial year, to rule on the financial statements for the financial year, subject to the extension of the deadline by a court decision.

It shall only deliberate validly, on a first convening, if the present and represented shareholders, or those voting by postal vote, hold at least the number of shares set out in applicable laws.

No quorum shall be required for the second convening. It shall rule with a majority of the votes validly cast by the present or represented shareholders or shareholders voting by post. Abstention and votes blank or void shall not be considered as votes cast.

For the purposes of calculating the quorum and majority, shareholders shall be considered to be present who take part in the General Meetings via videoconference or telecommunications media as detailed above.

Article 31. Extraordinary General Meeting

The Extraordinary General Meeting may amend the Articles of Association in all of their provisions and notably decide on the conversion of the Company into a limited liability company. It may nevertheless increase the commitments of the shareholders, subject to the operations resulting from a consolidation of shares effected in regular fashion.

The Extraordinary General Meeting may only deliberate validly if the present or represented shareholders or shareholders voting by postal vote possess on the first convening or on the second convening the number of shares set out by applicable laws. In the absence of this latter quorum, the second Meeting may be extended until a date two months later than the one on which it had been convened.

The Extraordinary General Meeting shall rule with a majority of two thirds of the votes validly cast by the present or represented shareholders, or voting by postal vote, unless there is a legal exemption. Abstention and votes blank or void shall not be considered as votes cast.

In constituent Extraordinary General Meetings, i.e. those convened to deliberate on the approval of a contribution in kind or the granting of a particular benefit, the grantor or beneficiary shall not have a vote, either for itself or as a representative.

For the purposes of calculating the quorum and majority, shareholders shall be regarded as present who take part in the General Meetings via videoconference or telecommunications media as detailed above.

Article 32. Special Meetings

If there are several categories of share, no modification may be made to the rights of the shares in one of these categories, without a requisite vote of an Extraordinary General Meeting, open to all of the shareholders and furthermore, without an equally requisite vote of a Special Meeting, open only to the owners of shares of the category in question.

The special Meetings may only deliberate validly if the present or represented shareholders hold on the first convening or on the second convening the number of shares of the relevant category set out by applicable laws.

Other meetings shall be convened and shall deliberate under the same conditions as the Extraordinary General Meetings, subject to the particular provisions applicable to Meetings of holders of shares with a priority dividend, but without voting rights.

For the purposes of calculating the quorum and majority, shareholders shall be regarded as present who take part in the Meeting via videoconference or telecommunications media as detailed above and for which the nature and conditions of application are determined by current legislative and regulatory provisions.

Article 33. Right of notification of the Shareholders

Every shareholder has the right to receive, under the conditions and at times set by law, the documents required for it to be able to pronounce knowledgeably and draw up a ruling on the management and control of the Company.

The nature of these documents and the conditions of their dispatch or provision shall be determined by the law and regulations.

TITLE V

COMPANY ACCOUNTS -

ALLOCATION AND DISTRIBUTION OF PROFITS

Article 34. Inventory - Annual Financial Statements

The Company shall maintain regular accounts of its operations, pursuant to the law and commercial practice.

At the end of each financial year, the Management Board shall draw up an inventory of the various elements of the assets and liabilities. It shall also draw up the annual reports and as appropriate, the consolidated financial statements, pursuant to the provisions of the French Commercial Code.

It shall attach a statement of guarantee deposits, endorsements and guarantees given by the Company to the balance sheet, together with a statement of sureties granted by it.

It shall draw up a management report containing the indications set by law.

The management report shall include, as per the case, the report on the management of the group, when the Company must draw up and publish consolidated accounts under the conditions provided by law.

As appropriate, the Management Board shall draw up provisional accounting documents under the conditions provided by law.

All of these documents shall be made available to the Statutory Auditors under the appropriate legal and regulatory conditions.

Article 35. Allocation and distribution of profits

First of all, amounts to be provisioned in legal reserves shall be deducted from the net profit for each financial year minus previous losses, if any. In this way, 5% shall be deducted to establish the legal reserve fund; this deduction shall cease to be obligatory when the said fund has reached one tenth of the share capital; it shall resume if, for any reason, the legal reserve has fallen below this fraction.

The distributable profits shall consist of the net profit for the financial year minus previous losses and the amounts provisioned to reserves by way of application of the law and the Articles of Association plus retained earnings.

For this profit, the General Meeting shall then deduct the amounts which it considers appropriate to allocate to optional, ordinary or extraordinary reserves or as retained earnings.

The balance, if any, may be allocated among all of the shares in proportion to their paid-up and unamortised amount and their respective pecuniary rights.

At the same time, except in the case of a capital reduction, no distribution may be made to the shareholders when the shareholders' equity is or becomes, following this distribution, less than the amount of the share capital plus the reserves for which distribution is prohibited, pursuant to the law or the Articles of Association.

The General Meeting may decide to distribute the amounts deducted from the optional reserves, either to provide or supplement a dividend, or by way of an exceptional distribution; in this event, the decisions shall expressly indicate the reserve items from which the deductions shall be made. At the same time, the dividends shall be distributed as a priority from the distributable profit for the financial year.

The losses, if any, shall be attributed, after the approval of the financial statements by the General Meeting, to a special account, for attribution to profits for future financial years, until they are extinguished.

Article 36. Payment of dividends

Ruling on the annual financial statements, the General Meeting has the right to grant an option to each shareholder for all or part of the distributed dividend or interim dividends, for payment of the dividend or interim dividends in cash or in shares.

The procedures for payment of dividends in cash shall be set by the General Meeting or failing this, by the Management Board.

However, the payment of dividends must take place within at most nine months of the end of the financial year, unless this deadline is extended by a judicial authorisation.

When financial statements drawn up during or at the end of the financial year and certified by a Statutory Auditor reveal that the Company has generated a profit, after the end of the preceding financial year, after establishing the necessary depreciation and provisions and deducting previous losses, if any, as well as amounts to be attributed to reserves by way of application of the law or Articles of Association and taking account of retained earnings, interim dividends may be distributed before approval of the annual financial statements. The amount of these interim dividend payments may not exceed the amount of the profit so defined.

The Company may only demand a repeat of the dividend from the shareholders if the distribution has been carried out in violation of the legal provisions and if the Company establishes that the beneficiaries were aware of the regular character of this distribution when it was made or could not have been unaware of the same in view of the circumstances. Actions for the return of undue payments shall be prescribed five years after the payment of these dividends. Dividends unclaimed within five years of their payment falling due shall be prescribed.

TITLE VI

SHAREHOLDERS' EQUITY - PURCHASE BY THE COMPANY

CONVERSION - EXTENSION - DISSOLUTION - LIQUIDATION

Article 37. Shareholders' equity less than half of the share capital

If, on account of the losses observed in the accounting documents, the shareholders' equity of the Company falls below half of the share capital, the Management Board shall be obliged,

within four months following the approval of the accounts which have revealed these losses, to convene the Extraordinary General Meeting for the purpose of deciding whether there are grounds for the advance dissolution of the Company.

If the dissolution is not pronounced, subject to the legal provisions relating to the minimum capital and within the legal deadline, the share capital shall be reduced by an amount equal to that of the losses which could not be attributed to the reserves if, within this deadline, the shareholders' equity could not be restored to a value equal to at least half of the share capital.

In any event, the decision of the General Meeting must form the object of notification formalities required by the applicable regulatory provisions.

In the event of failure to observe these prescriptions, any concerned party may apply to a court for the dissolution of the Company. The same shall apply if the shareholders are unable to deliberate in valid fashion.

At the same time, the court may not pronounce its dissolution if, on the day on which it rules on the merits, the adjustment has been made.

Article 38. Conversion

Pursuant to Article L. 229-10 of the French Commercial Code, the Company may be transformed into a limited liability Company, if, at the time of conversion, it has been in existence for at least two years and if it has drawn up financial statements for the last two financial years and these have been approved by its shareholders.

The conversion decision shall be taken on the basis of a report by one or several conversion auditors designated by a decision of the court, which attests that the shareholders' equity is at least equal to the share capital.

Article 39. Extension

At least one year before the expiry date of the Company, the Management Board must convene the Extraordinary General Meeting of shareholders for the purpose of deciding, under the conditions required for the amendment of the articles of Association, whether the Company must be extended.

The shareholders who oppose the said extension shall be obliged to assign their shares to the other shareholders within 3 months, starting from the resolution of the General Meeting which has decided on the extension, at the express demand of these latter parties by registered letter with notice of receipt. The assignment price of the shares shall be determined by an expert under the conditions provided in Article 1843-4 of the Civil Code. In the event that the purchase requests exceed the number of shares to be assigned, the allocation shall be made pro rata to the number of shares already held by the acquirers and within the limits of the shares to be assigned.

Article 40. Dissolution - Liquidation

Except in the cases of judicial dissolution provided by the law, and unless the Company is extended in regular fashion, it shall be dissolved on expiry of a deadline set by the Articles of Association or following a decision of an Extraordinary General Meeting of the shareholders.

One or several liquidators shall then be appointed by this Extraordinary General Meeting under the conditions of a quorum and majority provided for the Ordinary General Meetings.

The liquidator shall represent the Company. The entire company assets shall be realised and the liabilities discharged by the liquidator, who shall be vested with the broadest powers. He shall then allocate the available balance between the shares, pro rata to their participation in the share capital.

The General Meeting of shareholders may authorise it to continue with current business transactions or to undertake new ones for the purposes of the liquidation.

In the event that all of the shares are acquired by a single shareholder, any dissolution decision, whether voluntary or judicial, shall entail the transmission of the Company's assets, to the sole shareholder, under the conditions provided by law, without a liquidation being necessary.

TITLE VII

DISPUTES

Article 41. Disputes

Any disputes which may arise regarding the business of the company or the execution of the provisions of the Articles of Association, during the life of the Company or during its liquidation, whether between the shareholders, the management or controlling bodies of the

Company or the Statutory Auditors, or between the shareholders themselves, shall be submitted to the competent courts with jurisdiction over the registered office.

* *
*

Exhibit 2.3

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, 2022, 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, 2022, our issued share capital consisted of a total of 138,346,968 ordinary shares with a nominal value of €0.15 per share and 20,514 preferred shares convertible into ordinary shares, also with a nominal value of €0.15 per preferred share. Of these 138,346,968 issued ordinary shares, 138,222,646 shares are outstanding and 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 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.

Management Board

The Management Board is responsible for our management and is composed of a minimum of two members and a maximum of seven members who perform their duties under the supervision of the Supervisory Board.

Members of the Management Board

The members of the Management Board are appointed or have their appointments renewed by the Supervisory Board. The members of the Management Board must be individuals. They are not required to be shareholders. They may be French citizens or citizens of other countries. Members of the Management Board cannot be members of the Supervisory Board.

The maximum age for being a member of the Management Board and the limitations on having such an appointment concurrently with an appointment in another company are subject to our bylaws and the applicable legal and regulatory provisions. The age limit for the exercise of duties for a member of the Management Board is seventy years of age. A member of the Management Board is deemed to have resigned automatically at the end of the financial year during which the member reaches such age.

The term of office for the members of the Management Board is three years and may be renewed. If there is a vacancy, the Supervisory Board must fill the vacancy within two months. The replacement is appointed for the time remaining until the Management Board is up for renewal. A member of the Supervisory Board may be appointed by the Supervisory Board to exercise the duties of a member of the Management Board for the remaining period until the renewal of the Management Board, provided that such period lasts no more than six months. During this period, the duties of the party in question on the Supervisory Board shall be suspended.

The members of the Management Board may be removed from office, with or without cause, by the Supervisory Board or at any General Meeting of shareholders, by a simple majority vote.

Chairman of the Management Board

The Supervisory Board elects a Chairman from among the members of the Management Board to serve for the duration of his appointment as a member of the Management Board. The Chairman of the Management Board represents us in our relations with third parties.

The Supervisory Board may assign this power of representation to one or more other members of the Management Board. Assignees have the title of Managing Director.

Meetings and Powers of the Management Board

The Management Board meets as often as is in the Company's interest and is required to submit a report to the Supervisory Board at least once per quarter which summarizes the principal actions or events occurring in the management of the Company. Meetings are called by the Management Board's Chairman, its *Directeur Général* or by at least half of its members.

At least half of the members of the Management Board must be present to constitute a quorum and decisions are made by a majority of the members of the Management Board present or represented, unless the Management Board has only two members, in which case decisions must be unanimous.

The Management Board has broad power to act under all circumstances on our behalf. It exercises this power within the limits of our business purpose and subject to any powers expressly given to the Supervisory Board and Shareholders' Meetings by law and according to our bylaws, and abiding by any restrictions on powers decided by the Supervisory Board.

Compensation of the Management Board

The method and amount of compensation for each member of the Management Board is determined by the Supervisory Board when appointing such member.

Supervisory Board

Members of the Supervisory Board

The Management Board is supervised by a Supervisory Board made up of a minimum of three members and a maximum of eighteen. The members of the Supervisory 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 appointees are selected from among the shareholders and may be individuals or companies. Members of the Supervisory Board cannot be members of the Management Board.

The maximum age for membership on the Supervisory Board is eighty years old.

Chairman of the Supervisory Board

The Supervisory Board appoints from its members who are individuals a Chairman and a Deputy Chairman, who are in charge of convening the Supervisory Board and directing its discussions.

In a report to the General Meeting of shareholders attached to the Management Board's Management Report, the Chairman of the Supervisory Board reports on the conditions for preparing and organizing the work of the Supervisory Board as well as the internal control procedures set up by us.

Meetings and Powers of the Supervisory Board

The Supervisory Board meets as often as is in our interests but least once per quarter. Meetings are called by the Chairman or Vice Chairman, or by a member of the Management Board, under the circumstances and according to the conditions set forth in the bylaws.

Supervisory 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 Supervisory Board must be present to constitute a quorum and decisions are made by a majority of the members of the Supervisory Board present or represented. In the case of a tie vote, the Chairman of the Supervisory Board shall have the deciding vote.

The Supervisory Board exercises permanent control over our management by the Management Board and the powers explicitly conferred on it by the French laws. It alone has the authority to authorize certain significant transactions.

Under French law, any agreement entered into, directly or through an intermediary, between us and one of the members of the Management Board or Supervisory Board, 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 Supervisory Board. The interested member cannot vote on such decision. The same applies to agreements in which a person referred above has an indirect interest. Such prior authorization also applies to agreements between us and another company if one of the members of our Management Board or Supervisory Board is the owner, a partner with unlimited liability, manager, director, managing director, member of the Management Board or of the Supervisory Board, 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 Supervisory Board

Compensation for attendance at board meetings is determined at the annual ordinary General Meeting. The General Meeting of shareholders may allocate an annual fixed sum and our Supervisory Board allocates this sum among its members as it sees fit. In addition, the Supervisory 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 Supervisory Board may decide to establish committees responsible for reviewing matters which the Supervisory Board or its Chairman wish to submit to them for examination and advice.

Supervisory Board Observers

The Supervisory Board may appoint one or more observers. The observers may attend all Supervisory Board meetings, with the right to speak but not to vote. They hold the same information and communication rights as the Supervisory 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 the 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.

They 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 Management 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 Management 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 Management Board. The shareholders may delegate to our Management 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 following the recommendation of our Management Board. 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 Management Board 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.

Further, any investment:

i. by (a) any non-French citizen, (b) any French citizen not residing in France, (c) any non-French entity or (d) any French entity controlled by one of the aforementioned persons or entities;
ii. that will result in the relevant investor (a) acquiring control of an entity registered in France, (b) acquiring all or part of a business line of an entity registered in France, or (c) for non-EU or non-EEA investors crossing, directly or indirectly, alone or in concert, a 25% threshold of voting rights in an entity registered in France; and
iii. developing activities in certain strategic industries related to (a) activity likely to prejudice national defense interests, participating in the exercise of official authority or are likely to prejudice public policy and public security (including weapons, double-use items, IT systems, cryptology, date capturing devices, gambling, toxic agents or storage of data), (b) activities relating to essential infrastructure, goods or services (including energy, water, transportation, space, telecom, public health, farm products or media), and (c) research and development activity related to critical technologies (including cybersecurity, artificial intelligence, robotics, additive manufacturing, semiconductors, quantum technologies, energy storage or biotechnology) or dual-use items,

is subject to the prior authorization of the French Ministry of Economy, which authorization may be conditioned on certain undertakings.

In the context of the ongoing COVID-19 pandemic, the Decree (*décret*) n°2020 892 dated July 22, 2020, as amended (i) on December 28, 2020 by the Decree n° 2020-1729 and (ii) on December 22, 2021 by the Decree n° 2021-1758, has created until December 31, 2022 a new 10% threshold of the voting rights for the non-European investments made (i) in an entity with 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. A fast-track procedure shall apply for any non-European investor exceeding this 10% threshold who will have to notify the Minister of Economy who will then have 10 days to decide whether or not the transaction should be subject to further examination.

In the absence of such authorization, the relevant investment shall be deemed null and void. The relevant investor may be found criminally liable and may be sanctioned with a fine not to exceed the greater of the following amounts: (i) twice the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company or (iii) €5 million (for a company) or €1 million (for a natural person).

The Decree n°2022-1622 dated December 23, 2022 extended for a further year until December 31, 2023 the above mentioned measures.

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. 225-209 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. 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of 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 Management Board, or failing that, by the Supervisory 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 on items on the agenda. However, it may dismiss and replace one or more members of the Supervisory Boards any time. The General Meeting may also dismiss the members of the Management Board. 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.

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 Management 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 Management 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 Management 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 Supervisory Board appoints the members of the Management Board and shall fill any vacancy within two months;
- our Supervisory Board has the right to appoint members of the Supervisory Board to fill a vacancy created by the resignation or death of a member of the Supervisory 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 Supervisory Board;
- our Management Board can be convened by the Chairman of the Management Board, its chief executive officer or at least half of the members of the Management Board;
- our Supervisory Board can be convened by the Chairman or the Vice Chairman or one member of the Supervisory Board. A member of the Management Board or one-third of the members of the Supervisory Board may send a written request to the Chairman to convene the Supervisory Board. If the chairman does not convene the Supervisory Board 15 days following the receipt of such request, the authors of the request may themselves convene the Supervisory Board;
- our Supervisory 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 Supervisory 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 Management Board and/or members of the Supervisory 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;
- advance notice is required for nominations to the Supervisory Board or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a member of the Supervisory 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 Management and Supervisory Boards, and election and removal of members of the Management and Supervisory Boards 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 depositary 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 five 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 5% 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 directoire et conseil de surveillance*, 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 the members of the Management Board and of the Supervisory Board	Under French law, a *société européenne à directoire et conseil de surveillance* must have at least three and may have up to eighteen members of the Supervisory Board. The number of members of the Management Board cannot be greater than seven. In addition, the composition of the Management Board endeavors to seek a balanced representation of women and men. The number of members of the Management Board and of the Supervisory Board is fixed by or in the manner provided in the bylaws. The number of members of the Supervisory Board of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied will be null and void as well as the deliberations taken by the Supervisory Board member irregularly appointed. The members of the Supervisory Board are appointed at 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.
Members of the Management Board and of the Supervisory Board Qualifications	Under French law, a corporation may prescribe qualifications for the members of the Management Board and of the Supervisory Board under its bylaws. In addition, under French law, members of a supervisory board of a corporation may be legal entities (with the exception of the chairman of the supervisory board), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the supervisory board.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.

	France	Delaware
Removal of members of the Management Board and of the Supervisory Board	Under French law, the members of the Management Board and of the Supervisory Board may be removed from office, with or without cause and without notice, at any shareholders' meeting, by a simple majority vote of the shareholders present and voting at the meeting in person or by proxy. In addition, the members of the Management Board may be removed by the Supervisory Board if provided in the bylaws. Our bylaws provide this possibility.	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 Management Board and on the Supervisory Board	Under French law, vacancies on the Management Board resulting from death or a resignation have to be filled by the Supervisory Board within two months. In case of a vacancy on the Management Board, the Supervisory Board may appoint, for the time remaining until the renewal of the member (which may not exceed six months) one of its members to serve as a member of the Management Board, resulting in the suspension from his or her duties on the Supervisory Board. Vacancies on the Supervisory Board resulting from death or a resignation, may be filled by the remaining members of the Supervisory Board pending ratification by the shareholders by the next shareholders' 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 Management Board and notified to the shareholders in the convening notice of the annual meeting, within six months after the close 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.

	France	Delaware
General Meeting	Under French law, general meetings of the shareholders may be called by the Management Board or, failing that, by the statutory auditors, or by a court appointed agent (*mandataire ad hoc*) 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 Management Board or the relevant person. General meetings of the shareholders may also be called by the Supervisory Board.	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 first convening notice 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 meeting. Subject to special legal provisions, the meeting notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin (*journal d'annonces légales*) of the registered office department and in the BALO. Further, the holders of registered ordinary shares for at least a month at the time of the latest of the insertions of the notice of meeting 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 registered shareholders 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 his e-mail address. When the shareholders' 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 Commerce 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.

	France	Delaware
Proxy	Each shareholder has the right to attend the meetings and participate in the discussions (i) personally, or (ii) by granting proxy to another shareholder, his/her spouse, his/her partner with whom he/she has entered into a civil union or to any natural or legal person of his/her 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 Management Board), or (iv) by voting by correspondence, or (v) by video conference or another means of telecommunication in accordance with applicable laws that allow identification. 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.	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.

	France	Delaware
Shareholder action by written consent	Under French law, shareholders' action by written consent is not permitted in a *société européenne*.	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 ordinary shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a *pro rata* basis unless such rights are waived by a two-thirds majority of the votes held by the shareholders present at the extraordinary meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. The votes cast do not include votes attached to shares held by shareholders who did not take part in the vote, abstained or whose votes were blank or null. In case such rights are not waived by the extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period shall not be less than five trading days. Preferential subscription rights are transferable during a period equivalent to the subscription period but starting two business days prior to the opening of the subscription period and ending two business days prior to the closing of the subscription period.	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.

	France	Delaware
Sources of Dividends	Under French law, dividends may only be paid by a French *société européenne* out of "distributable profits," 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" 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 bylaws.	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.

	France	Delaware
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, Market Abuse Regulation 596/2014 of April 16, 2014 provides for safe harbor exemptions when the acquisition is made for the following purposes: • to decrease its share capital, with the approval of the shareholders at the extraordinary general meeting; • to meet obligations arising from debt securities that are exchangeable into equity instruments; or • with a view to distributing the relevant shares to employees or managers under a profit-sharing, restricted free ordinary share or share option plan. All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L. 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules. Under the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) and in accordance with the General Regulations 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. 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 members of the Management Board and of the Supervisory Board	Under French law, the bylaws may not include any provisions limiting the liability of members of the Management Board. Civil liabilities of the members of the Management Board and of the Supervisory Board may be sought for (1) an infringement of laws and regulations applicable to a company, (2) breach of the bylaws and (3) management failure. Civil liabilities of the members of the Supervisory Board may be sought for the infractions committed by the members of the Management Board if, by knowing it, they did not reveal it to the shareholders' meeting.	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: • 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. As from April 2016, double voting rights are automatically granted to the shares held in registered form for more than two years, unless provided otherwise in the bylaws. Our bylaws do not provide otherwise.	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	Generally, under French law, completion of merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: • the approval of the Management Board; 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 meeting or, in the case of a merger with a non-European Union company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the Management Board authority to decide a merger-absorption or to determine the terms and conditions of the merger plan).	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: • 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	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	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.

	France	Delaware
		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: • 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. • 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.
Standard of Conduct for members of the Management Board and of the Supervisory Board	French law does not contain specific provisions setting forth the standard of conduct of a member of the Management Board and of the Supervisory Board. However, members of the Management Board and of the Supervisory Board have 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*). In addition, members of the Management Board shall take into account social and environmental issues arising out of the Company's activity.	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.

	France	Delaware
Shareholder Suits	French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the Management Board (but not from the Supervisory Board) 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 are borne by the relevant shareholder or the group of shareholders. 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. A shareholder may alternatively or cumulatively bring individual legal action against the members of the Management Board only, 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.	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: • 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. 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.
Amendment of Certificate of Incorporation	Under French law, corporations are not required to file a certificate of incorporation with the French Registry of Commerce and Companies (*registre du commerce et des sociétés*) and only have bylaws (*statuts*) as organizational documents.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: • 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 Supervisory Board to amend the by-laws to comply with legal provisions, subject to the ratification of such amendments by the next extraordinary 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 *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

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 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.

From: **Valneva Scotland Limited** ("**Purchaser**")
Oakbank Park Road,
Livingston, Scotland
EH53 0TG, United Kingdom

And: **Valneva Austria GmbH** (**"Valneva Austria**")
Campus Vienna Biocenter 3
1030 Vienna
Austria

To: **Dynavax Technologies Corporation** ("**Dynavax**")
2100 Powell Street, Suite 900
Emeryville, CA 94308
USA

8 March 2022 (the "**Amendment Date**")

Dear Sirs

Supply Agreement between Dynavax, Purchaser and Valneva Austria dated 12 September 2020, as amended to date (the "Agreement")

To the extent not otherwise defined in this letter ("**Amendment**"), capitalized terms used but not otherwise defined in this Amendment (including Appendix One hereto, which is incorporated herein by this reference) will have the same meanings as given to them in the Agreement.

The Parties agree that, with effect from the Amendment Date (subject to execution and delivery of this Amendment by all Parties as provided below), the Agreement shall be amended as set out in Appendix One.

The Agreement, as varied by this Amendment, shall remain in full force and effect in accordance with its terms.

This Amendment may be executed in two or more counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument, but will not be effective until each Party has executed and delivered at least one counterpart to the other Parties. This Agreement may be executed and delivered electronically, including by DocuSign, or by facsimile, and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered.

This Amendment, and all questions regarding the existence, validity, interpretation, breach, or performance of this Amendment, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of laws principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded. Section 11.3 of the Agreement shall apply to this Amendment, *mutatis mutandis*.

[*Signature page follows*]

Please confirm your acceptance of the terms of this Amendment by signing and returning to us a copy of this Amendment.

Yours faithfully

Valneva Scotland Limited

Signed: [***]

Name: [***]

Date: 8 March 2022

Valneva Austria GmbH

Signed: [***]

Name: [***]

Date: 8 March 2022

We agree to the above proposal.

For and on behalf of **Dynavax Technologies Corporation**

Signed: [***]

Name: [***]

Date: 8 March 2022

Attachment: Appendix One

Appendix One

1. The Parties wish to vary the Agreement and agree that, with effect from the Amendment Date:

(a) Sections 2.4(b) is deleted in its entirety and replaced as follows:

"**2.4 Delivery Terms.**

(b) [***]. Ahead of Regulatory Approval of the Product, Dynavax will use commercially reasonable efforts to ensure that the CpG Materials shall, at the time of delivery in accordance with Section 2.4(a), [***].

[End of Appendix One]

[***] = 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.

PRODUCT SCHEDULE Chikungunya lyophilized presentation (LYOPHILIZED PRODUCT)

This Product Schedule (this "**Product Schedule**") is entered into as of December 16, 2022 ("**Effective Date**") by and between:

(1) **VALNEVA AUSTRIA GMBH** whose registered office is at Campus Vienna Biocenter 3, 1030 Vienna, Austria ("**Valneva**")

(2) **IDT BIOLOGIKA GMBH**, whose principal place of business is at Am Pharmapark, 06861 Dessau-Rosslau, Germany ("**IDT**")

Each of Valneva and IDT shall be referred to as a "**Party**" herein, and together as the "**Parties"**

1. AGREEMENT

This Product Schedule is entered into by IDT and Valneva as envisaged by Clause 1.1 of the Master Supply and Commercial Manufacturing Services Agreement between the Parties dated November 26, 2021 ("**Master Agreement**"). The terms and conditions of the **Master Agreement** are referred towards in this Product Schedule.

This Product Schedule concerns the ordering by Valneva and the Manufacturing, Release (as defined below) and Shipment by IDT of lyophilized Product (as defined below) of Valneva's proprietary vaccine candidate VLA1553 for Chikungunya.

In case of any conflict between this Product Schedule and the Master Agreement, the provisions of this Product Schedule shall prevail, provided that any QAA (as defined below) shall prevail for all matters concerning quality related matters pertaining to the Product.

2. DEFINITIONS

2.1 **"Additional Quality Parameters"** shall mean quality parameters in addition to the Product Specifications (**Appendix 2**) which parameters are relevant for the determination whether a Product is defective. The Additional Quality Parameters are set forth **in Appendix 2** and shall be tested by Valneva.

2.2 "**Batch**" shall mean the output of a series of manufacturing steps in accordance with GMP and the Specification(s) with uniform character and quality.

2.3 [***]

2.4 [***]

2.5 [***]

2.6 "**Conflict of interest**" shall mean a situation where the Manufacture and performance of related Services by IDT is compromised for reasons involving family, emotional life, political or national affinity, related to the subject matter of the Master Agreement and/or this Product Schedule

2.7 "**Forecasted Order Quantities**" means the quantities of Product to be ordered by Valneva and to be Manufactured by IDT during the Term and consists of (i) the Order Commitment, (ii) IDT's Supply Commitment for the calendar years [***] pursuant to Clause 3.1 and (iii) IDT's Reservation Commitment for the calendar years [***] pursuant to Clause 3.6.

2.8 "**Late Delivery Fee"** shall be defined in Clause 10.1.

2.9 "**Manufacturing Plan**" means the plan of Manufacture of the Product in the years 2022 through 2025 and is equivalent to the Supply Commitment as set forth in **Appendix 1**.

2.10 **"Minimum Yield"** shall be defined in Clause 5.2.

2.11 "**Order Commitment**" means the [***] period preceding the applicable date of Manufacture set forth in the Manufacturing Plan or in any agreed Forecast.

2.12 "**Price**" means the price for the Products as set out in Clause 11.1 to this Product Schedule.

2.13 "**Product**" shall mean the formulated (i.e. the lyophilized), filled and visual inspected Valneva Material Manufactured in accordance with and conforming to the Specifications and the Additional Quality Parameters set forth in **Appendix 2** attached hereto.

2.14 "**QAA**" means the Quality Assurance Agreement entered into between the Parties and effective as of 28 November 2022, defining the Parties' responsibilities of and to the interaction between the Parties with respect to quality assurance practice requirements and the good manufacturing practice requirements relating to the Manufacturing of the Product in accordance with GMP (including EU and US GMP guidelines).

2.15 **"Reservation Commitment"** shall be defined in Clause 3.6.

2.16 **"Shipment"** shall be defined in Clause 7.

2.17 [***]

2.18 "**Supply Commitment**" shall mean the manufacture of Product by IDT in accordance with the manufacturing slots set forth in the Manufacturing Plan (**Appendix 1**).

2.19 "**Valneva Material**" shall have the meaning set forth in Clause 4.1.

Any capitalized terms used but not defined in this Project Schedule shall have the meanings ascribed to them in the Master Agreement

3. FORECASTING, SUPPLY COMMITMENT AND FORECASTED ORDER QUANTITIES

3.1 Forecasting: The Parties amend Clause 2.1 of the Master Agreement and agree on the following:

[***]

3.2 Forecasting of Excessive Amounts. The Parties further agree to amend Clause 2.1 of the Master Agreement as follows: Any amounts in excess of the Order Commitment or for the Manufacturing of Product beyond the Manufacturing Plan, the Reservation Commitment or the Forecasted Order Quantities shall also be set forth in the [***] Forecast referred to in Clause 3.1 (ii) above.

3.3 Within [***] Business Days after receipt of the [***] Forecast set forth in Clauses 3.1 ii) and 3.2 above, IDT shall confirm each such [***] Forecast which complies with this Product Schedule and the Master Agreement provided that it (i) complies with the Forecasted Order Quantities, or (ii) IDT has available resources to Manufacture Products in excess of the Forecasted Order Quantities and, (iii) with regard to the distribution of the manufacturing of the total number of Batches throughout the relevant year, the requirements set forth by Valneva in each [***] Forecast comply with IDT's capacity planning. If the Forecast does not comply with IDT's planning, IDT will discuss with Valneva possible manufacturing slots and, following the discussion, confirm the Forecast with amendments to the manufacturing time. If IDT has no additional resources available it will only refuse the [***] Forecast to the extent the Products are in excess of the Forecasted Order Quantities.

3.4 [***].

3.5 Supply Commitment: In accordance with Clause 4.3 of the Master Agreement, IDT firmly commits to Manufacture, reserve capacity and supply Valneva with Product in the amounts set forth in **Appendix 1** and as otherwise forecasted by Valneva and confirmed by IDT in accordance with Clauses 3.1ii and 3.2 above. IDT shall retain and employ personnel and authorized subcontractors who have the experience, skill, diligence, and expertise necessary and appropriate to standards and service levels required under this Product Schedule.

3.6 Reservation Commitment: [***], IDT firmly commits to reserve manufacturing slots for the number of Batches and supply Valneva with Product as set forth in **Appendix 1**. The Parties acknowledge and agree that the Manufacture of the Product will be provided in Campaigns unless otherwise set forth in a Forecast confirmed by IDT.

3.7 Forecasted Order Quantity: Subject to Clause 3.8 below, in accordance with Clause 5.2 of the Master Agreement, Valneva shall order the Product in accordance with the Order Commitment corresponding to the Supply Commitment and the Reservation Commitment.

3.8 Cancellation of [***]: Valneva shall have the right to cancel [***].

[***]

3.9 Purchase Orders: Valneva shall issue purchase orders in accordance with Clause 3.1 of the Master Agreement corresponding to the amounts of Product pursuant to the Order Commitment not later than [***] prior to the Shipment of the Product. For the sake of clarity, if Valneva does not provide a Purchase Order according to this provision, IDT shall not manufacture the relevant Batch and the Order Commitment shall be deemed cancelled, provided that IDT shall send a reminder if IDT does not receive the Purchase Order as expected.

3.10 Available Slots: [***] Valneva shall provide IDT with an Order if Valneva wishes to order excessive amounts of Product within [***] calendar days after receipt of notice of such available slot. Any confirmed excessive amounts shall also be included in the Forecasting procedure set forth in Clause 3.2 above.

3.11 Outbreaks: The Parties acknowledge that Valneva has entered into a funding agreement with the Coalition of Epidemic Preparedness Innovation ("**CEPI Agreement**") aiming to accelerate regulatory approval of Valneva's proprietary Chikungunya vaccine candidate VLA1553, secure supply of the Chikungunya vaccine in regions where outbreaks occur and, support WHO prequalification to facilitate broader access in lower- and middle-income countries ("**CEPI Purpose**").

To support the CEPI Purpose, Valneva shall notify IDT in the event of an outbreak of Chikungunya or if there is an increased outbreak preparation need in any country of the world ("**Outbreak Notice**"). Upon Valneva's request IDT is committed to use commercially reasonable efforts to support Valneva to comply with the CEPI Purpose. The Parties shall discuss in good faith (i) opportunities to increase the Manufacture and supply of Product in excess of the Order Commitment, (ii) additional Product development at Valneva's expense or (iii) other activities, including providing reasonable support to Valneva in connection with Valneva's pursuit of regulatory approvals and licensure to the extent not already obtained.

4. VALNEVA MATERIAL

4.1 Valneva Material: Valneva shall provide IDT with its proprietary VLA1553 Drug Substance ("**Valneva Material**") [***] prior to the planned Manufacture according to Appendix 1 and the Forecast by IDT [***]. Valneva, [***], shall supply Valneva Materials to IDT in accordance with this Product Schedule and the Master Agreement. [***]

4.2 With each provision of Valneva Material Valneva shall provide IDT with a Certificate of Analysis including but not limited to [***].

4.3 Consumption Report: On the date of finalization of the Manufacture of a Batch, and in any event not later than [***] Business Days after completion (dispatch packaging), IDT shall provide Valneva with a report ("**Consumption Report**") including the amount of Valneva Materials used during the Manufacture together with the actual Product in doses ("**Actual Yield**") of such a Batch.

4.4 Stock Report: At the [***] Business Day of each calendar month, IDT shall provide Valneva with a stock report (showing the end of month inventory value) both in Excel and pdf. format listing all Valneva Material including batch number, quantity, material number and status (bulk, in process, filled, released) that remains at IDT. Such stock report shall be sent to the email address: [***].

4.5 IDT Valneva Material Forecast, Section 8.1 of the Master Agreement: The Parties agree that IDT shall not provide a Forecast for the Valneva Material according to Section 8.1 of the Master Agreement. Valneva shall provide the Valneva Material in accordance with Section 4.1.

4.6 [***].

4.7 [***].

5. MANUFACTURING AND MINIMUM YIELD

5.1 Manufacturing Requirements: IDT shall Manufacture the Product in accordance with the requirements set forth in the Master Agreement, the Product Specifications set forth in Appendix 2 as may be updated in accordance with Clause 25.6 of the Master Agreement following final approval by the Food and Drug Administration ("**FDA**"), Manufacturing Specifications, QAA and in accordance with GMP. The Product shall comply with the Specifications set forth in **Appendix 2**. Both Parties acknowledge that these Specifications may need to be revised post requests by regulatory authorities as part of the regulatory approval process of the Product. Any change in Specifications will follow the Change Control process defined in the QAA, Clause 25.6 of the Master Agreement and shall be incorporated herein by reference hereto.

5.2 Minimum Yield: IDT shall Manufacture not less than [***] ("**Minimum Yield**"). [***] Valneva shall have the right, at its own discretion, to request either the destruction of, or Shipment to Valneva of such a Batch in Non-Conformance due to

not meeting the Minimum Yield. If Valneva chooses the Shipment of such a defective Batch, it shall pay the Price for the vials of such Batch in accordance with Section 13.1 c.

6. RELEASE AND RELEASE TIMELINES

6.1 Quality Release Testing: IDT shall perform quality release tests as set forth in **Appendix 2**.

6.2 Additional Quality Parameters: Valneva shall perform quality tests as set forth in **Appendix 2**.

6.3 Timelines: IDT shall perform the tests and Release the Product within [***] working days after the finalization of the Manufacture. Valneva shall perform the tests according to Clause 6.2 within the same period of time. For the sake of clarity, with the QP Release Statement IDT confirms the Manufacturing in accordance with the Manufacturing Specifications and the compliance of the Product with the Product Specifications.

7. SHIPMENT

7.1 Time of Shipment: The Parties agree that IDT shall Ship the Products within [***] working days after the Release unless Valneva informs IDT about a confirmed non-conformity of the Product with the Additional Quality Parameters.

7.2 Release Documentation: IDT shall provide the IDT QP Release documentation as set out in the QAA [***] prior Shipment.

7.3 Product Ready for Shipment: For clarity, IDT shall Ship the Products to Valneva ready for sale/export with the necessary documentation, in accordance with the applicable Incoterms; it being understood that the IDT QP Release documentation is available on the date of Shipment.

7.4 Terms of Shipment: Furthermore, the following terms apply to Shipment:

Incoterms 2020	[***]

7.5 Risk and Title: Risk in the Products shall pass to Valneva in accordance with Clause 7.4. Title and ownership shall transfer at the same time as risk.

8. PRODUCT RECALL

8.1 Recall Procedure: In addition to Clause 11 of the Master Agreement, which is incorporated herein by reference hereto, the following apply:

The decision to initiate a Recall or to take other corrective action, if any, with respect to the Product will be made by Valneva. In case of a recall, IDT undertakes to assist Valneva in the recall process, as appropriate, having regard to Applicable Laws, and especially (a) the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use and Veterinary Use – Part 1 – Chapter 8 “Complaints, Quality Defects and Product Recalls” and (b) the compilation of Community procedures on inspections and exchange information in the meaning of article 3 (1) of the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles

and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

9. TERM AND TERMINATION OF PRODUCT SCHEDULE

9.1 Term: This Product Schedule shall enter into effect on the Effective Date and shall remain in effect until 31 December 2029 ("**Initial Term**"). Thereafter, this Product Schedule will automatically renew [***], (ii) unless the Product Schedule is otherwise extended, modified or sooner terminated as permitted under the Master Agreement, or (iii) in accordance with Clause 10.2 below. The Parties acknowledge and agree that, unless otherwise agreed, the Master Agreement shall be amended to remain in effect during such a Renewal Term.

9.2 Continued Performance: In case of termination by IDT in accordance with Clauses 19.5 of the Master Agreement and in case Valneva disputes such termination in good faith, without waiving any potential rights to effectively terminate this Product Schedule due to a material breach of Valneva, IDT shall be obliged to continue the Manufacturing and supply Product to Valneva in accordance with the Supply Commitment and/or any Forecast in accordance with the terms of this Product Schedule until the dispute is resolved by the Parties.

9.3 Consequences of termination: If this Agreement is terminated by any of the Parties, except for a termination by IDT in accordance with Clauses 19.5 of the Master Agreement, then in addition to any other remedies, [***]. The Product shall be Manufactured in accordance with the Product Specifications and terms of this Agreement, at the Price in force at the time of termination of this Agreement.

10. FAILURE, NON-CONFORMANCE, SHORTAGES AND DELAYS

10.1 Delays in the Manufacturing and Liquidated Damages: The Parties amend Clause 4.3 of the Master Agreement and agree to the following: If IDT fails to Ship Product in accordance with this Agreement, in particular the Manufacturing Plan and its Supply Commitment or the Forecast and Purchase Order, [***].

10.2 Information Rights: In case IDT is in default with the Shipment of [***], Valneva shall have the right to request from IDT appropriate evidence that IDT has still reserved sufficient capacity for the proper and timely fulfilment of its manufacturing and supply obligations under this Agreement. [***]

10.3 Remedies due to Non-Conformance: [***].

10.4 Performance: IDT shall not be released from performing its obligations under this Agreement nor shall it claim that its obligations under this Agreement should be limited or reduced or excluded in any manner and in any circumstances on the grounds that Valneva exercises any of its rights under this Agreement. IDT further agrees to proceed diligently with the performance of its obligation under this Agreement, including the Shipment of Product, pending resolution of any dispute, unless otherwise instructed by Valneva. IDT shall have no right of retention with respect to Valneva's right for supply with Product under this Agreement, unless (i), Valneva unreasonably rejects IDT's right of retention, (ii) IDT's claims are undisputed or (iii) have been granted by way of a final or enforceable court judgment or arbitral award.

11. PRICE AND PAYMENT

11.1 Price: The Price of Product shall be set forth in in **Appendix 3**, subject to adjustments pursuant to Clause 11.4 and Clause 11.5. [***].

11.2 [***].

11.3 Payment Terms: The following terms apply to the Price and payment for the Products:

Payment Period	Payments shall be made in accordance with the Master Agreement
Invoice Currency	Euro
Invoice Address	[***]
IDT Bank Account	[***]

11.4 Price Adjustment: [***] Written Notice of increases or decrease to the Price will be sent by IDT to Valneva. [***] IDT shall send a Notice to Valneva determining such price increase and must include in each such Notice documentation evidencing the year-over-year percentage price increase and, additionally, provide transparent evidence of Price changes for Valneva's financial review. In the event of the amount that IDT must pay to Third Party suppliers (including all discounts and credits) of one or more of the Raw Materials has instead decreased, the same principle shall apply for such decrease and the reduction of Price.

12. REGULATORY SUPPORT

The Parties agree that, upon Valneva's request and subject to Part D of the Master Agreement IDT shall provide regulatory support services consisting of the provisions of data and documents pertaining to the Manufacturing of Product to support finalization of the initial Product registration (Marketing Authorization) in the US or EU.

13. MISCELLANEOUS

Interim Relief: Without prejudice to Clause 22.12 of the Master Agreement, the arbitral tribunal shall have the power to grant any remedy or relief that it deems appropriate, whether provisional or final, including conservatory relief and injunctive relief, and any such measures ordered by the arbitral tribunal may, to the extent permitted by applicable law, be deemed to be a final award on the subject matter of the measures and shall be enforceable as such. Nothing herein shall affect either party's right to apply to court of competent jurisdiction an injunction for performance or other remedy available for a breach of any provision of this Product Schedule.

Signature page follows

Execution

This Product Schedule is executed by the authorised representatives of the Parties as of the Effective Date.

SIGNED for and on behalf of **Valneva Austria GmbH**	**SIGNED for and on behalf of** **IDT Biologika GmbH**
By:	By:
Name: [***]	Name: [***]
Title: [***]	Title: [***]
Date:	Date:

SIGNED for and on behalf of **Valneva Austria GmbH**	
By:	
Name: [***]	
Title: [***]	
Date:	

Appendix 1 – Manufacturing Plan, Supply Commitment, Reservation Commitment

1. **Supply Commitment/Manufacturing Plan**

[***]

2. **Reservation Commitment**

[***]

Appendix 2

[***]

Appendix 3 – Price of Product

[***]

[***] = 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. 4 to
Research Collaboration and License Agreement
("Amendment No. 4")

Date: November 22, 2022

Name of Agreement: Research Collaboration and License Agreement ("Original Agreement"), as amended by Amendment No. 1 to Agreement dated as of July 14 2021 Amendment No. 2 to Agreement dated as of 10 November 2021 and Amendment No. 3 dated as of June 19, 2022 (the "Agreement")

Effective Date of Original Agreement: April 29, 2020

Parties: Pfizer Inc. ("Pfizer") and Valneva Austria GmbH ("Company")

WHEREAS, the parties hereto desire to amend, among other things, certain terms of the Agreement, subject to the terms and conditions of this Amendment No. 4.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the parties hereby agree as follows:

1. Defined Terms. Capitalized terms used but not defined herein shall have the respective meanings ascribed to such terms in the Agreement.

2. Amendment(s) to the Agreement.

1.1 Pursuant to Section 4.3.1(a) of the Agreement, the existing Development Budget is amended and restated as set forth on Exhibit A hereto.

1.2 The first sentence of Section 3.2 of the Agreement will be replaced in its entirety as follows:

"Subject to the terms and conditions of this Agreement, the Development Costs incurred by the Parties pursuant to the Development Plan in accordance with the Development Budget ("**Shared Costs**") from the Effective Date through April 30, 2022 will be borne seventy percent (70%) by Pfizer and thirty percent (30%) by Valneva. Shared Costs incurred after April 30, 2022 will be borne sixty percent (60%) by Pfizer and forty percent (40%) by Valneva, subject to the terms and conditions of this Section 3.2 (the "**60/40 Shared Cost Split**"). Notwithstanding the 60/40 Shared Cost Split after April 30, 2022, beginning on May 1, 2022 with respect to Shared Costs incurred on or after May 1, 2022:

(a) until the occurrence of any Phase 3 Clinical Trial Cessation, with respect to a maximum aggregate of **[***]** of such Shared Costs, (i) Pfizer will bear **[***]** of such Shared Costs in 2022, then Valneva shall bear the subsequent **[***]** of such Shared Costs, then Pfizer shall bear the subsequent **[***]** of such Shared Costs, then Valneva shall bear

the subsequent **[***]** of such Shared Costs and then Pfizer shall bear the subsequent **[***]** of such Shared Costs, and (ii) with respect to all such Shared Costs in excess of **[***]**, the 60/40 Cost Sharing Split shall be applied to any such additional Shared Costs incurred following the exhaustion of such total **[***]** as allocated above; and

(b) effective upon the occurrence of any Phase 3 Clinical Trial Cessation, the Parties understand and agree that all Shared Costs incurred on or after May 1, 2022 shall be borne sixty percent (60%) by Pfizer and forty percent (40%) by Valneva.

As used herein (i) "Phase 3 Clinical Trial Cessation" shall mean any (x) termination of any Phase 3 Clinical Trial prior to completion in accordance with the terms of the protocol for such Phase 3 Clinical Trial or (y) any temporary halt or Clinical Hold of any Phase 3 Clinical Trial which lasts for longer than 180 days; and (ii) "Clinical Hold" shall mean (x) an order issued by the FDA pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound in the United States or (y) an equivalent order issued by a Regulatory Authority other than the FDA in any other country or group of countries."

3. Ratification of the Agreement. Except as expressly set forth in Articles 2 and 3 above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 4 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.

4. Counterparts. This Amendment No. 4 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of Pfizer and Company have executed this Amendment No. 4 as of the date first above written.

Valneva Austria GmbH

By: **[***]**

Print Name: **[***]**

Title: **[***]**

(Duly authorized)

By: **[***]**

Print Name: **[***]**

Title: **[***]**

(Duly authorized)

Pfizer Inc.

By: **[***]**

Print Name: **[***]**

Title: **[***]**

(Duly authorized)

Exhibit A

[***]

DISTRIBUTION 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.

This Distribution Agreement ("**Agreement**") shall be effective as of 15 December, 2022 ("**Effective Date**") by and between:

VBI Vaccines B.V., organized under the laws of the Netherlands, with its registered office at Queen's Tower #714, Delflandlaan 1, 1062EA Amsterdam, the Netherlands, hereinafter referred to as "**SUPPLIER**",

and

Valneva Austria GmbH, CIN: [***], organized under the laws of Austria, with its registered office at Campus Vienna Biocenter 3, 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, SUPPLIER is engaged in the research, development and manufacture of biopharmaceutical products, including its proprietary hepatitis B vaccine PreHevbri™ ("**the Product**"), and is the exclusive owner or licensee of proprietary rights in such Product;

Whereas, DISTRIBUTOR and its Affiliates (as defined below) are engaged in the marketing of pharmaceutical products and have the facilities, personnel and technical expertise to market, sell, promote and distribute the Product in the Territory (as defined below); and

Whereas, SUPPLIER is willing to exclusively sell the Product in the Territory to DISTRIBUTOR, and DISTRIBUTOR is willing to acquire the Product from SUPPLIER and use its Affiliates having commercial operations in the specified countries for resale to customers in their own name and on their own account in their respective countries within the Territory, on the terms and conditions set forth in this Agreement. Notwithstanding the foregoing, and for a limited period of time until DISTRIBUTOR has set up its ERP systems properly, DISTRIBUTOR will have the right to delegate the rights and responsibilities under this Agreement to such Affiliates,

which Affiliates will purchase Product directly from SUPPLIER and resell to customers in their respective countries within the Territory, on the terms and conditions set forth below; provided, however, DISTRIBUTOR will remain liable for any breach of this Agreement by its Affiliates.

NOW, THEREFORE, in consideration for the premises and promises contained herein, the Parties, intending to be legally bound, agree as follows:

1 DEFINITIONS

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 **"Affiliate"** means, with respect to a Party, any entity that is controlled by, controls, or is under common control with such Party. For such purpose, the term "control" means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting interest in an entity, or more than fifty percent (50%) interest in the income of the entity in question, or the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity.

1.2 **"Agreement"** means this contract together with all attachments and amendments agreed upon by the Parties in writing.

1.3 **"Anti-Corruption Laws"** means any and all applicable local, European or other legislations/regulations regarding corruption that may be applicable to one or both Parties, including but not limited to the following legislations/regulations as amended from time to time: (a) the Criminal Law Convention on Corruption (Council of Europe), (b) the Organization for Economic Co-Operation and Development Convention on Combating Bribery of Foreign Officials in International Business, (c) the UK Bribery Act of 2010, and (d) the United States Foreign Corrupt Practices Act of 1977.

1.4 **"Applicable Laws"** means applicable laws, rules, and regulations, including any rules, regulations, guidelines, and other requirements of a Governmental Authority, as may be in effect from time to time, including but not limited to the Anti-Corruption Laws.

1.5 "**Average Net Selling Price**" or "**ASP**" means Net Sales in the Territory divided by total number of doses, for doses sold in the Territory during a calendar year (1 January – 31 December).

1.6 **"Business Day"** means any day other than a Saturday, Sunday or statutory holiday in the Territory.

1.7 **"Change of Control"** means an acquisition by any third party, directly or indirectly, of voting securities or capital stock, or other comparable ownership interest, of a Party or its applicable Affiliate, resulting in such third party, together with its Affiliates, owning, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or capital stock, or other comparable ownership interest, of a Party.

"Confidential Information" means any trade secrets, confidential data or any other confidential information, whether oral or written, relating to the other Party's past, present and/or future efforts in research, development, manufacturing, and business

activities that is disclosed to or obtained by the receiving Party in connection with, and during the Term of, this Agreement.

1.8 **"DAP"** means Delivery At Place to DISTRIBUTOR's or its Sub-Contractor's designated warehouse in the United Kingdom, in accordance with the ICC Incoterms 2020, International Rules for the Interpretation of Trade Terms, ICC Publication No. 723E.

1.9 **"DDP"** means Delivered Duty Paid To DISTRIBUTOR's or its Sub-Contractor's designated warehouse(s) in each respective country of the Territory, except the United Kingdom, in accordance with the ICC Incoterms 2020, International Rules for the Interpretation of Trade Terms, ICC Publication No. 723E.

1.10 **"Designated Wholesaler"** means an Affiliate or a third-party logistics service provider contracted by the DISTRIBUTOR, its Affiliates or its Sub-Contractors for storage and/or physical distribution services of the Product within the Territory, listed in ANNEX I as from time to time updated.

1.11 **"Effective Date"** means the date of this Agreement as designated in the preamble to this Agreement on the first page.

1.12 **"Expected Average Selling Price"** or "**EASP**" means an estimate defined by the Parties at the beginning of each calendar year based on the previous year's ASP.

1.13 "**GDP**" means, as relevant to the Product, the then-current good distribution practices and similar rules, regulations and guidelines, as amended from time to time, applicable to the proper handling, transport, storage, importation, marketing, promotion, sale and distribution of pharmaceutical products in the Territory, including but not limited to the then-current guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended) (i.e: as of the Effective Date, the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use).

1.14 "**GMP**" means, as relevant to the Product, the principles and guidelines of good manufacturing practice as contained in the Commission Directive 2003/94/EC, of 8 October 2003, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, as such principles and guidelines are interpreted and expanded in "The Rules Governing Medicinal Products in the European Community, Volume IV. Good Manufacturing Practice for Medicinal Products".

1.15 **"Governmental Authority"** means and includes all governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, having jurisdiction over the marketing authorization, pricing, reimbursement, importation, promotion, distribution and/or sale of the Product in the Territory.

1.16 **"In-Market Sales Tax"** means all forms of statutory taxation, duties, levies and fees imposed, assessed or enforced by any local, municipal, governmental, state, federal or

other body or Governmental Authority in any of the respective countries within the Territory on DISTRIBUTOR's commercialization and distribution of the Products.

1.17 **"Intellectual Property Rights"** means and includes all copyrights, designs, databases, mask works, patents, Trademarks, Confidential Information, trade secrets, trade names, Know How and other proprietary rights, and all registrations and applications therefor, which SUPPLIER may at any time own, control, adopt, use, license or register, with respect to the Product or its business, to the extent such rights are enforceable by Applicable Laws.

1.18 **"Know How"** shall mean any and all materials, information, experience and data, formulae, procedures, results and specifications, regulatory filings and clinical and pre-clinical data, in written or electronic form, which are related to the Product, including, but not limited to the composition and chemical, structural, toxicological, physical and environmental characteristics of Product including any process information relating to the manufacturing thereof; all conclusions, opinions, advice and reports needed to comply with all appropriate laws and regulations pertaining to the Marketing Authorization, the manufacturing, the marketing and the distribution of Product, such as analytical specifications, test methods, stability test methods and the necessary reference standards and disclosed by SUPPLIER to DISTRIBUTOR in connection with this Agreement.

1.19 **"Marketing Authorization"** the European marketing authorization referenced EU/1/22/1641/001, and the UK MHRA marketing authorization referenced PLGB 54272/0001, as such marketing authorizations may be modified from time to time.

1.20 **"Net Sales"** means the gross amount received by DISTRIBUTOR or Affiliates for sales, and other dispositions of the Product less (i) all trade, quantity, and cash discounts actually allowed, (ii) all credits and allowances actually granted due to rejections, returns, billing errors, recalls, rebates, charge-backs and retroactive price reductions.

1.21 **"Person"** means and includes any agency, association, company, individual, or other entity regardless of the type or nature thereof.

1.22 **"Pricing Approval(s)"** means any approval or authorization of any Governmental Authority establishing a pricing scheme and/or health insurance reimbursement scheme for the Product or any of them in the Territory, but excluding Marketing Authorization.

1.23 **"Product"** shall mean the product manufactured by or on behalf of SUPPLIER, for the indication(s) and application(s) specified in the approved Summary of Product Characteristics, in ready to-sell-form, filled, labelled, controlled and released to the applicable market within the Territory, as further set forth in ANNEX A.

1.24 **"Quality Agreement"** means the agreement between the Parties, or between the applicable Affiliates of SUPPLIER and DISTRIBUTOR that sets out the quality assurance standards and responsibilities pertaining to this Agreement and the Products, incorporated herein by reference hereto.

1.25 **"Reasonable Commercial Efforts"** means (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts

as such Party would normally use to accomplish a similar objective under similar circumstances and, in any event, no less effort than that which would be reasonably expected of a third party company with similar resources and experience as such Party; and (b) with respect to any objective relating to the commercialization and distribution of the Product by DISTRIBUTOR, the application by DISTRIBUTOR, consistent with the exercise of its prudent commercial and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts DISTRIBUTOR would devote to any other product.

1.26 "**Sales Tax**" shall mean value added tax ("VAT").

1.27 **"Start Date"** shall mean the specific dates set forth in ANNEX I whereby SUPPLIER appoints DISTRIBUTOR as SUPPLIER's exclusive distributor in accordance with Section 2.1.1 below.

1.28 **"Sub-Contractor"** means 1) the Affiliates of DISTRIBUTOR listed in ANNEX I or any other Affiliate that has commercial operations in the specific countries within the Territory, which Affiliates shall be appointed as Sub-Contractors by DISTRIBUTOR as soon as DISTRIBUTOR has completed the development and implementation of appropriate ERP systems, or 2) third parties that have been appointed by DISTRIBUTOR and approved by SUPPLIER pursuant to Section 2.2.2, to promote, market and distribute the Product in the Territory. For clarity, a Designated Wholesaler (as defined above) shall not be included in the definition of a "Sub-Contractor".

1.29 **"Tax"** or **"Taxes"** means all forms of taxation and all withholdings, duties, imposts, levies, and social security contributions imposed, assessed or enforced by any local, municipal, governmental, state, federal or other body or authority in the Netherlands, the Territory or elsewhere, in all cases being in the nature of taxation and any interest, penalty, surcharge or fine in connection therewith.

1.30 **"Tax Authority"** means any taxing, revenue or other authority competent to impose or collect any liability to Tax.

1.31 **"Term"** means the term of this Agreement as determined in accordance with Section 17.1.

1.32 **"Territory"** shall mean the countries set forth in ANNEX B of this Agreement.

1.33 **"Trademarks"** means the word and design marks, and corresponding registrations applicable to the Territory, owned by, or licensed to SUPPLIER (with the right to sublicense), solely pertaining to the Product, which Trademarks are listed in ANNEX A.

1.34 **"Trade Secret"** means information:

(a) which is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) it has commercial value because it is secret; and

(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

1.35 **"Transfer Taxes"** means all stamp, registration, transfer taxes or their equivalents (excluding for the avoidance of doubt, any corporate income tax, income tax or capital gains tax or similar Tax and any Sales Tax).

In this Agreement, unless a contrary intention appears, the singular shall include the plural, each gender shall include each other gender and the terms "include" and "including" shall be construed without limitation.

2 GRANT OF RIGHTS

2.1 Exclusive Distribution and Supply

2.1.1 Distribution License Rights. Subject to the terms and conditions of this Agreement, and with effect from the Start Date(s), SUPPLIER hereby grants to DISTRIBUTOR, and DISTRIBUTOR accepts, an exclusive license (subject to SUPPLIER's retained rights in Section 2.1.2) under the Intellectual Property Rights to distribute, market, promote and sell the Product in the Territory under this Agreement. Such right being exclusive shall mean that SUPPLIER will not during the Term hereof (1) grant rights to distribute, market, sell and import the Product in and to the Territory to any other Person, nor (2) directly or indirectly through Affiliates distribute, market, sell and import the Product in and into the Territory.

2.1.2 DISTRIBUTOR's First Right of Refusal. SUPPLIER shall grant to the DISTRIBUTOR, or its Affiliates', the first right of refusal to enter into a distribution agreement for the distribution, marketing, promotion and sale of the Product in and into Austria, Canada and/or France (including DOM-TOM). The SUPPLIER shall provide written notice to DISTRIBUTOR of its intent to engage a Person, or sell itself, within Austria, Canada and/or France (incl. DOM-TOM) and the Parties shall not later than within [***] calendar days thereafter meet and negotiate a distribution agreement with similar terms and conditions as this Distribution Agreement, for the relevant country, with the aim of finalizing such distribution agreement withing [***] calendar days following such notice.

2.1.3 No Other License. Neither Party grants to the other any rights or licenses, implicit or otherwise, to its products or under its intellectual property rights, including but not limited to its patents, trademarks, and know how, other than those expressly set forth in this Agreement.

2.1.4 Appointment of Distributors Outside the Territory. DISTRIBUTOR acknowledges that SUPPLIER may grant exclusive marketing rights for the Product to other Persons in countries outside the Territory or that SUPPLIER may retain exclusive marketing rights for itself or its Affiliates for the same purpose. It is however understood, that by operation of law, restrictions on passive sales which includes the sale of the Product over the

internet, may not be permitted and that DISTRIBUTOR shall not be entitled to receive any compensation for such sales in the Territory by any other distributor.

2.1.5 Exclusive Supply. During the Term, DISTRIBUTOR shall purchase all of its requirements of the Product for the Territory from SUPPLIER or any party designated by SUPPLIER for this purpose.

2.2 Delegation and Sub-distribution Rights

2.2.1 Appointment. DISTRIBUTOR shall have the right to delegate its rights and responsibilities under this Agreement, and/or appoint Sub-Contractor(s) to market, promote and distribute Product in the countries of the Territory pursuant to the licenses granted herein and in accordance with this Section 2.2. The Parties agree and acknowledge that, until DISTRIBUTOR has completed the development and implementation of appropriate ERP systems, DISTRIBUTOR will, and shall have the right to delegate its rights and obligations under this Agreement to its Affiliate having commercial operations in the specified countries within the Territory whereby such Affiliate(s) shall have the right to purchase Product directly from SUPPLIER, in Euros (EUR) for resale to their customers in their respective countries. The approximate estimated time for the development and implementation of such ERP systems is [***] months after the Effective Date of this Agreement. DISTRIBUTOR agrees and acknowledges that Affiliate will comply with all applicable laws in the Territory and procure all necessary permits, to the extent applicable, to perform its role hereunder.

2.2.2 Sub-Contractor Notification and Approval. Except for the Affiliates and Sub-Contractors listed in ANNEX I, DISTRIBUTOR shall notify SUPPLIER in writing of the identity of any other Sub-Contractor, and except for any Affiliate, shall request SUPPLIER's prior written approval for any other third-party Sub-Contractor. SUPPLIER shall not unreasonably withhold, deny or condition such approval and shall either grant or deny such approval in writing within [***] calendar days from receipt of a written request from DISTRIBUTOR, which request shall include, at SUPPLIER's request, background information on such third-party Sub-Contractor. The addresses used for this communication are defined in ANNEX J.

2.2.3 Liability for Performance of Sub-Contractors. DISTRIBUTOR shall remain solely responsible and liable to SUPPLIER for the performance of this Agreement by its Affiliates, Sub-Contractors and Designated Wholesalers.

2.3 Trademarks and Trade Name Use

2.3.1 Trademark Freedom to Operate. SUPPLIER agrees that neither SUPPLIER nor its Affiliates shall assert any trademarks or trade names owned or controlled by SUPPLIER or its Affiliates based on DISTRIBUTOR´s or its Affiliates' or Sub-Contractor(s)´ commercialization of the Product provided any use is compliant with the terms and conditions of this Agreement including that the use shall be consistent with standards for trademark use that are generally accepted within the pharmaceutical industry.

2.3.2 Additional Trademarks. SUPPLIER shall have the right to select additional Trademarks and register them at its expense, and such Trademarks shall be owned by SUPPLIER and added to ANNEX A, initially as secondary Trademarks. If (i) a Governmental Authority does not approve the then-current primary Trademark indicated on ANNEX A, (ii) a third party asserts that such Trademark infringes its trademarks, (iii) such Trademark is successfully opposed by a third party, (iv) a petition to cancel such Trademark is filed by a third party, (v) there is an infringement of such Trademark by any third party against which SUPPLIER does not enforce its rights pursuant to Section 12.3, or (vi) there is a bona fide issue with such Trademark which is supported by an opinion of DISTRIBUTOR's outside trademark attorneys, then SUPPLIER shall designate one of the secondary Trademarks (as indicated on ANNEX A) as a replacement primary Trademark. If there are no remaining secondary Trademarks, DISTRIBUTOR shall have the right to select another trademark of its choosing after having received the written consent of SUPPLIER. Any such trademark selected by DISTRIBUTOR shall be registered in the name of SUPPLIER, at SUPPLIER's expense, shall be added as a Trademark to ANNEX A and shall be owned by SUPPLIER.

2.3.3 Trademark Use in Materials. Subject to the terms and conditions of this Agreement, DISTRIBUTOR shall use or have used the Trademarks related to the Product indicated in ANNEX A, and no other trademarks or trade names, in connection with its marketing, promotion, sale and distribution of the Product in the Territory, unless otherwise agreed by the Parties and provided, however, that DISTRIBUTOR may use its own trademarks and trade names on brochures and other promotion materials to identify itself as the distributor of the Product. DISTRIBUTOR agrees to provide copies of all such materials to SUPPLIER for Trademark use review and approval prior to publication and distribution. SUPPLIER agrees that its approval of such materials will not be unreasonably withheld. The Parties agree that SUPPLIER will be deemed to approve any such materials if it does not respond to DISTRIBUTOR within [***] calendar days after having received said materials. The addresses used for this communication are defined in ANNEX J.

2.3.4 Trademark Use Undertakings. DISTRIBUTOR's use of the Trademarks related to the Product in ANNEX A shall be consistent with standards for trademark use that are generally accepted within the pharmaceutical industry. DISTRIBUTOR shall in particular (1) not use Trademarks in a manner which would bring into disrepute the Trademarks or the trade name of SUPPLIER; (2) avoid in any case the use of the Trademarks as generic names; and (3) report to SUPPLIER all matters which, to the best of its knowledge, may affect the validity of the Trademarks, including any imitations of Product or infringements of the Trademarks and report them without unreasonable delay to SUPPLIER.

2.3.5 Trademark Audit Right. SUPPLIER shall have the right to audit DISTRIBUTOR's use of the Trademarks related to the Product in ANNEX A. DISTRIBUTOR shall remedy any

non-compliant use identified by SUPPLIER as soon as is possible using commercially reasonable efforts after notification by SUPPLIER.

2.4 Wholesale License and Import License

2.4.1 Wholesale License. DISTRIBUTOR shall ensure that it, and its Sub-Contractors, holds and shall maintain, throughout the term of this Agreement and for a period of six (6) months thereafter, a wholesale license or adequate license issued by the applicable authority of the Territory granting DISTRIBUTOR permission to store, distribute, market and sell medical products including vaccines at its own cost and expenses. A copy of such license is attached to this Agreement as ANNEX F.

2.4.2 Loss of License. DISTRIBUTOR shall immediately inform SUPPLIER of the loss or the threat of loss of its, or any of its Sub-Contractor's loss of wholesale license. The failure of DISTRIBUTOR to maintain its wholesale license in a country within the Territory shall give SUPPLIER the right, in its sole discretion, to terminate this Agreement with regard to such country, in accordance with Section 17.2, with [***] calendar days prior written notice, unless DISTRIBUTOR has cured every such diligence infringement within that [***] calendar day period.

2.4.3 Import License and QP Release. SUPPLIER shall obtain at its own costs any import licence or other authorization and carry out under its responsibility, where applicable, all customs formalities required to import Product in and into the Territory that are specific to Product. For clarity, SUPPLIER shall provide DISTRIBUTOR with Product in ready-to sell form, released for the EU and UK market by the SUPPLIER Qualified Person. Notwithstanding the foregoing, DISTIBUTOR or its Affiliate in the United Kingdom shall ensure import license and customs formalities in accordance with DAP.

3 NON-COMPETITION COVENANTS

3.1 No Active Sales in other Territories. DISTRIBUTOR covenants not to actively sell the Product or to establish or maintain branches, sales offices or distribution depots, set up subsidiaries or maintain deposits for the purpose of the sales of the Product in any countries outside the Territory allocated to another distributor, to SUPPLIER or any of its Affiliates for the exclusive distribution of the Product. The Parties understand that fulfilling orders made over the internet or unsolicited orders received from customers outside the Territory is permitted under EU competition law and is not prohibited hereunder.

3.2 No Manufacturing or Distribution of Competing Products. During the term of this Agreement, but in no event for a period of more than [***] years from the Effective Date of this Agreement, DISTRIBUTOR will not, without the written consent of SUPPLIER, physically distribute, sell or promote in the Territory any pharmaceutical products that directly compete with the Product in ANNEX A, that are generically substitutional to the Product and sold for the same indications as the Product in ANNEX A ("**Competing Product**").

4 MARKETING AND PROMOTION

4.1 Diligent Marketing Efforts

4.1.1 Diligent Efforts. DISTRIBUTOR shall ensure that its Sub-Contractors use Reasonable Commercial Efforts to promote, sell, and distribute the Product within the Territory, at their own expense. Such efforts shall include but not be limited to professional sales calls on target medical audiences (e.g. physicians, hospitals, pharmacists), advertising the Product in appropriate media and participating in trade shows, conferences, expositions, and promotional seminars, all with due consideration for the local marketing environment in the Territory.

4.1.2 Medical Affairs. The Parties agree that both DISTRIBUTOR and SUPPLIER may both employ (directly or via its Sub-Contractors) medical affairs personnel in some or all of the countries in the Territory. In such cases, DISTRIBUTOR and SUPPLIER will jointly create an annual Medical Affairs plan, to be reviewed at least quarterly, in each specific country in the Territory, which details the activities and responsibilities of the Parties' respective medical affairs personnel.

4.1.3 Offices and Personnel. DISTRIBUTOR shall ensure that its Sub-Contractors maintain offices adequate to market and support the Product within the Territory and retain and have at their disposal sufficient and adequate staff of trained and qualified personnel to perform their respective obligations under this Agreement.

4.1.4 Compliance. DISTRIBUTOR shall ensure that its Sub-Contractors conduct their marketing activities in accordance with Applicable Law and in accordance with appropriate or applicable standards of pharmaceutical product promotional practices, fair trade, fair competition and business ethics.

4.1.5 Product Launch. DISTRIBUTOR shall launch, i.e. actively promote the Product in the Territory ("**Launch**") as soon as reasonably possible, but not later than [***] calendar months for Sweden, Finland, Denmark, Norway, Belgium, and the Netherlands from the Effective Date, and not later than [***] calendar months from the Effective Date for the UK. DISTRIBUTOR shall promptly inform SUPPLIER of the proper date of the Launch ("**Launch Date**").

4.1.6 Diligence Failure. Failure to meet DISTRIBUTOR's diligence obligations, as set forth in this Section 4.1 shall give SUPPLIER the right, in its sole discretion, with [***] calendar days prior written notice (if DISTRIBUTOR has failed to cure either such diligence obligation within such [***] calendar day period), to either (i) terminate the Agreement, in accordance with Section 16.2; or (ii) appoint additional distributor(s) for the Territory or parts thereof, and convert the exclusive licenses of Section 2.1.1 and 2.3.1 into non-exclusive licenses.

4.2 Distribution

4.2.1 Inventory. DISTRIBUTOR shall at all times maintain a stock of Product so as to adequately serve and fulfill the normal and reasonably foreseeable sales of Product within the Territory, however such stock not to be less than [***] month's supply of Product. In

particular, DISTRIBUTOR or its Sub-Contractors shall maintain suitable premises for the storage and handling of Product and shall assure proper storage and handling of Product in accordance with Good Distribution Practice (GDP) standards and Product requirements as set forth in the Marketing Authorization.

4.2.2 Distribution. DISTRIBUTOR shall ensure that the Product is adequately packaged for shipment and distribution within the Territory. DISTRIBUTOR shall ensure that its Designated Wholesalers use suitable transport systems and handle Product in accordance with Good Distribution Practice (GDP) standards and Product requirements.

4.2.3 Alterations. DISTRIBUTOR shall ensure that the Product is distributed, sold, promoted, marketed and advertised in the form and with the labeling or marking designated by SUPPLIER and in accordance with the applicable regulations in the Territory and, in particular, shall not alter, remove, or deface any Trademark without the written approval of SUPPLIER.

4.3 Promotional Materials

4.3.1 Promotional Materials. DISTRIBUTOR may develop sales literature, product descriptions, sales aids and advertising and promotional materials (collectively "Promotional Materials") from background information and materials provided by SUPPLIER, provided however, that all costs and expenses incurred by DISTRIBUTOR in the preparation and distribution of such sales literature and promotional materials shall be borne solely by DISTRIBUTOR.

4.3.2 Provision of Promotional Materials. To the extent that it is legally and contractually permitted to do so, SUPPLIER will share with DISTRIBUTOR Promotional Materials developed and used by SUPPLIER, its other distributors or licensees in respect of each Product as soon as practicable; and hereby grants to DISTRIBUTOR a royalty free, non-exclusive license during the Term to reproduce and/or adapt the Promotional Materials solely for the purpose of promoting the Product in the Territory, provided that DISTRIBUTOR shall bear all costs of reproducing and/or adapting such Promotional Materials.

4.3.3 Copyright. DISTRIBUTOR shall retain the copyright in any Promotional Material developed by DISTRIBUTOR and any adaptation of the Promotional Materials provided by SUPPLIER (the "**DISTRIBUTOR Promotional Materials**"). DISTRIBUTOR shall promptly notify SUPPLIER of any claims or objections where its use of the DISTRIBUTOR Promotional Materials in connection with the marketing, support or service of the Product may or does infringe the copyrights, patents, trademarks or other proprietary rights of another Person.

4.3.4 Compliance and Approval. DISTRIBUTOR shall ensure Promotional Materials comply with the Marketing Authorization, all Applicable Laws and all other applicable rules and regulations in the Territory. DISTRIBUTOR shall submit Promotional Materials to SUPPLIER for review and approval, in sufficient advance to allow SUPPLIER to verify if such Promotional Materials comply with SUPPLIER’s global branding strategies and

the relevant Marketing Authorization. DISTRIBUTOR shall, at its own risk, cost and expense, translate Promotional Materials into the English language or certify in writing that any Promotional Material in a local language is a correct translation of the Promotional Material provided by SUPPLIER and that the translation was made by a certified translator. SUPPLIER shall provide comments or approval within fifteen (15) Business Days from receipt of a complete submission. If SUPPLIER does not give approval or comments within that fifteen (15) Business Day period, such Promotional Material shall be deemed approved.

5 AUTHORIZATIONS, PHARMACOVIGILANCE, COMPLAINTS, RECALLS AND ESCALATIONS

5.1 Regulatory and Pricing Approval

5.1.1 No Marketing of Product without Marketing Authorization. Except to the extent permitted by Applicable Law and approved in writing by SUPPLIER, DISTRIBUTOR shall not market, promote, offer for sale or sell any Product unless and until the appropriate Marketing Authorization in respect of the Product has been obtained. DISTRIBUTOR shall transport, store, market, promote, offer for sale or sell and distribute the Product in accordance with the Marketing Authorization.

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 [***] months 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. 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 [***] calendar days prior written notice to SUPPLIER, unless SUPPLIER has obtained the necessary Marketing Authorization within that [***] calendar day 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 SUPLIER'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 [***] Business Days 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.

5.1.3 Serialization. The Parties agree and acknowledge that the Falsified Medicines Directive (Directive 2011/62/EU) as amended by Directive 2001/83/EC and the European Commission delegated regulation (EU) 2016/161 of 2 October 2015 ("**Delegated Regulation**") supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use ("**Serialization**"), apply to the sales of the Product in the Nordics, Belgium and the Netherlands, and potentially also for products supplied to the United Kingdom. The Parties shall adhere to the requirements of the Delegated Regulation and Products designated for the respective Territories where Serialization is required and Products shall include a unique identifier and all other mandatory master data as further detailed in the Delegated Regulation (e.g. 2D-Data matrix Code, Human readable). The SUPPLIER shall register and pay any and all fees associated with the Serialization of the Products at the applicable National Medicines Verification Organizations, or equivalent, running the applicable national repositories. Upon reasonable request by SUPPLIER, DISTRIBUTOR shall provide support to SUPPLIER as necessary for SUPPLIER to perform a proper root cause analysis or resolution of possible product falsifications (e.g. in connection with European Medicines Verification System alerts, triggered in the respective Territory, including but not limited to Delegated Regulation countries). The handling of potential falsifications will be further agreed upon in the Quality Agreement.

5.1.4 Pricing Approvals. DISTRIBUTOR shall be solely responsible for obtaining and maintaining Pricing Approval(s) for the sale of Product in the Territory, unless otherwise agreed by the Parties or legally required. For this purpose, SUPPLIER shall provide DISTRIBUTOR with data and documentation required for obtaining and maintaining Pricing Approval(s). This includes timely response to requests for the submission of pricing data by the local Governmental Authorities. Without prejudice to

DISTRIBUTOR's right to grant discounts to its customers in its sole discretion, DISTRIBUTOR shall use reasonable commercial efforts to obtain Pricing Approval(s) reflecting research and development and marketing investments.

5.1.5 Ownership of Pricing Approvals. As between DISTRIBUTOR and SUPPLIER, and without limiting DISTRIBUTOR's obligations under this Agreement, SUPPLIER shall be the sole owner of all Pricing Approval(s) for the sale of the Product in the Territory and related documentation, regardless of whether such approvals and/or documentation are in the name of DISTRIBUTOR or SUPPLIER, or any of their designees.

5.2 Manufacturing License and Batch Release

5.2.1 Manufacturing License. SUPPLIER shall be responsible, without any additional cost to DISTRIBUTOR, for securing and maintaining all necessary governmental approvals, licenses, authorisations and permissions, which may be required for SUPPLIER to manufacture (or have manufactured) the Product for distribution in the Territory. A copy of such license shall be attached to the Agreement as ANNEX M. Any renewal of such license will be sent to DISTRIBUTOR at the address given in ANNEX J. SUPPLIER shall inform DISTRIBUTOR of the loss or the threat of loss of such license immediately, however not later than twenty-four (24h) hours from knowledge thereof. The failure of SUPPLIER to maintain the manufacturing license shall give DISTRIBUTOR the right, in its sole discretion, to terminate this Agreement, in accordance with Section 16.3 below subject to the right of SUPPLIER to cure such loss within thirty (30) days.

5.2.2 Batch Release. SUPPLIER shall be responsible for securing batch release relating to Product with an European Official Medicinal Control Laboratory and where necessary, with the National Institute for Biological Standards and Control of the Medicines and Healthcare products Regulatory Agency, and shall provide DISTRIBUTOR with relevant information forms and certificates as further specified in ANNEX E. DISTRIBUTOR shall be entitled to rely upon such information forms and certificates without the necessity of performing additional testing. DISTRIBUTOR is responsible to obtain and hold all necessary regulatory registrations regarding distribution in the Territory.

5.3 Pharmacovigilance and Clinical Trials

5.3.1 Pharmacovigilance. DISTRIBUTOR shall adopt and maintain a service responsible to handle pharmacovigilance in the Territory concerning Product as detailed in the Pharmacovigilance Agreement as attached hereto as ANNEX G and any subsequent revisions of the same. The obligations of DISTRIBUTOR to forward any Safety Report to SUPPLIER (as further specified in ANNEX G) shall survive expiry or termination of this Agreement and be effective until [***] after the expiry date of the last batch of the Product distributed by DISTRIBUTOR.

5.3.2 Clinical Development. DISTRIBUTOR shall not initiate, sponsor or support any structured data collection schemes involving the Product in the Territory unless otherwise agreed to in writing by DISTRIBUTOR and SUPPLIER, including but not limited to:

(i) interventional clinical trials; and/or

(ii) non-interventional clinical studies, compassionate use/named subject use programs, or any other subject support programs.

5.4 Recalls, Technical Complaints etc

5.4.1 DISTRIBUTOR and SUPPLIER shall accept and follow the responsibilities and processes for recalls, complaints and other quality related issues as described in the Quality Agreement.

5.5 Medical Information Services

5.5.1 DISTRIBUTOR shall provide medical information services for the Product in the Territory through qualified personnel in accordance with this Agreement and as further detailed in this Section 5.5. Medical queries from the Territory received by the SUPPLIER shall be directed to DISTRIBUTOR´s Address for Medical Information Purposes as further detailed in ANNEX J.

5.5.2 Product Queries. DISTRIBUTOR shall perform the medical information services for the Product by using up-to-date and SUPPLIER approved resources (i) Summary of Product Characteristics or local equivalent (ii) English Product Questions & Answers (Q&A) document(s) and (iii) Standard Response Documents (SRDs) approved by the SUPPLIER. DISTRIBUTOR shall translate into English at its risk and expense all (i) Product medical queries outside the scope of the Summary of Product Characteristics (or local equivalent), English Product Q&A and English SRDs it receives and forward them in an anonymous form to SUPPLIER's Address for Medical Information Purposes (ANNEX J) within [***] Business Days of receipt. The answer will be compiled in English by SUPPLIER's respective department or med info service provider and will be sent as soon as practicable to DISTRIBUTOR, who shall be responsible for translation to the local language(s) at its risk and expense, for ensuring that answers are compliant with local laws and regulations e.g. by adding specific required information and for contacting and liaising with its customer.

5.5.3 Information Flow Between DISTRIBUTOR and SUPPLIER. SUPPLIER will provide DISTRIBUTOR with the updated English version of the English Product Q&A and English SRDs on at least a yearly basis. The English Product Q&A and SRD document(s) can be translated by DISTRIBUTOR to the local language(s) of the Territory at its own risk and expense. Every [***] months the DISTRIBUTOR shall provide SUPPLIER, in an anonymous form and in English, a summary of all Product medical queries (without DISTRIBUTOR's reply to such queries) it has received. Such information shall be directed to the SUPPLIER's Address for Medical Information Purposes (ANNEX J). Any newly identified safety issue relating to the Product shall be communicated promptly (but not later than within one (1) Business Day of the notifying Party becoming aware of the issue) to the other Party, and as per the terms defined in the Pharmacovigilance Agreement (ANNEX G), for review and discussion and for a decision to be made on the appropriate course of action(s) to be taken, if any.

5.5.4 Training. SUPPLIER's respective department shall provide DISTRIBUTOR's qualified personnel with an annual medical information training, whose form shall be at the discretion of the SUPPLIER (e.g. training manual, web-based or face to face training) and it is DISTRIBUTOR's responsibility to assure that its qualified personnel attends such training.

5.5.5 Continuing Obligation. After expiry or termination of this Agreement, and for a period of no longer than [***] calendar months following the expiry of the shelf life of the last Product sold and distributed by the DISTRIBUTOR, DISTRIBUTOR shall continue to forward in English any Product related medical query and/or stability query it received to SUPPLIER's Global Medical Information department as indicated by such department within one (1) Business Day of receipt.

5.5.6 Archiving. During the term of this Agreement, DISTRIBUTOR will document and archive all Product related medical queries and/or product quality queries it received together with DISTRIBUTOR's reply to such queries, and if required by a Governmental Authority, provide them to SUPPLIER and/or Governmental Authority.

5.6 Exchange and Update of Essential Information

5.6.1 SUPPLIER shall keep DISTRIBUTOR informed about any changes in accordance with the Quality Agreement, including but not limited to variations, regarding or having any effect on (1) the procedure according to which a Product is manufactured, (2) the composition and/or pharmaceutical characteristics of a Product and/or (3) the content and/or the wording of the Summary of Product Characteristics (SPC) for a Product in accordance with the timelines set forth in the Quality Agreement.

5.6.2 Whenever a change as described in section 5.6.1 occurs or becomes foreseeable, SUPPLIER will inform DISTRIBUTOR about all necessary details in accordance with the timelines set forth in the Quality Agreement. The Parties will then initiate and carry out a change control procedure that is compliant with all applicable standards of Good Manufacturing Practice (GMP) as detailed in the Quality Agreement.

6 FORECASTS AND ORDERS

6.1 Minimum Annual Purchase Quantities

6.1.1 Minimum Annual Purchase Quantities. In any full calendar year following the Start Date, whereby DISTRIBUTOR retains exclusive rights, DISTRIBUTOR shall purchase the Minimum Annual Purchase Quantities set forth in ANNEX D.

6.1.2 Failure to Fulfill Minimum Annual Purchase Quantities. If DISTRIBUTOR has failed to purchase the Minimum Annual Purchase Quantity of Product for [***] consecutive calendar years following the Start Date and the Parties have been unable to agree the remedial action, SUPPLIER may, at its option and upon [***] months prior written notice either (1) appoint additional distributor(s) for the Territory whereby DISTRIBUTOR'S rights hereunder will automatically be converted to non-exclusive, or (2) terminate this Agreement in accordance with Section 17.3 below.

6.2 Forecasts and Orders

6.2.1 Forecasts. DISTRIBUTOR shall provide SUPPLIER with its best estimate of future [***] anticipated orders of Product for the Territory on a rolling, monthly basis in accordance with ANNEX C hereto. Except the Binding Portion of the forecast (as defined in ANNEX C) which cannot be decreased, DISTRIBUTOR shall be entitled to increase or decrease the quantities of Product required according to the percentage limits outlined in ANNEX C, and to amend any forecast accordingly, to the extent necessary to take into account (i) any delay in the Launch of, (ii) any shortfall in supply of, or (iii) any defect, in the Product, or any of them, whether or not such delay, shortfall or defect is due to the default of SUPPLIER. For the avoidance of doubt, a forecast, shall have no bearing on the Minimum Annual Purchase Quantities referred to in Section 6.1 above.

6.2.2 Firm Purchase Orders. DISTRIBUTOR shall place orders within the lead-time defined in ANNEX C and which are consistent with the forecast for Products for the Territory provided by DISTRIBUTOR in accordance with ANNEX C ("**Firm Orders**"). Each order shall contain a valid purchase order number, and shall be duly signed by DISTRIBUTOR. The terms and conditions of this Agreement shall apply to all orders placed by DISTRIBUTOR and shall override and supersede any different or additional terms on orders from, or any general conditions maintained by DISTRIBUTOR. All orders are subject to written acceptance by SUPPLIER and will not be binding on SUPPLIER until the order has been accepted in writing as set out in Section 6.3.

6.2.3 Minimum Orders. Any single order placed by DISTRIBUTOR shall amount to not less than [***] doses of Product. Whenever possible, DISTRIBUTOR shall use Reasonable Commercial Efforts to place orders in amounts that are multiples of [***] doses. DISTRIBUTOR shall use Reasonable Commercial Efforts to not place more than [***] purchase orders per calendar year. In the event that the DISTRIBUTOR does place more than [***] orders, SUPPLIER will use its Reasonable Commercial Efforts to comply with such additional orders.

6.2.4 Problem Notification and Stock-Out Situations. SUPPLIER will use its Reasonable Commercial Efforts to deliver to DISTRIBUTOR the Product in the quantities and at the dates specified on the purchase orders submitted by DISTRIBUTOR in accordance with the agreed forecasts and which have been accepted in writing by SUPPLIER. If a purchase order cannot be (fully) shipped, SUPPLIER will promptly notify DISTRIBUTOR, and the Parties will jointly determine an appropriate new shipment schedule. SUPPLIER shall use Reasonable Commercial Efforts to inform DISTRIBUTOR of any supply issues as soon as discovered. SUPPLIER shall, as soon as practicable after receipt of each monthly rolling forecast, notify DISTRIBUTOR of any prospective problems it then knows it will have with respect to meeting DISTRIBUTOR's forecasted order quantities or estimated shipment dates. Should DISTRIBUTOR believe that such supply issue would result in a potential Stock-Out-Situation it will promptly, but not later than within [***] Business Days upon receipt of notice, inform SUPPLIER

thereof and SUPPLIER shall inform the Governmental Authority of the potential Stock-Out-Situation in accordance with Section 5.1.2.

6.3 Order Confirmation and Rescheduling

6.3.1 Acceptance of Orders. No firm purchase order shall be binding upon SUPPLIER until accepted by SUPPLIER in writing and SUPPLIER reserves the right to accept or reject any order, offer or request for Product. SUPPLIER shall review DISTRIBUTOR's submitted firm purchase orders and respond with a written order acceptance confirming the quantity, delivery date, price and payment terms, or a written order rejection indicating the reason for rejection.

6.3.2 Rescheduling. In the event that DISTRIBUTOR requests that any shipment be rescheduled, the Parties shall discuss in good faith, how such rescheduling shall occur and what impact it shall have, for example, on shipment costs and/or shelf life of any order accepted by SUPPLIER.

7 SHIPMENT AND DELIVERY

7.1 Shipment. The Product shall be shipped DDP to DISTRIBUTOR's designated warehouse(s) in Sweden and France respectively and DAP to DISTRIBUTOR's designated warehouse in the United Kingdom, and risk shall pass to DISTRIBUTOR accordingly. Title and control to the Products shall however pass when Products have been received at DISTRIBUTOR's designated warehouse(s) in the respective countries in the Territory.

7.2 Packaging for Shipment. The Product shall be delivered to DISTRIBUTOR in suitable packaging, so as to permit safe storage and transport. Where appropriate, SUPPLIER shall ensure that the Product is monitored using temperature loggers, which DISTRIBUTOR shall handle in accordance with the requirements set forth in the Quality Agreement.

7.3 Shelf-Life. The Product shall have not less than [***] of the total shelf-life remaining on delivery to DISTRIBUTOR, unless otherwise agreed upon, in writing, between the Parties.

7.4 Quantities. DISTRIBUTOR agrees and accepts that due to the particularity of the Product, the quantity of Product supplied to DISTRIBUTOR may differ by plus/minus [***] percent [***] from the ordered and confirmed quantity and that the actual delivered quantity of Product will be invoiced.

7.5 Delivery Delay and Failure. SUPPLIER will use Reasonable Commercial Efforts to supply and deliver ordered and confirmed quantity of Product, however, due to the particularities of the manufacturing processes and provided SUPPLIER has used Reasonable Commercial Efforts SUPPLIER shall not be liable for any failure, shortfall or delay in delivery of ordered and confirmed Product. If an event occurs that will or may affect the delivery of Product under an accepted Firm Order, SUPPLIER shall give written notice to DISTRIBUTOR as soon as it becomes aware that it may not be able to

deliver the Products by the delivery date or in the quantities set out in the accepted Firm Order stating the reasons for such delay or shortfall. SUPPLIER shall in any event use Reasonable Commercial Efforts to prevent an inventory shortage and to recommence production as soon as possible. In case of failure, shortfall or delay, the Parties will jointly determine an appropriate new shipment schedule for such ordered and confirmed Products. For the avoidance of doubt, in the event of delay, shortfall or failure to supply caused solely by SUPPLIER, the Parties shall discuss and agree in good faith a pro rata adjustment to the Minimum Annual Purchase Quantities as required to take account of such delay, shortfall or failure to supply.

8 PRODUCT WARRANTY

8.1 Product Supply Warranties. SUPPLIER represents and warrants, each time SUPPLIER supplies Product to DISTRIBUTOR under this Agreement, that each Product supplied hereunder shall:

(1) conform in all material aspects to the Product specifications consistent with the data contained in the Marketing Authorizations;

(2) be manufactured in accordance with current Good Manufacturing Practice ("GMP"), as amended from time to time, and

(3) not be adulterated or misbranded.

8.2 Audit Right. SUPPLIER or its authorized representatives are entitled to audit the DISTRIBUTOR and its or it's Sub-Contractors' facilities to assess the handling of Products and the activities undertaken by DISTRIBUTOR pursuant to this Agreement as provided for in ANNEX E. Such audits are aimed to ensure compliance with this Agreement and all Applicable Laws and regulations, including but not limited to GDP and shall be carried out during normal business hours and upon reasonable prior written notice. DISTRIBUTOR or its authorized representatives are entitled to audit SUPPLIER's facilities in accordance with GDP and GMP to assess the distribution and handling of Products and activities undertaken by SUPPLIER pursuant to this Agreement as provided for in ANNEX E. Each Party shall bear its own cost in relation to any audits undertaken by it pursuant to this Section 8.2.

8.3 Inspection. DISTRIBUTOR shall inspect or shall ensure that its Sub-Contractors inspect each shipment of Product visually promptly upon receipt of shipment at DISTRIBUTOR's or its Sub-Contractor's designated third-party logistics service provider in the Territory. If the Product supplied fail to meet the Product specifications and standards set forth or referenced herein or otherwise fail to comply with the terms and conditions of this Agreement, DISTRIBUTOR shall within [***] Business Days from receipt of the Product notify SUPPLIER (to the attention of its Quality Assurance Department and its Supply Chain Customer Service) of such non-compliance, including a description thereof in accordance with the provisions set forth in ANNEX E. Failures to give such notice within the aforesaid time period shall constitute acceptance of the

Product by DISTRIBUTOR as to defects reasonably discoverable upon visual inspection. Warranty claims for hidden defects, shall be made promptly after discovery of the hidden defect, but may only be made before expiration of the shelf-life of the Product. Any Product found to be non-compliant in line with this Section 8.3, shall be put into quarantine and kept there until SUPPLIER has decided upon its further disposition. After such disposition it shall be dealt with as decided by SUPPLIER.

8.4 Non-Conforming Product. Where DISTRIBUTOR alleges that any delivered Product is non-conforming, DISTRIBUTOR shall, or shall ensure that its Sub-Contractors, upon request of SUPPLIER, provide SUPPLIER (or SUPPLIER's designee) with a sample of such allegedly non-conforming Product, within [***] Business Days after the detection of such defects. SUPPLIER or such designee will examine such allegedly non-conforming Product within the lead times set forth in the Quality Agreement.

8.5 Remedy. If SUPPLIER agrees that the Product is non-conforming or if such non-conformance has been established by an independent laboratory in accordance with Section 8.7 below SUPPLIER shall use its Reasonable Commercial Efforts to dispatch to DISTRIBUTOR replacement Product as soon as is reasonably practicable but in any event within [***] Business Days following DISTRIBUTOR's notification of non-conformity, all shipment costs in respect of which shall be borne by SUPPLIER.

8.6 Return of Defective Product. DISTRIBUTOR agrees, if so requested by SUPPLIER, to return to SUPPLIER at SUPPLIER's expense, such Product that does not meet the Product specifications therefor, or otherwise dispose of such Product and provide written certification of such destruction to SUPPLIER, at SUPPLIER's expense and in compliance with all applicable rules and regulations, as SUPPLIER may direct. If SUPPLIER does not so direct, within [***] Business Days following DISTRIBUTOR's notification of non-conformity, DISTRIBUTOR may dispose of such Product at SUPPLIER's expense as DISTRIBUTOR may deem reasonably appropriate. SUPPLIER shall reimburse DISTRIBUTOR for the reasonable costs and expenses of such disposal and DISTRIBUTOR shall certify to SUPPLIER in writing that such Product has been destroyed.

8.7 Independent Testing. If the Parties disagree as to whether any delivered Product meets the applicable Product specifications, or SUPPLIER alleges that the defects are not attributable to the manufacture of the Product, the Parties will submit representative samples of the shipment to a mutually acceptable independent testing laboratory and the results of said laboratory shall be binding on the Parties. The costs associated with submission will be paid by the Party, whose position is not substantiated by the independent laboratory.

9 PRICES AND PAYMENTS

9.1 Price of Product. SUPPLIER shall sell Product to DISTRIBUTOR at the prices and in accordance with the terms set forth in ANNEX C hereto. Payment terms are [***]

calendar days from date of invoice. Upon shipment of Product ordered SUPPLIER shall invoice prices in Euro (EUR). Invoices shall be sent to the e-mail as outlined in ANNEX J or as otherwise notified by DISTRIBUTOR. Invoices shall include DISTRIBUTOR's contact details and VAT number: Valneva Austria GmbH, Campus Vienna Biotech 3, 1030 Vienna, Austria, VAT number: [***] Any Transfer Taxes due under the laws and regulations of the Territory in connection with the execution or entry into force of this Agreement shall be borne by DISTRIBUTOR. Further, should this Agreement be required to be registered with any Governmental Authority in the Territory, DISTRIBUTOR shall cause such registration to be made and shall bear any expense or Transfer Taxes payable in respect thereof. For clarity, until DISTRIBUTOR has completed the development and implementation of appropriate ERP systems, SUPPLIER shall send the invoices to the respective Affiliate's purchasing Product as detailed in Annex J.

9.2 Changes in Applicable Laws. If either Party becomes aware of any changes in Applicable Laws relating to any of the Products or otherwise to this Agreement, then such Party will notify the other Party of such changes. SUPPLIER shall have the right to increase or decrease the Price of any Product to reflect the impact of such changes in Applicable Laws.

9.3 Pricing Modifications. The Price and payment terms as specified in ANNEX C can be reviewed annually and adjusted if the Parties so agree in writing. In case of modifications, ANNEX C shall be amended accordingly. Either Party may initiate pricing discussions [***] based a valid reason. For the purpose of this Agreement "valid reasons" shall mean substantial increase of labor, material cost or significant changes in the relevant Product markets in the Territory, as described in ANNEX C. In such a case, the Parties shall negotiate in good faith upon a mutual acceptable pricing modification. Such changes shall take effect immediately after the Parties have mutually agreed in writing upon the modifications. If the Parties fail to reach agreement within [***] months following year end after the initiation of such discussions, the Price then in effect may be increased by [***].

9.4 Pricing of Orders in Progress. Firm purchase orders placed with SUPPLIER before the Parties have reached written agreement for a pricing modification shall be carried out at previous pricing conditions and payment terms.

9.5 Late Payment. If any payment under this Agreement is not made by the date on which the same becomes due and payable, DISTRIBUTOR shall automatically, without any further notification being given by SUPPLIER, owe SUPPLIER interest calculated at a rate of [***] percent [***] above the European Central Bank Base Rate per annum, or the maximum rate permitted under Applicable Law, whichever is lower.

9.6 Selling Prices and Other Terms of Sale. SUPPLIER acknowledges that DISTRIBUTOR has the sole right to establish selling prices, and all other terms and conditions applicable to, sales of Product to its customers in the Territory, and nothing in this Agreement will

be construed as giving SUPPLIER any right or authority to determine or influence such selling prices or terms. DISTRIBUTOR acknowledges that it shall be responsible for invoicing and collecting any and all amounts for Products sold and delivered to its customers and shall be responsible for the payment of all fees or expenses associated with such sales, except for any In-Market Sales Tax as set forth in Section 9.11 below.

9.7 Withholding Tax. Any and all amounts to be paid to SUPPLIER under this Agreement will be made without any deductions or withholdings in respect of Applicable Laws. If any deductions or withholding are required by Applicable Laws, the DISTRIBUTOR shall withhold or deduct an amount equal to any Tax required by such Applicable Laws to be deducted or withheld from the amount due to the SUPPLIER. The DISTRIBUTOR shall account for such Tax to the relevant Tax Authority within the time required by Applicable Laws and provide to the SUPPLIER reasonable evidence of the payment of such Tax. Any such Tax withheld or deducted shall be treated as having been paid by the DISTRIBUTOR to the SUPPLIER for all purposes of this Agreement. Each Party shall cooperate with respect to all documentation required by any Tax Authority or which may be reasonably requested by the other party to secure a reduction in the rate of applicable withholding taxes or to permit the other party to obtain a repayment of or credit for all Taxes withheld or deducted in respect of any payments under this.

9.8 Sales Tax. All payments (or other consideration) due to SUPPLIER under the terms of this Agreement are expressed to be exclusive Sales Tax howsoever arising and DISTRIBUTOR shall pay to SUPPLIER in addition to those payments all Sales Tax, for which SUPPLIER is liable to account to any Tax Authority in relation to any transfer, sale, use, transaction or supply made or deemed to be made for Sales Tax purposes to this Agreement subject to receipt of a valid Sales Tax invoice or invoices from the SUPPLIER.

9.9 Sales Tax Refund. If any Sales Tax originally paid by one Party ("**Party A**") of the relevant transfer, sale, use transaction or supply for Sales Tax purposes to the other Party ("**Party B**") in accordance with the terms of this Agreement is in whole or in part subsequently determined not to have been chargeable, Party B will take reasonable steps to obtain a refund of such Sales Tax from the relevant Tax Authority and Party B shall pay an amount equal to any such Sales Tax repaid by the relevant Tax Authority to Party A of the relevant supply within [***] Business Days of receipt from the Tax Authority (whether receipt is by way of repayment, credit or set off) and to the extent that Party B has not so accounted to a Tax Authority, Party B shall promptly pay an amount equal to such Sales Tax to the relevant recipient.

9.10 Costs and Reimbursements. Where SUPPLIER is required under this Agreement to pay an amount in respect of any cost, charge or expense incurred by DISTRIBUTOR or otherwise reimburse DISTRIBUTOR in respect of any cost, charge or expense, SUPPLIER shall not be required to pay or reimburse any amount in respect of Sales Tax which is recoverable (whether by way or repayment, credit or set off) by DISTRIBUTOR

and DISTRIBUTOR shall use all reasonable endeavours to seek to minimise irrecoverable Sales Tax.

9.11 In-Market Sales Tax. SUPPLIER shall be responsible for any In-Market Sales Tax applicable under Applicable Laws on Products sold to DISTRIBUTOR's customers, howsoever arising and DISTRIBUTOR shall pay to any Tax Authority or other applicable authority all such In-Market Sales Tax. SUPPLIER shall reimburse such In-Market Sales Tax paid by DISTRIBUTOR within [***] Business Days after receipt of an invoice from DISTRIBUTOR.

9.12 Adjustments. Where any amount stated as payable hereunder constitutes an adjustment, rebate or refund of an amount previously paid together with Sales Tax, such adjustment, rebate or refund shall be computed so as to include an amount in respect of Sales Tax and the Party to whom the amount was previously paid shall issue a valid Sales Tax credit note (or other appropriate document) in accordance with Applicable Law. For the avoidance of doubt the Parties shall generally issue invoices and credit notes in accordance with Applicable Laws consistent with Sales Tax requirements and irrespective of whether sums or consideration may be netted for settlement purposes.

9.13 Cooperation. Each Party agrees that it shall provide each other any information and copies of any documents reasonably requested by the other Party for the purposes of (a) determining the amount of Sales Tax chargeable on any supply made under this Agreement, (b) establishing the time or place of supply or other transfer for Sales Tax purposes of any supply or other transfer made under this Agreement, (c) complying with its Sales Tax accounting or reporting obligations or (d) recovering any Sales Tax that has or will be charged in respect of any supply or other transfer under this Agreement.

10 SALES RECORDS AND REPORTING OBLIGATIONS

10.1 Sales Records. DISTRIBUTOR shall maintain and retain all records relating to Product sales, contracts, invoices, customers, accounts, complaints and other transactions concerning Product for the period required by Applicable Laws, but in no case less than seven (7) years from the date on which such records arose.

10.2 Reports. DISTRIBUTOR shall keep SUPPLIER informed of significant market developments in the Territory especially in the field of the vaccination policy. DISTRIBUTOR shall or shall cause its Sub-Contractors to provide SUPPLIER with monthly reports in the format provided by SUPPLIER in ANNEX K and shall be due on the [***] Business Day of the following month. Reports shall be sent to SUPPLIER's e-mail address: [***]. In case of major volume shortfalls, DISTRIBUTOR will immediately inform SUPPLIER about the reasons of such deviation and propose corrective actions.

10.3 Annual Statements. SUPPLIER acknowledges and agrees that annual statements will be published and available on DISTRIBUTOR's website www.valneva.com as soon as audited and released following 31 December in any calendar year.

10.4 Tenders. DISTRIBUTOR shall duly inform SUPPLIER about any and all tenders, along with its terms and obligations, concerning the Product issued by any Governmental Authority or any relevant public institution in the Territory where DISTRIBUTOR intends to participate and quote. Upon DISTRIBUTOR's reasonable request, SUPPLIER shall supply DISTRIBUTOR with all information and documents required by DISTRIBUTOR to submit a valid offer. DISTRIBUTOR shall consult and provide SUPPLIER with all relevant information with respect to the tender offer prior to submission of such tender offer in order to receive SUPPLIER's written approval as to agreed delivery dates and potential penalties. Any agreement by the SUPPLIER to supply under a tender would be subject to separate agreement, including as to whether or not such supply is included in the calculation of the Average Selling Price and associated Reconciliation under ANNEX C.

10.5 Compensation for DISTRIBUTOR Costs Resulting from Failures to Comply with Tender Delivery Obligations. In respect of any Tender, provided that SUPPLIER has agreed with DISTRIBUTOR (a) to supply Product by given delivery dates provided for in the Tender and (b) to pay the penalties provided under the Tender documents, and (c) DISTRIBUTOR complies with its inventory obligations, DISTRIBUTOR will have the right to be reimbursed by SUPPLIER for penalties, liabilities, liquidated damages, price reductions and other costs incurred resulting from such Tenders due to SUPPLIER's default as further described in this Section 10.5. In the event that SUPPLIER fails to deliver a shipment of Product in accordance with the delivery dates agreed to between the Parties and that such failure is SUPPLIER's responsibility under the terms of this Agreement and is not attributable to Force Majeure (a "**Failed Shipment**"), then, to the extent that such failure causes DISTRIBUTOR (1) to be unable to deliver Product in accordance with the conditions of a Tender granted to DISTRIBUTOR, (2) that the terms of the Tender impose additional costs on DISTRIBUTOR as a consequence of such inability, and (3) such additional costs are actually incurred, then SUPPLIER shall compensate DISTRIBUTOR in an amount equal to the following amounts:

– if such failure is SUPPLIER's responsibility under the terms of the Distribution Agreement and is not attributable to Force Majeure; [***] of the penalties, liabilities, liquidated damages, price reductions and other costs imposed on the DISTRIBUTOR and actually incurred pursuant to the terms of the tender as a result of DISTRIBUTOR's failure to deliver Product for the tender by the delivery dates agreed with the tendering party; or

- if such failure is attributable to Force Majeure under the terms of the Distribution Agreement, however not regarded as force majeure under a Tender, [***] of the penalties, liabilities, liquidated damages, price reductions and other costs imposed on the DISTRIBUTOR and actually incurred pursuant to the terms of the tender as a result of

DISTRIBUTOR’s failure to deliver Product for the tender by the delivery dates agreed with the tendering party; or

- if such failure is DISTRIBUTOR’s responsibility under the terms of the Distribution Agreement and is not attributable to Force Majeure; [***] of the penalties, liabilities, liquidated damages, price reductions and other costs imposed on the DISTRIBUTOR and actually incurred pursuant to the terms of the tender as a result of DISTRIBUTOR’s failure to deliver Product for the tender by the delivery dates agreed with the tendering party.

The foregoing sets forth DISTRIBUTOR's sole and exclusive remedy, and SUPPLIER's sole and exclusive liability, in respect of any Failed Shipment.

10.6 Notwithstanding the above, DISTRIBUTOR acknowledges that it has a general obligation to take reasonable measures to mitigate the possible consequences resulting from a Failed Shipment.

10.7 Financial Audit. The Parties shall have the right to audit each other not more than [***] following Start Date to ensure compliance with the subject matter of this Agreement. Such audit will be performed by an independent third-party auditor acceptable to both Parties at the auditing Party's expense. The auditing Party shall provide reasonable advance written notice to the other Party of its desire to initiate an audit and the audit shall be scheduled so that it does not adversely impact or interrupt the other Party’s business operations. If the audit reveals any material discrepancies, the Party responsible for the deviation shall reimburse the other for any material discrepancies within [***] Business Days after completion of the audit. The results of such audit shall be kept confidential by the auditor and only the discrepancies shall be reported to the Parties and be limited to discrepancies identified by the audit. Notwithstanding the foregoing, any auditor reports shall not disclose any of DISTRIBUTOR’s pricing or terms of sale to DISTRIBUTOR’s customers nor the manufacturing costs of SUPPLIER.

11 INTELLECTUAL PROPERTY RIGHTS

11.1 Intellectual Property Rights

11.1.1 Acknowledgment. DISTRIBUTOR acknowledges that, prior to entering into this Agreement, it has no right, title or interest in and to any and all Intellectual Property Rights pertaining to the Product. DISTRIBUTOR shall not at any time during or after the Term of this Agreement take any act or step impairing the Intellectual Property Rights or do anything that may otherwise adversely affect the Intellectual Property Rights, provided that any legal proceedings or oppositions shall not be deemed to be such an act or step.

11.1.2 Preservation of Trademarks. DISTRIBUTOR agrees to take any action, at SUPPLIER's expense, which SUPPLIER reasonably deems necessary to establish and preserve SUPPLIER's exclusive rights in and to the relevant Trademarks, including but not limited to cooperating in the registration of the Trademarks on the trademark registry or other appropriate registration procedure within the Territory. DISTRIBUTOR shall not adopt, use, or register any acronym, trademark, trade names, service mark or other marketing name that is confusingly similar to the SUPPLIER's Trademarks or the SUPPLIER name.

11.1.3 Benefit. DISTRIBUTOR agrees that all its use of SUPPLIER's Trademarks shall be for the sole and exclusive benefit of SUPPLIER and the goodwill and reputation accrued in connection with DISTRIBUTOR's use of those Trademarks shall accrue to SUPPLIER.

11.2 Third Party Claims

11.2.1 SUPPLIER Third Party Claims. DISTRIBUTOR shall promptly notify SUPPLIER of any claims or objections that claims that SUPPLIER's use of the Intellectual Property Rights in connection with the distribution, sale, marketing, and promotion of the Product infringes the copyrights, patents, design rights, trademarks or other proprietary rights of another Person provided DISTRIBUTOR´s use of the Intellectual Property Rights is in accordance with the terms and conditions of this Agreement ("**SUPPLIER Third Party Claim**"). If DISTRIBUTOR is served with a legal action or otherwise forced to respond in a legal proceeding due to a SUPPLIER Third Party Claim, SUPPLIER shall conduct the defense of such SUPPLIER Third Party Claim at its own cost. SUPPLIER shall have the sole control over the defense and settlement of any SUPPLIER Third Party Claims. For that purpose, DISTRIBUTOR shall (1) if requested by SUPPLIER, without delay, at SUPPLIER's expense in accordance with SUPPLIER's instructions, submit the defense of such SUPPLIER Third Party Claim on behalf of SUPPLIER; and (2) render SUPPLIER all reasonable assistance, at SUPPLIER's expense, in connection with the defense of any such SUPPLIER Third Party Claim or objection, whether in the courts, before administrative agencies, or otherwise. DISTRIBUTOR shall not, except as required by law, knowingly make any admission to jeopardize, compromise or otherwise limit the validity of Intellectual Property Rights.

11.2.2 DISTRIBUTOR Third Party Claims. SUPPLIER shall promptly notify DISTRIBUTOR of any claims or objections which SUPPLIER becomes aware of, that claim that SUPPLIER's or DISTRIBUTOR's use of the DISTRIBUTOR Promotional Materials in connection with the distribution, sale, marketing, and promotion of the Product may or will infringe any Intellectual Property Rights of another Person ("**DISTRIBUTOR Third Party Claim**"). If SUPPLIER is served with a legal action or otherwise forced to respond in a legal proceeding due to a DISTRIBUTOR Third Party Claim, DISTRIBUTOR shall have the initial right, but not the obligation, to conduct the defense of such DISTRIBUTOR Third Party Claim at its own cost. DISTRIBUTOR shall have the sole control over the defense and settlement of any DISTRIBUTOR Third Party Claims. For

that purpose, SUPPLIER shall (1) if requested by DISTRIBUTOR, without delay, at DISTRIBUTOR’s expense in accordance with DISTRIBUTOR’s instructions, submit the defense of such DISTRIBUTOR Third Party Claim on behalf of DISTRIBUTOR; and (2) render DISTRIBUTOR all reasonable assistance, at DISTRIBUTOR's expense, in connection with the defense of any such DISTRIBUTOR Third Party Claim or objection, whether in the courts, before administrative agencies, or otherwise. SUPPLIER shall not, except as required by law, knowingly make any admission to jeopardize, compromise or otherwise limit the validity of intellectual property rights related to the DISTRIBUTOR Promotional Materials. If DISTRIBUTOR declines to defend a DISTRIBUTOR Third Party Claim, SUPPLIER may do so at its own expense.

11.3 Infringement of Intellectual Property Rights

11.3.1 Notification. DISTRIBUTOR shall promptly notify SUPPLIER of any infringement or suspected infringement of Intellectual Property Rights in the Territory, of which infringement DISTRIBUTOR becomes aware, and provide SUPPLIER with any available evidence of such infringement or suspected infringement.

11.3.2 Enforcement. SUPPLIER may at its own discretion, institute enforcement proceedings ("**Enforcement Proceedings**") in respect of an infringement or unauthorized use of Intellectual Property Rights in the Territory.

11.3.3 Assistance. DISTRIBUTOR agrees to provide all reasonable co-operation and assistance to SUPPLIER in relation to any such Enforcement Proceedings (and agrees to be named as a party if legally required). Any reasonable fees and costs related to DISTRIBUTOR's assistance, which were borne by DISTRIBUTOR, shall be reimbursed by SUPPLIER. SUPPLIER shall be entitled to any recovery in damages.

12 NON-DISCLOSURE AND NON-USE OBLIGATIONS

12.1 Non-disclosure of Agreement

12.1.1 Non-disclosure of Agreement. Neither Party shall disclose any information about this Agreement without the prior written consent of the other.

12.1.2 Exceptions. Consent shall not be required, however, for (1) disclosures to a Tax Authority or to existing or bona fide potential Sub-Contractors, with a need to know, to the extent required or contemplated by this Agreement, provided, that in connection with such disclosure, the Party making the disclosure obtains undertakings from the recipient of the Confidential Information to keep such Confidential Information confidential on terms at least as stringent as those set out in this Section 12; (2) disclosures for which the written consent has previously been obtained, or (3) information which had previously been publicly disclosed by a party other than the Party making the disclosure. Each Party shall have the further right to disclose the terms of this Agreement as required by Applicable Law, including the rules and regulations promulgated by any relevant securities and exchange commission and/or the regulatory bodies/authorities governing securities issues in foreign jurisdictions and to disclose such information to stockholders or potential

investors as is customary for publicly-held companies (as the case may be at the time of disclosure), provided the disclosing Party provides to the other Party prompt notice of such request and the opportunity to limit such disclosure, to the extent not legally prohibited, a copy of the information to be disclosed and an opportunity to comment thereon prior to such disclosure, and, to the extent practicable, consults within a reasonable time in advance of the proposed disclosure with the other on the necessity for the disclosure and the text of the proposed release.

12.2 Non-disclosure and non-use of Confidential Information

12.2.1 Non-disclosure and non-use of Confidential Information. SUPPLIER and DISTRIBUTOR hereby agree to hold in strictest confidence and not to disclose to any third party or use itself (except to enable each Party to perform its obligations in connection with this Agreement) any Confidential Information of the other Party without the prior written consent of the other Party. This confidentiality obligation shall remain in effect for Confidential Information for a period of [***] years following termination of this Agreement provided that if any Confidential Information is a Trade Secret and the owner of such Trade Secret has notified the other Party in writing that it is a Trade Secret, the confidentiality obligation in respect of such Trade Secret shall remain in effect for such Trade Secret following termination of this Agreement for a period as long as required by Applicable Laws.

12.2.2 Exceptions. The confidentiality obligations under Section 12.2.1 of this Agreement shall not apply to the extent that: (1) the Party who has received the Confidential Information ("**Recipient**") is required to disclose Confidential Information by order or regulation of a governmental agency or court of competent jurisdiction subject to the provisions below, or (2) disclosures of Confidential Information are made to a Tax Authority in connection with the Tax affairs of the disclosing Party, or (3) the Recipient can demonstrate that (i) the disclosed Confidential Information was at the time of such disclosure to Recipient already in the public domain, or falls into the public domain, other than as a result of actions of Recipient, its Sub-Contractors, its Affiliates, agents, direct employees, consultants or representatives, in violation hereof; (ii) the disclosed Confidential Information was known by Recipient (as shown by its written records) prior to the date of disclosure to Recipient from sources legally entitled to disclose the same or is independently developed without regard to the Confidential Information (as shown by its written records); or (iii) the disclosed Confidential Information was received by Recipient (as shown by its written records) on an unrestricted basis from a source unrelated to any Party to this Agreement and not under a duty of confidentiality to the other Party. Each Party shall have the further right to disclose the Confidential Information of the other Party as required by Applicable Law, including the rules and regulations promulgated by any relevant securities and exchange commission and/or the regulatory bodies and authorities governing securities issues in foreign jurisdictions and to disclose such information to stockholders or potential investors as is customary for publicly-held

companies (as the case may be at the time of disclosure), provided the disclosing Party provides to the other Party, to the extent not legally prohibited, prompt notice of such request, a copy of the information to be disclosed and an opportunity to limit such disclosure, an opportunity to comment thereon prior to such disclosure, and, to the extent practicable, consults within a reasonable time in advance of the proposed disclosure with the other Party on the necessity for the disclosure and the text of the proposed release.

12.2.3 Confidentiality Agreements. Both Parties shall ensure that each of their directors, officers and employees and the directors, officers and employees of its Affiliates, respectively, Sub-Contractors, and SUPPLIER's assignees, who will receive Confidential Information shall at all material times be bound by appropriate undertakings or company policy as to the confidentiality of such information which shall be no less stringent than those set out in this Section 12. DISTRIBUTOR and SUPPLIER, respectively, shall have the right, at their own expense to undertake the enforcement of any such obligations of confidentiality in the event of any breach thereof.

12.2.4 Ownership of other Party's Materials. All confidential information disclosed hereunder, including but not limited to, files, lists, records, documents, drawings, specifications and records provided by a Party (the "**Disclosing Party**"), whether in written or electronic form, which incorporate or refer to all or a portion of the Disclosing Party's Confidential Information shall remain the sole property of the Disclosing Party. Such materials shall be promptly returned (1) upon the Disclosing Party's reasonable request, or (2) in accordance with Section 18.3 of this Agreement upon termination of this Agreement, whichever is earlier; provided, however, that Receiving Party may retain one (1) copy of Confidential Information to the extent that retention of such Confidential Information is necessary to comply with Receiving Party's document retention policies for the purpose of complying with the terms of this Agreement, corporate governance, or regulatory compliance and any such retained Confidential Information shall remain subject to the confidentiality and use restrictions set forth herein, notwithstanding any termination of this Agreement. Recipient shall make no attempt to recover such Confidential Information from servers or back-up sources, which shall remain subject to the confidentiality and use restrictions set forth herein, notwithstanding any termination of this Agreement.

13 DATA PRIVACY

13.1 DISTRIBUTOR is a data controller for the processing of personal data under this Agreement. DISTRIBUTOR collects and processes name and contact details of SUPPLIER's personnel in connection with this Agreement. This information is necessary in order for DISTRIBUTOR to be able to administer the contractual relationship between the Parties. SUPPLIER is also a data controller for the processing of personal data under this Agreement. SUPPLIER collects and processes name and contact details of DISTRIBUTOR's personnel in connection with this Agreement. This information is

necessary in order for SUPPLIER to be able to administer the contractual relationship between the Parties. The Parties will work together in good faith to ensure the information referred to in applicable data protection legislation is made available to their respective personnel in relation to the processing by either Party when acting as a controller.

13.2 DISTRIBUTOR may transmit personal data of SUPPLIER (where applicable) and SUPPLIER may transmit personal data of DISTRIBUTOR (where applicable) to their respective Affiliates and their respective agents worldwide for the purpose of execution of this Agreement or in order to adhere to laws and regulations. Accordingly, if legally obliged, personal data may be transmitted to countries outside the European Economic Area, such as the United States, which the EU has determined currently lack appropriate privacy laws providing an adequate level of privacy protection. Nonetheless, the Parties and their respective Affiliates and agents will apply adequate privacy safeguards to protect such personal data. Personnel of SUPPLIER and DISTRIBUTOR ("**Data Subjects**") can contact SUPPLIER or DISTRIBUTOR to exercise any rights of access, correction or deletion regarding their data. If a Data Subject makes a written request to a Party to exercise their rights that concerns processing in respect of which the other Party is the data controller, that other Party shall provide reasonable co-operation and assistance in relation to that request to enable the Party to respond to such request and meet applicable timescales set out under applicable data protection legislation.

13.3 Additionally, if a Data Subject has any issues with DISTRIBUTOR's or SUPPLIER's processing of personal data, it has the right to lodge a complaint with the applicable supervisory authority. If either Party receives any complaint, notice or communication from a supervisory authority which relates directly or indirectly to the other Party's: (i) processing of personal data under this Agreement; or (ii) a potential failure to comply with applicable data protection legislation, the Party receiving the complaint, notice or communication shall, to the extent permitted by law, promptly forward the complaint, notice or communication to the other Party and provide the other Party with reasonable co-operation and assistance in relation to the same.

13.4 In addition to the rights outlined above, to the extent applicable data protection legislation provides, Data Subjects have a right to object to certain processing of personal data, a right to request restriction of the processing of personal data, and a right to data portability. The right to data portability covers such personal data that SUPPLIER processes either based on the Agreement as such or based on consent.

13.5 If a Data Subject wishes to exercise any of the rights above or has any questions regarding SUPPLIER's processing of personal data under this Section, the Data Subject can contact SUPPLIER by sending a letter to the SUPPLIER's address stated in the preamble of this Agreement or by sending an e-mail to: [***] and can contact DISTRIBUTOR by sending a letter to DISTRIBUTOR's address stated in the preamble

of this Agreement or by sending an e-mail to: [***]. Further information on how DISTRIBUTOR processes personal data is found at www.valneva.com.

13.6 If either Party becomes aware of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data processed under this Agreement, it shall notify the other Party without undue delay, and each Party shall co-operate with the other, to the extent reasonably requested, in relation to any notifications to supervisory authorities or to Data Subjects which either Party is required to make under applicable data protection legislation.

14 REPRESENTATIONS AND WARRANTIES

14.1 SUPPLIER Representations and Warranties. SUPPLIER represents, and warrants, as of the Effective Date, the following:

(1) SUPPLIER is not in any material breach of any agreement with third parties relating to the Product or the Intellectual Property Rights which would or might prejudice the rights of DISTRIBUTOR in the Territory (the "**Third Party Agreements**");

(2) there are no actions, suits or claims pending against SUPPLIER with respect to the Product or the Intellectual Property Rights in the Territory;

(3) the sale and use of the Product in accordance as outlined in this Agreement, in the Territory does not infringe the proprietary rights of any third party in the Territory; and

(4) it has disclosed appropriately and has not misrepresented, to DISTRIBUTOR, any material matters relating to the Intellectual Property Rights, marketing, adverse events, supply, clinical and regulatory information pertaining to the Product in the Territory.

14.2 DISTRIBUTOR'S Representations and Warranties. DISTRIBUTOR represents, and warrants, as of the Effective Date, the following:

(1) DISTRIBUTOR has disclosed appropriately and has not misrepresented, to SUPPLIER any material matters relating to DISTRIBUTOR's promotion, marketing and distribution capabilities in the Territory, and

(2) DISTRIBUTOR and/or its Sub-Contractors holds all licenses, permits, certificates, applications or other documentation (including but not limited to a wholesale license) as required by DISTRIBUTOR and Applicable Law to perform its obligations under this Agreement.

(3) DISTRIBUTOR and/or its Sub-Contractors has sufficient and adequate staff of trained and qualified personnel to perform their respective obligations under this Agreement.

14.3 DISCLAIMERS. TO THE FULL EXTENT PERMITTED BY LAW, APART FROM THE WARRANTIES STATED IN THIS AGREEMENT AND INDEMNITIES

BELOW, NEITHER PARTY MAKES ANY ADDITIONAL REPRESENTATIONS OR WARRANTIES AND HEREBY DISCLAIMS ALL WARRANTIES, REPRESENTATIONS, AND LIABILITIES, WHETHER EXPRESS OR IMPLIED, ARISING FROM CONTRACT OR TORT (EXCEPT FRAUD), IMPOSED BY STATUTE OR OTHERWISE, RELATING TO THE PRODUCTS AND/OR ANY PATENTS OR TECHNOLOGY USED OR INCLUDED IN THE PRODUCTS, INCLUDING ANY WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR PURPOSE, CORRESPONDENCE WITH DESCRIPTION, OR NON-INFRINGEMENT.

15 INDEMNITIES AND LIMITATIONS OF LIABILITY

15.1 SUPPLIER's Indemnity

15.1.1 SUPPLIER's Indemnity. SUPPLIER shall defend, indemnify and hold DISTRIBUTOR, its Sub-Contractors, managers, officers, directors, agents and employees (the "**DISTRIBUTOR Indemnitees**") harmless on an after-Tax basis against any and all third party losses, damages, claims, liabilities, Taxes (excluding recoverable Sales Tax), costs and expenses including reasonable attorneys' fees ("**Claim**") resulting from the following:

(1) the personal injury to or death of any person or any property damage caused by the defective design and/or manufacture of the Product or inadequate warnings or instructions, or the failure of any Product to meet its Product specification;

(2) SUPPLIER's negligent or wilful misconduct of transportation, storage, use and handling relating to the Products;

(3) any material breach by SUPPLIER of any of SUPPLIER's representations and warranties set forth in this Agreement; or

(4) any act of omission by SUPPLIER which would constitute a violation of ANNEX H (Anti-Corruption Laws) and Applicable Law.

15.1.2 Limitation of SUPPLIER's Indemnification.

SUPPLIER's indemnification under this Section 15.1 shall not apply to any Claim to the extent that it is directly and/or indirectly related to the negligent activities, reckless misconduct or intentional misconduct attributable to DISTRIBUTOR its Sub-Contractors or its employees, directors or officers.

15.2 DISTRIBUTOR's Indemnity

15.2.1 DISTRIBUTOR's Indemnity. DISTRIBUTOR shall indemnify and hold SUPPLIER and its managers, officers, directors, agents and employees (the "**SUPPLIER Indemnitees**") harmless on an after-Tax basis against any and all losses, damages, claims, liabilities, Taxes (excluding recoverable Sales Tax), costs and expenses including reasonable attorneys' fees ("**SUPPLIER's Claim**) resulting from the following:

(1) the personal injury to or death of any person or any property damage caused by DISTRIBUTORs and/or any of its Sub-Contractors' transportation, storage, use, promotion, marketing, sales, distribution and handling of the Product;

(3) any act or omission by DISTRIBUTOR or its Sub-Contractor(s) which would constitute a violation of ANNEX H (Anti-Corruption Laws) and Applicable Law; or

(4) any material breach by DISTRIBUTOR of any of DISTRIBUTOR's representations and warranties set forth in this Agreement.

15.2.2 Limitation of DISTRIBUTOR's Indemnification.

DISTRIBUTOR's indemnification under this Section 15.2 shall not apply to any SUPPLIER's Claim to the extent that it is directly and/or indirectly related to the negligent activities, reckless misconduct or intentional misconduct attributable to SUPPLIER or its employees, directors or officers.

15.3 Indirect damages and Limitation of Liability. EXCEPT FOR OBLIGATIONS TO MAKE PAYMENT UNDER THIS AGREEMENT, EACH PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTION 15, LIABILITY FOR BREACH OF CONFIDENTIALITY, LIABILITY FOR INFRINGEMENT OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY RIGHTS, NEITHER PARTY NOR ITS REPRESENTATIVES IS LIABLE TO THE OTHER PARTY FOR CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR ENHANCED DAMAGES, LOST PROFITS OR REVENUES OR DIMINUTION IN VALUE, ARISING OUT OF OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF (A) WHETHER SUCH DAMAGES WERE FORESEEABLE, (B) WHETHER OR NOT IT WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND (C) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT, OR OTHERWISE) UPON WHICH THE CLAIM IS BASED, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

15.4 Indemnification Procedure

15.4.1 Notification. Each Party shall promptly notify the other in writing of any claim, action or suit potentially giving rise to an indemnification obligation hereunder of the other Party hereunder. If indemnification is sought as a result of any third-party claim or suit, such notice to the indemnifying party shall be made within [***] Business Days after receipt by the indemnified Party of notice of such claim or suit; provided however that the failure to give notice within such time period shall not relieve the indemnifying party of its obligation to indemnify unless it shall be materially prejudiced by such failure.

15.4.2 Procedure. The indemnifying Party shall have the sole and absolute control of, and discretion in, the handling of the defense and/or settlement of any third-party claim, action or suit, including, without limitation, the selection of defense counsel, provided that the indemnified party shall have the right to participate, at its own expense, with

counsel of its own choosing, in such defence. The indemnified Party shall fully cooperate with the indemnifying Party in the defense and settlement of all such claims, actions or suits, subject to reimbursement of the indemnified Party's reasonable costs and expenses. The indemnified Party shall take reasonable steps to mitigate any loss suffered by the indemnified Party. The indemnifying Party shall make no offer of settlement, settlement or compromise without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld, conditioned or delayed) unless such settlement fully releases the indemnified Party without any liability, loss, cost or obligation

16 GOOD ETHICAL BUSINESS PRACTICES AND ANTI-CORRUPTION LAWS

16.1 Good Ethical Business Practice. Each Party shall in connection with its activities under this Agreement or otherwise relating to Product:

(i) not disparage the name, good will, or reputation of the other Party;

(ii) not engage in deceptive, misleading, or unethical practices;

(iii) not make any false or misleading representations or other statements with regard to the other Party or Product;

(iv) represent only such facts about Product as are in accordance with the Market Authorization, the Summary of Product Characteristics or, in case of DISTRIBUTOR, as otherwise expressly approved by Supplier in writing, and

(v) in no event make any representations, warranties, guarantees or other statements in the other Party's name or on the other Party's behalf, except as approved in advance in writing by the other Party.

16.2 Anti-Corruption Laws. DISTRIBUTOR understands and shall comply with Anti-Corruption Laws and in accordance with ANNEX H attached to this Agreement.

16.3 Human Rights. Each Party represents that, with respect to its respective obligations under this Agreement, it will:

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if applicable); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage, where applicable, and provide any legally mandated benefits;
(g) comply with laws on working hours and employment rights;
(h) respect employees' right to join and form independent trade unions;
(i) encourage subcontractors under this Agreement to comply with these standards; and
(j) maintain a complaints process to address any breach of these standards.

16.4 Non-Compliance. A Party's failure to abide by the provisions of Sections 16.1, 16.2 and/or 16.3 shall be deemed a material breach of this Agreement, allowing the other Party to immediately terminate this Agreement at its sole discretion without any notice to the defaulting Party.

17 TERM AND TERMINATION

17.1 Term and Extensions. The Term of this Agreement shall commence on the Effective Date and shall continue until 31 December 2025 ("**Initial Term**"). Not later than by [***], either Party shall notify the other in writing if it wishes to prolong this Agreement for an additional two (2) year period until 31 December 2027 ("**Extended Term**"). Such prolongation shall be mutually agreed between the Parties in writing. This Agreement may subsequently be renewed for additional periods following the Extended Term if mutually agreed between the Parties in writing.

17.2 Termination Events. This Agreement may forthwith be terminated by either Party, at its sole discretion: (1) in its entirety; or (2) in respect of any specified part of the Territory only, by giving written notice of termination in the event that:

(1) the other Party breaches any of its material obligations under this Agreement, and fails to cure such breach within [***] calendar days of receiving a written notice specifying such breach and requiring it to be cured; provided that such termination shall not be effective where such breach is capable of cure within such [***] calendar days period and where DISTRIBUTOR has commenced good faith and Reasonable Commercial Efforts to cure such breach within such [***] calendar days period and cures such breach within [***] calendar days after the receipt of notice of material breach;

(2) the other Party is in breach of its material obligations under this Agreement which is not capable of being cured;

(3) the other Party enters into insolvency or bankruptcy or is unable to pay its debts as they fall due, or a trustee or receiver or the equivalent is appointed to the other Party, or proceedings are instituted against the other Party relating to dissolution, liquidation, winding up (other than on a reconstruction), bankruptcy, insolvency or the relief of creditors, if such proceedings are not terminated or discharged within [***] calendar days;

(4) with [***] months' written notice in the event of a Change of Control of the other Party;

(5) immediately in case of withdrawal of the Marketing Authorization in the Territory;

(6) immediately in case other Party is in breach of any provision of ANNEX H of this Agreement; or

(7) as otherwise specifically provided for in this Agreement.

17.3 Termination by SUPPLIER.

17.3.1 This Agreement may forthwith immediately be terminated by SUPPLIER, at its sole discretion, by giving written notice of termination, in the event that:

(1) DISTRIBUTOR ceases to carry on business in the marketing of pharmaceutical products in the Territory; and

(2) DISTRIBUTOR fails to achieve the Minimum Annual Purchase quantities as provided for in Section 6.1 above.

18 EFFECTS OF TERMINATION OR EXPIRATION

18.1 Cessation of Rights. Upon expiration or termination of this Agreement (collectively "**Termination**") for any reason whatsoever as provided herein, all rights and obligations of the Parties hereunder shall cease, except as provided in Section 18.2 of this Agreement; provided, however, that Termination of this Agreement shall not relieve the Parties hereto of any obligations accrued prior to said Termination.

18.2 Survival of Terms. Termination of this Agreement shall not release either Party from any liabilities or obligations set forth in this Agreement which (i) the Parties have expressly agreed shall survive any such Termination, or (ii) remain to be performed or by their nature would be intended to be applicable following any such Termination.

18.3 Return of Confidential Information. Upon Termination, each Party shall and shall cause its agents, employees, consultants or representatives and Sub-Contractors, if any, to promptly return to the other Party or, as requested by the other Party, destroy, or deliver to a third party designated by that other Party, all of the other Party's Confidential Information in written, recorded or other tangible form.

18.4 Trademarks. Upon Termination of this Agreement, DISTRIBUTOR shall itself, and shall procure that its Sub-Contractors, if any, cease promoting, marketing and advertising the Products and neither DISTRIBUTOR nor any Sub-Contractor, shall use or permit the use of any Product Intellectual Property Rights, Trademarks and trade names of SUPPLIER or similar trademarks, denominations, label designs or package presentations. If DISTRIBUTOR acquires any right, title or interest in or to or relating to the Product Intellectual Property Rights, Trademarks for any reason, effective immediately upon the expiration or termination of this Agreement, DISTRIBUTOR hereby assigns, at no cost, all such right, title and interest, together with any related goodwill or reputation, to

SUPPLIER. DISTRIBUTOR agrees to promptly execute all documents reasonably requested by SUPPLIER in connection with such assignment.

18.5 Orders upon Termination. DISTRIBUTOR shall be entitled to purchase under the terms and conditions of this Agreement, any Product ordered for which the orders were accepted by SUPPLIER prior to the effective date of Termination, even though shipment of the Product may be made subsequent to the date of Termination.

18.6 Repurchase of Inventory. Upon receipt of notice of Termination or expiry of this Agreement for any reason, DISTRIBUTOR shall as soon as possible and in any event within [***] Business Days of the date of Termination, prepare and submit to SUPPLIER an inventory of its remaining stock of Products. SUPPLIER shall have the option, exercisable at its sole discretion by written notice to DISTRIBUTOR within [***] calendar days after Termination, but subject to DISTRIBUTOR's non-cancelable contractual obligations existing as of the Termination, to repurchase all or part of DISTRIBUTOR's remaining inventory of Product. The price payable by SUPPLIER upon the exercise of the option shall be the net price paid by DISTRIBUTOR to SUPPLIER for the Product. Upon receipt of SUPPLIER's notice of exercise of its option pursuant to this Section 18.6, DISTRIBUTOR shall ship its inventory of Product on hand to such location as SUPPLIER may designate at SUPPLIER'S own cost. If SUPPLIER does not exercise its rights under this Section 18.6, DISTRIBUTOR shall have the right to sell its existing inventory for a period of [***] months following the date of Termination. Thereafter, DISTRIBUTOR shall no more be allowed to sell the Product, and stock still held by DISTRIBUTOR will have to be destroyed or otherwise disposed of. Following the repurchase of the stock by SUPPLIER, sale by DISTRIBUTOR or destruction of the Products by DISTRIBUTOR, accounts receivables between the Parties will be netted out and the balance shall be settled within the payment terms specified in ANNEX C.

18.7 No Compensation. No indemnity whatsoever shall be due by reason of expiration or ordinary termination of this Agreement by either Party to the other. Neither Party shall be entitled to compensation, reimbursement, or damage on account of the loss of prospective profits on anticipated sales or on account of marketing investments in connection with the business or goodwill of SUPPLIER or DISTRIBUTOR.

19 GENERAL PROVISIONS

19.1 Precedence. In the event of any conflict between the terms of this Agreement and any agreement, purchase order, terms and conditions, invoice terms, the Quality Agreement and the Pharmacovigilance Agreement the terms of this Agreement shall prevail, save that (i) with respect to terms relating to quality assurance, the terms of the Quality Agreement shall prevail over this Agreement, and (ii) with respect to terms relating to medical and safety related information and pharmacovigilance, the terms of the Pharmacovigilance Agreement shall prevail over this Agreement.

19.2 Independent Contractors. The relationship of SUPPLIER and DISTRIBUTOR established by this Agreement is of seller and buyer, or independent contractors, and nothing in this Agreement shall be construed:

(1) to give either Party the power to direct or control the daily activities of the other Party, or

(2) to constitute the Parties as principal and agent, partners, or otherwise as participants in a joint undertaking, or to provide a Party with the power or authority to make or give any representation or warranty or to incur any liability or obligation, or to waive any right, on the other Party's behalf, except as may be specifically provided for herein. SUPPLIER shall have no obligation or authority, express or implied, to exercise any control whatsoever over the employees or the business affairs of DISTRIBUTOR.

19.3 Insurance. Both Parties shall obtain and at all times during the term of this Agreement maintain, and bear the cost of, adequate and appropriate insurance including comprehensive general liability insurance which is adequate to cover their respective activities under this Agreement and as required by Applicable Laws and which shall have a minimum limit of at least [***] per claim or series of claims. A certificate of insurance and any other documentation necessary to prove compliance with this provision will be provided to the other Party upon request. Each Party shall notify the other not less than [***] calendar days prior to the termination or reduction of such coverage.

19.4 Assignments. This Agreement is entered into by SUPPLIER in reliance upon the facilities, personnel and technical expertise of DISTRIBUTOR, and DISTRIBUTOR may only transfer or delegate the performance of the Agreement or any part thereof to a Sub-Contractor pursuant to the terms and conditions of Section 2.2. In all other cases, DISTRIBUTOR may not assign this Agreement or its respective rights, duties and obligations thereunder to any third party or parties without having previously secured the written consent of the SUPPLIER, and any assignment or transfer in violation of this Section shall, at the option of SUPPLIER, be null and void and shall have no force or effect. SUPPLIER may assign or transfer this Agreement, or any of its rights or obligations under this Agreement, in whole or in part, without DISTRIBUTOR's consent (i) to an Affiliate, (ii) in connection with the transfer or sale of all or substantially all of the assets and/or business to which the Agreement pertains, or (iii) in connection with its merger or consolidation with another company.

19.5 Waivers. The waiver by either Party of a breach or default in any of the provisions of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver.

19.6 Entire Agreement and Amendments. This Agreement (including the attachments hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements between the Parties, whether written or oral, relating to the same subject matter. No modification, amendments or supplements to this Agreement shall be effective for any purpose unless in writing, signed by each Party.

19.7 Contract Formation. This document is not an offer unless signed by a Party and shall not constitute or reflect a legally binding contract unless signed by both Parties. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which taken together shall be deemed to constitute one and the same instrument. Counterparts may be executed either in original, by electronic signatures by use of ValidSign or an equivalent system using advanced electronic signatures form and the Parties shall adopt any signatures received by email as original signatures of the Parties.

19.8 Annexes. The following documents are understood to be an integral part of this Agreement:

Description of Product ANNEX A
Description of Territory and Trademarks ANNEX B
Price Schedule; Payment Terms; Forecasts and Orders ANNEX C
Minimum Purchase and Sales Quantities ANNEX D
[Intentionally left blank ANNEX E]
Wholesale License ANNEX F
[Intentionally left blank ANNEX G]
Compliance with anti-corruption laws ANNEX H
Sub-Contractors and Start Date(s) ANNEX I
Contact Address List ANNEX J
Reporting Format ANNEX K

19.9 Language. All written correspondence between the Parties shall be in the English language.

19.10 Further Assurances. Each Party agrees to do such acts and execute such further documents as may be reasonably necessary or desirable to enable the performance of and to fulfill the provisions and intent of this Agreement.

19.11 Force Majeure. Neither Party shall be liable to the other Party for any delay or omission in the performance of any obligation under this Agreement, other than the obligation to pay monies, to the extent not affected by the Force Majeure event, where the delay or omission is due to any cause or condition beyond the reasonable control of the Party obliged to perform, including but not limited to acts of God, acts of government (in particular with respect to the refusal to issue necessary import or export licenses), inability of SUPPLIER to obtain sufficient raw materials, fire, flood, earthquake, war, riots, outbreaks, epidemics, pandemics (including any governmental mandated lockdown) or embargoes, but excluding the COVID-19 pandemic, strikes or other labor difficulties

affecting SUPPLIER ("**Force Majeure**"). The Party affected ("**Affected Party**") shall promptly notify the other Party of the condition constituting Force Majeure and shall exert Reasonable Commercial Efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. Notice of the commencement and termination of such Force Majeure will be provided by the Affected Party to the other Party. Any obligations of the Affected Party will be extended for a period of time equal to the number of days of the delay, provided however, that in the event that such party is unable to overcome such Force Majeure Event within [***] months, the other Party may terminate this agreement on written notice.

19.12 Notices. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and in English, effective upon receipt, and may be delivered personally, or may be sent by registered letter or e-mail, addressed as defined in ANNEX J.

In addition, the Parties shall notify each other of the names of the respective contacts in the important areas, including sales, shipping, marketing, pharmacovigilance, and regulatory. For the avoidance of doubt, all information and/or notices pursuant this Agreement, such as but not limited to, restricted and highly restricted (business and personal) information, shall be exchanged and/or sent by one Party to the other Party via secure channels, such as but not limited to encrypted e-mails.

19.13 Severability. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

19.14 No Third Party Rights. A Person that is not a party to this Agreement may not enforce any of the terms of this Agreement. Where any clause of this Agreement anyhow entitles any Person to enforce any term of the Agreement, the Parties reserves the right to vary that term or any other term of this Agreement without the consent of that Person.

19.15 Authorized Signatories. The persons signing below certify that they have all required authority to execute this Agreement on behalf of the entity they are acting for.

20 CHOICE OF LAW AND DISPUTE RESOLUTION

20.1 Choice of Law. Notwithstanding its place of performance or execution, this Agreement is governed by, and shall be construed in accordance with, the laws of Austria without regard to its conflict of laws rules. It is understood that the application of the United Nations Convention on Contracts for the International Sales of Goods (CISG, Vienna 1980) shall be excluded.

20.2 Disputes. The Parties shall endeavour to resolve amicably any and all disputes arising under or in connection with this Agreement, including but not limited to the interpretation of this Agreement, its validity and the performance hereunder. In the event the Parties are unable to resolve any dispute, the Parties agree that any controversy or claim arising out of or relating to this Agreement, including the formation, interpretation, breach or termination thereof, including whether the claims asserted are arbitrable, will be referred to and finally determined by arbitration in accordance with the Arbitration Rules of the International Chamber of Commerce ("ICC"). The ICC tribunal will consist of a sole arbitrator. The seat of the arbitration will be Vienna, Austria. The language to be used in the arbitral proceedings will be English. Judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof.

The Parties shall maintain the confidential nature of the arbitration proceeding and the award, including the privacy of the hearing, except as may be necessary to prepare for or conduct the arbitration hearing on the merits, or except as may be necessary in connection with a court application for a preliminary remedy, a judicial challenge to an award or its enforcement, or unless otherwise required by law or judicial decision.

In any arbitration arising out of or related to this Agreement, the arbitrator(s) shall award to the prevailing Party, if any, the reasonable costs for legal representation incurred by the prevailing party in connection with the arbitration. If the arbitrator(s) determine a Party to be the prevailing party under the circumstances where the prevailing party won on some but not all of its claims and counterclaims, the arbitrator(s) may award the prevailing party an appropriate percentage of the reasonable costs for legal representation incurred by the prevailing party in connection with the arbitration.

_____

(Signature page follows)

IN WITNESS WHEREOF, each Party has caused its duly authorized representative to execute and deliver this Agreement in reliance on the due authority of the representative of the other Party, to be effective as of the date written on the first page above.

VBI Vaccines B.V. Valneva Austria GmbH

Date: Date:

By: By:
Name: Name:
Title: Title:

Valneva Austria GmbH

Date:

By:
Name:
Title:

ANNEX A **Description of Product and Handling Requirements**

PreHevbri™ [Hepatitis B vaccine (recombinant, adsorbed)]

[***]

Handling Requirements
Transport and storage at +2 to +8 degrees Celsius.

ANNEX B **Description of Territory and Trademark**

Territory
Sweden, Norway, Denmark and Finland [***]

United Kingdom [***]

Belgium and the Netherlands [***]

Optional: Austria, France (incl. DOM-TOM) and Canada

Trademark
Registration No.

European Community Registration No. [***]

United Kingdom Registration No. [***]

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 one (1) package consisting of 10x1 (1,0ml) dose of Product.

Table 1:

Country	Product name	Price in %/dose	Minimum Order Quantity (per shipment)/doses
[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

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 [***] Business Days 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.

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 [***] calendar days 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 [***] months rolling monthly forecast to be submitted not later than the [***] Business Day of each calendar month covering the next [***] calendar months ("**Forecast**"). The first [***] calendar months 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 [***] per cent [***] or less (*i.e.* the quantities for such months in the Forecast may be varied by [***] per cent [***] or less). If DISTRIBUTOR requests for valid business, and in good faith, to alter the Forecast for such months by more than [***] per cent [***], SUPPLIER will use its Reasonable Commercial Efforts to satisfy such request.

In respect of the [***] through to the [***] calendar months of each Forecast DISTRIBUTOR may decrease or increase the quantities set forth during such period by [***] per cent [***] (i.e. the quantities for such months in the Forecast may be varied by [***] per cent [***] or less). If DISTRIBUTOR requests for valid business reasons, and in good faith, to alter the Forecast for such months by more than [***] per cent [***], 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 [***] calendar months.

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.

ANNEX E **QUALITY AGREEMENT**

The Parties to this Distribution Agreement agree that the Quality Agreement

between

VBI Vaccines B.V.

And

Valneva Austria GmbH, Valneva UK Ltd., Valneva Sweden AB and Valneva France SAS

shall be incorporated herein by reference hereto and shall apply to the present Distribution Agreement accordingly.

ANNEX F **Wholesale License(s)**

ANNEX G **Pharmacovigilance Agreement**

The Parties to this Distribution Agreement agree that the Pharmacovigilance Agreement

between

VBI Vaccines B.V.

And

Valneva Austria GmbH

Is incorporated herein by reference hereto and shall apply to the present Distribution Agreement accordingly.

ANNEX H **Compliance with Anti-Corruption Laws**

Notwithstanding anything to the contrary in the Agreement, SUPPLIER and DISTRIBUTOR hereby agree on the following provisions:

Section 1 - Compliance with Applicable Law

In exercising its rights and performing its obligations under this Agreement, DISTRIBUTOR will:
DISTRIBUTOR shall, and shall cause its employees, external workforce, agents, consultants, Sub-Contractors and Designated Wholesalers to, comply with any and all Anti-Corruption Laws in all respects.

Notwithstanding anything to the contrary in this Agreement, DISTRIBUTOR hereby agrees that DISTRIBUTOR shall not, and shall cause its employees, external workforce, agents, consultants, Sub-Contractors and Designated Wholesalers not to, take any actions (i) that are prohibited by Anti-Corruption Laws, and/or (ii) which would make SUPPLIER liable for a violation of Anti-Corruption Laws.

DISTRIBUTOR notably represents and warrants that:

(a) it will not, directly or indirectly, make or authorize or promise an offer, payment or gift, of anything of value, to any government employee, any official (including but not limited to any governmental or regulatory official), any political party or official thereof, or any candidate for political office, or any other third party that may have any influence in relation to the activities contemplated under this Agreement, that would violate Anti-Corruption Laws,

(b) it will not engage in any activity that would expose SUPPLIER or any of its Affiliates to a risk of penalties or of violations under laws or regulations of any relevant jurisdiction that prohibit improper payments, including but not limited to bribes, to officials of any government of any agency, instrumentality or political subdivision thereof, to political parties or political party officials or candidates for public office, or to any employee of any customer or supplier.

Section 2 - Procedures/Code of Business Conduct

During the term of this Agreement, the DISTRIBUTOR shall have in place, maintain and follow a code of business conduct/reasonable procedures designed to prevent, detect and manage possible violations of Anti-Corruption Laws.

Section 3 - No Government Official Employees

DISTRIBUTOR shall inform SUPPLIER if any employee of DISTRIBUTOR performing any activities under this Agreement is a governmental official or government employee. DISTRIBUTOR shall, furthermore, advise SUPPLIER in writing in the event that DISTRIBUTOR becomes aware that any person engaged in the performance of the Agreement becomes a governmental employee, a political party official or a candidate for political office.

Section 4 - No Anti-Corruption Law Offences

DISTRIBUTOR represents and warrants that, as of the Effective Date:

(a) it has not been convicted of, pleaded guilty to or charged with any offence involving fraud, corruption or bribery, or breach of any Anti-Corruption Laws in any jurisdiction or country,

(b) it is not subject to or threatened by any actions, suits or proceedings for any alleged violation of any Ant-Corruption Laws.

Section 5 - Immediate Disclosure by Distributor

DISTRIBUTOR agrees to immediately inform SUPPLIER of the occurrence of any possible violation by DISTRIBUTOR and/or its Sub-Contractors of any Anti-Corruption Laws have taken place.

Section 6 - Right to Disclose

DISTRIBUTOR agrees that full disclosure of information relating to a possible violation by DISTRIBUTOR and/or its Sub-Contractors of Applicable Laws, including a violation of the Anti-Corruption Laws, may be made by SUPPLIER at any time and for any reason to any Governmental Authority or competent institution or court.

Section 7 - Training

DISTRIBUTOR hereby represents and warrants that (i) all persons employed by DISTRIBUTOR who perform work under this Agreement and interact with government officials or health care professionals in the normal course of their responsibilities, and (ii) any other Sub-Contractors or Designated Wholesalers it uses in the conduct of activities in connection with this Agreement, are appropriately trained on Anti-Corruption Laws as well as applicable rules on interactions with health care professionals on a regular basis and at least once per year. For this purpose, DISTRIBUTOR has requested SUPPLIER to provide DISTRIBUTOR with its online training available on https://www.valneva.com

Section 8 - Certification & Audit Rights

DISTRIBUTOR shall certify on an annual basis that:

(a) appropriate training and training materials on Anti-Corruption Laws, incuding including SUPPLIER's online trainings available at https://www.valneva.com, as well as applicable rules on interactions with health care professionals, have been provided to all persons employed by DISTRIBUTOR who perform work under this Agreement and interact with government officials or health care professionals in the normal course of their responsibilities, and to any other Related Persons used by DISTRIBUTOR in the conduct of activities in connection with the Agreement; and

(b) to the best of DISTRIBUTOR's knowledge, there have been no violations of Anti-Corruption Laws by DISTRIBUTOR or its Sub-Contractors and Designated Wholesalers in the performance of the Agreement; and

(c) DISTRIBUTOR has maintained true and accurate records necessary to demonstrate compliance with the requirements of this ANNEX H.

DISTRIBUTOR shall maintain and provide SUPPLIER and its auditors and other representatives with access to records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement as may be requested by SUPPLIER in order to document or verify compliance with the provisions of this ANNEX H.

Section 9 - Distributor's Failure To Comply With Obligations Under This ANNEX H

In addition to the indemnification obligations set forth in Section 14.2, if DISTRIBUTOR fails to comply with any of the provisions of this ANNEX H, SUPPLIER shall have the right to terminate the Agreement in accordance with Section 17.3, without SUPPLIER incurring any financial liability or other liability of any nature resulting from any such termination.

Furthermore, if DISTRIBUTOR is found to have made any improper payment or otherwise violated the provisions of this ANNEX H, then, in addition to other rights and remedies available to SUPPLIER under this Agreement and Applicable Laws, SUPPLIER will have the right to recover from DISTRIBUTOR or withhold from payment due to DISTRIBUTOR under this Agreement or any other agreement between SUPPLIER and DISTRIBUTOR or its Affiliates:

(a) the amount or value of the improper payment; and

(b) any fines, expenses or attorneys' fees incurred in connection with the improper payment or violation of this ANNEX H.

ANNEX I **List of Affiliates, Sub-Contractors, Designated Wholesalers and Start Date(s)**

As of the Effective Date, Affiliates and Sub-Contractors and Designated Wholesalers of DISTRIBUTOR are:

[***]

ANNEX J **List of Contact Address and Means of Communication**

[***]

ANNEX K **Reporting Format (Section 10.2 of the Agreement)**

Market Development Report

A. Update on Development and Marketing of Product in the respective Territory (incl. description on promotional activities performed)

B. Quantitative Product Information

- Brand
- Country
- Company Name & Address
- Batch
- Sales in doses/returns
- Turnover
- ASP in the reporting period and year-to-date

In the format requested by SUPPLIER. As way of example:

Market Development Report								**Month/Year**	
							Units		Value
Brand	Name	Street	ZIP	City	Batch nr	Exp. date	Sales	Returns	Sales
PreHevbri™	Customer 1	Street 1	11000	City1					

VALNEVA SE

Terms and conditions of the 2022 Employee Stock Option Plan

1. Preliminary statement

1.1 The 2022 Employee Stock Option Plan governed by these Terms and Conditions (the "**2022 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.

"**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 or paternity 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 2022 ESOP and be Beneficiary Employees only if they also met the above-mentioned conditions on September 2, 2022 and have been continuously employed by the Group between September 2, 2022 and the working day immediately preceding the Grant Date.

"Beneficiary Employee(s)" shall however 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 or mutual termination agreement), without continuous Group employment in another Group entity, or (ii) is on educational leave, or (iii) is in the legal situation of external workforce (*e.g.* as consultant, intern or trainee).

1.2 The Company voluntary grants stock options by way of this 2022 ESOP. Such grant shall not give rise to a legal right for the Beneficiary Employees to participate in a subsequent or similar plan. The 2022 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 2022 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 the Management Board of Valneva. 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. 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 The exercise of Options shall be deemed in time insofar as the form referred to in Section 3.7 above is received by the Plan Manager at the earliest on the first day of the relevant Exercise Period, and no later than 5 p.m., Paris time, on the last day of such Time Frame. 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 2022 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 Euronext Paris 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 Euronext Paris 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 Company (via 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 2022 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.

Delivery of Shares

3.13 Provided that all applicable fees, taxes and duties have been paid, the Beneficiary Employee shall receive his/her Shares within (20) twenty trading days following the end of the relevant Exercise Period.

4. Validity period of Options - Lapse

4.1 The Options may be exercised within a period ending on the tenth (10^{th}) 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 continuous 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 2022 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 2022 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 2022 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, pursuant to Section 3.13 above, pay the corresponding amount to that entity before the Shares are transferred to a securities account designated for this purpose and held by a licensed bank.

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 2022 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 2022 ESOP at any time, subject to applicable laws and regulations.

VALNEVA SE

VALNEVA SE

Terms and conditions of the 2022 Senior Leadership Group Stock Option Plan

1. Preliminary statement

1.1 The 2022 Senior Leadership Group Stock Option Plan governed by these Terms and Conditions (the "**2022 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 2022 SLG SOP is combined with a free share plan so that such employees and officers benefit from both stock options and free ordinary shares.

"**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 or paternity 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 2022 SLG SOP and be Beneficiary Employees only if they also met the above-mentioned conditions on September 2, 2022 and have been continuously employed by the Group between September 2, 2022 and the working day immediately preceding the Grant Date.

"Beneficiary Employee(s)" shall however 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 or mutual termination agreement), without continuous Group employment in another Group entity, or (ii) is on educational leave, or (iii) is in the legal situation of external workforce (*e.g.* as consultant, intern or trainee).

1.2 The Company voluntary grants stock options by way of this 2022 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 2022 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 2022 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 the Management Board of Valneva. 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. Employees and officers 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 The exercise of Options shall be deemed in time insofar as the form referred to in Section 3.7 above is received by the Plan Manager at the earliest on the first day of the relevant Exercise Period, and no later than 5 p.m., Paris time, on the last day of such Time Frame. 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 2022 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 Euronext Paris 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 Euronext Paris 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 Company (via 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 2022 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.

Delivery of Shares

3.13 Provided that all applicable fees, taxes and duties have been paid, the Beneficiary Employee shall receive his/her Shares within (20) twenty trading days following the end of the relevant Exercise Period.

4. Validity period of Options - Lapse

4.1 The Options may be exercised within a period ending on the tenth (10^{th}) 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 continuous Group employment in 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 2022 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 2022 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, pursuant to Section 3.13 above, pay the corresponding amount to that entity before the Shares are transferred to a securities account designated for this purpose and held by a licensed bank.

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 2022 SLG SOP 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 2022 SLG SOP at any time, subject to applicable laws and regulations.

VALNEVA SE

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) 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. 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
   c. 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 30, 2023

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) 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. 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
    c. 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 30, 2023

By: /s/ Peter Bühler

Peter Bühler

Chief Financial Officer

EXHIBIT 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

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, 2022, 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.*

EXHIBIT 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

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, 2022, 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 30, 2023, 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, 2022.

/s/ Deloitte & Associés

Bordeaux, France

March 30, 2023

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 30, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers Audit

Neuilly-sur-Seine, France
March 30, 2023