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, 2021

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: 105,190,223 outstanding as of December 31, 2021**

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

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

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

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

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

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

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

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

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

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

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

If “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

CONTENTS

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;
- 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 and, with respect to VLA2001, the potential for this vaccine candidate to complement other COVID-19 vaccines or to be used as a booster;
- our ability to successfully develop and advance our pipeline of product candidates;
- our expectations and forecasts for sales of our approved products;
- the present and future effects of the COVID-19 pandemic 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, particularly with respect to our development of a COVID-19 vaccine;
- our ability to meet our obligations under our various collaboration, partnership and distribution arrangements;

- the potential impacts to us of the termination of the UK Supply Agreement, including impacts to our financial position;
- the timing or likelihood of regulatory filings and approvals, including the potential eligibility to receive a Priority Review Voucher for VLA1553;
- 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 propriety 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 will continue to incur significant operational losses over the next several years and may never achieve or maintain profitability.
- DUKORAL and IXIARO are aimed at diseases that largely threaten travelers. If international travel does not resume as quickly or as much as anticipated as a result of the COVID-19 pandemic, this will continue to significantly adversely affect the sale of these vaccines.
- 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.
- The development and manufacturing of our COVID-19 vaccine candidate requires substantial financial resources and we may ultimately be unsuccessful in our efforts to develop, manufacture and commercialize a COVID-19 vaccine.
- We are contractually obligated to meet specific regulatory approval and product delivery deadlines for VLA2001, and failing to meet these deadlines could negatively impact our business.
- The termination of the UK Supply Agreement has caused disruption to our VLA2001 development plans, and may continue to negatively affect our business.
- Our business has been and could continue to be materially adversely affected by the effects of health pandemics or epidemics, including the current 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.
- 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.
- 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 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 such existing agreements or enter into additional arrangements, our business could 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, for our COVID-19 vaccine candidate, 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 will continue to incur significant operational losses over the next several years and may never achieve or maintain profitability.

We have a history of incurring significant net losses. Our net loss was €73.4 million, €64.4 million and €1.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated net loss of €307.0 million. We expect to continue to incur significant expenses and 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, VLA15, VLA1553, and VLA2001;
- initiate, conduct and complete any ongoing, anticipated or future pre-clinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;

- continue to commercialize our two products, DUKORAL and IXIARO (marketed as JESPECT in Australia and New Zealand), and commercialize any current or future product candidate for which we may obtain marketing approval;
- invest in our manufacturing facilities;
- market and distribute vaccines for third parties, such as Bavarian Nordic;
- 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 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 otherwise; 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 approvals for and commercialize our product candidates. We have historically been substantially dependent on sales of our two commercial products, DUKORAL and IXIARO, for revenue. Our Lyme and chikungunya vaccine candidates have not received regulatory approval, and regulatory review of our COVID-19 vaccine remains ongoing. Unless and until we obtain the regulatory approval 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 our 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. 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 or 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 does not resume as quickly or as much as anticipated as a result of the ongoing COVID-19 pandemic, this will continue to 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 ongoing COVID-19 pandemic, travel has significantly decreased worldwide, and many countries have instituted travel restrictions and advisories. As a result, sales of these vaccines have decreased significantly, adversely impacting our financial results. If international travel does not resume as quickly or as much as anticipated as a result of the ongoing COVID-19 pandemic, 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, 2021, we had total assets of €817.4 million, including cash and cash equivalents of €346.7 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 and the ongoing COVID-19 pandemic environment generally. 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. 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;
- 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, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review and approval of our product candidates;
- 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 continued impact of the COVID-19 pandemic 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. Accordingly, we may need or choose to seek additional financing to achieve our business objectives.

The ongoing COVID-19 pandemic continues to evolve rapidly and has already resulted in a significant disruption of global financial markets. Global financial markets have also been negatively impacted as a result of the ongoing armed conflict 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, 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.

Our COVID-19 vaccine candidate is still in development and will require substantial financial resources to develop, manufacture and commercialize, and we may ultimately be unsuccessful in such efforts.

We are pursuing a vaccine candidate, VLA2001, to address the ongoing COVID-19 pandemic caused by the virus SARS-CoV-2. Although as of the date of this Annual Report we have received an Emergency Use Authorization for VLA2001 in Bahrain, the testing, development, and regulatory approval processes of VLA2001 remain ongoing, and we may be unable to produce a commercially successful vaccine in a timely manner and in sufficient quantities, if at all.

We are committing substantial financial resources, particularly research and development expenses and investment in our manufacturing facilities and personnel, to the development and manufacturing of VLA2001, which may cause delays in or otherwise negatively impact our other development programs. The termination of the UK Supply Agreement, as defined below, required us to assume a greater degree of investment in the VLA2001 development program. We will receive additional funding for this program via a grant from Scottish Enterprise, but we will need to continue investing our own resources as well. While we believe investing in research and development and our manufacturing facilities is crucial to the potential success of VLA2001, such capital commitments plus any future commitments, in aggregate, may, in the future, exceed our available cash and cash equivalents and short-term investments. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs.

Our business could also be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and constantly evolving, as a result of which our vaccine candidate may not be sufficiently effective or meet the current needs of potential customers and global demand. Alternatively, the threat of SARS-CoV-2 or of a particular strain of the virus could significantly change, including due to increasing rates of vaccination with approved vaccines and due to the arrival of new variants which are associated with milder symptoms, which could lead to a decrease in demand for our vaccine candidate. If we do not receive initial and final regulatory approvals in some or all the countries covered by current or future supply agreements, or if we fail to successfully manufacture or commercialize VLA2001 if approved, we may not be able to achieve a return on our investment.

The speed at which multiple stakeholders have moved to create, test and approve vaccines for COVID-19 is highly unusual and may increase the risks associated with traditional vaccine development. Given this accelerated timeline, we and regulators, such as the MHRA and EMA, may make decisions more rapidly than is typical. Evolving or changing plans or priorities of governments and regulatory bodies, including based on new knowledge of COVID-19, how the disease affects the human body, the longevity of protection given by existing vaccines, the identification of potential side effects and the resulting choices regarding the deployment of specific vaccines in various countries or in various age groups, may significantly affect our plans and pathways for clinical development, regulatory approval, manufacturing and commercialization of VLA2001. There is no guarantee that initial demand for VLA2001 will be sustained or that we will be able to remain competitive in geographies where we may initially receive approval for and sell VLA2001.

These processes are interconnected and there can be no guarantee that evolutions in one process will not impact one or more of the others. For example, as the number of people who have received a primary vaccination against COVID-19 has risen, health authorities are increasingly shifting attention to booster vaccine regimens, and the use of VLA2001 as a booster would require separate clinical data and regulatory approval. We are seeking to collect our own data on the use of VLA2001 as a booster but cannot provide any assurance that these data will be positive or compare favorably to other vaccines, or that we will be able to obtain approval for use of VLA2001 as a booster in either a homologous (following primary vaccination with VLA2001 or another inactivated vaccine) or heterologous (following primary vaccination with a different type of vaccine) context. Although we announced positive homologous booster data from our own clinical studies in December 2021, VLA2001 was also evaluated as a heterologous booster in the Cov-Boost study conducted in the autumn of 2021 by University Hospital Southampton NHS Foundation Trust in the United Kingdom, and the data with respect to seven different COVID-19 vaccines administered as a booster three months following the second dose of primary vaccination (earlier than the six-month interval typically recommended for inactivated vaccines) suggested that VLA2001 may be less effective in a heterologous context. The results from the Cov-Boost trial will not serve as the basis for any regulatory approval we may eventually seek, and we are conducting our own heterologous study using at least a six-month interval. Furthermore, we may seek to adapt VLA2001 to target different variants of the virus as the global pandemic evolves. If the VLA2001 product is modified to address a variant of concern of SARS-CoV-2, we may adjust our manufacturing process and will need to produce clinical trial material and conduct further clinical trials, which could result in additional time and expense and divert our manufacturing resources away from production of the existing VLA2001 product. The regulatory path, manufacturing requirements and overall timeline for adaptations of VLA2001 are uncertain and could require substantial investment that we may not ultimately recover through our commercial efforts.

We face certain risks relating to clinical trials and regulatory approval of VLA2001. Success in clinical trials of VLA2001, such as our initial data from our Cov-Compare pivotal Phase 3 clinical trial, may show promise against a particular strain of the virus that causes COVID-19, but these results may not be indicative of VLA2001's potential efficacy against different strains or when used as a booster in either homologous or heterologous settings. Although Cov-Compare presented some indication of protection against cases of COVID-19 caused by recent variants of the virus (e.g. the Delta variant at the time of the trial) and laboratory studies have indicated that VLA2001 produced neutralizing antibodies against the Delta and Omicron variants, further analysis and studies are required to confirm protection against these and other variants, and results of these initial studies may not be replicated in larger clinical trials. Additionally, our Cov-Compare Phase 3 clinical trial compares our vaccine candidate to AstraZeneca's AZD1222 (ChAdOx1-S). If we wanted to seek regulatory approval for VLA2001 in a jurisdiction that has not yet approved AZD1222, notably the United States, we would have to redesign our regulatory strategy, and we may be unable to rely solely on the VLA2001-301 trial results as the pivotal trial in support of a regulatory submission. Additional clinical trial requirements could require significant investment and time. Finally, our Phase 3 clinical trial, Cov-Compare, is ongoing in the United Kingdom. We depend on funds received from the UK Authority to pay costs associated with our ongoing Cov-Compare clinical trial in the UK. Such funding has been received and is to be received pursuant to the Clinical Trials Agreement, which was executed in conjunction with the UK Supply Agreement in order to finance the cost of clinical trials associated with the development of VLA2001. The Clinical Trials Agreement remains in place, but the cost of the Cov-Compare trial, as a result of mutual agreement between Valneva and the UK Authority, has exceeded the amount originally budgeted for in the Clinical Trials Agreement, and it is not certain that the UK Authority will provide Valneva with the additional funding necessary to make required payments to clinical sites or other providers. Without such funding, Valneva will have to bear costs substantially beyond those originally foreseen, which could negatively impact our business.

We also face substantial risks and uncertainties in the manufacture of VLA2001. Manufacturing vaccines is a complex process and it is not uncommon for yields to vary materially from plans. We cannot guarantee that we will be able to timely and effectively produce VLA2001, or any variant-based version thereof, in adequate quantities to meet global demand and contractual obligations, which could result in cancellation of existing orders or termination of supply agreements. We have outsourced the majority of production of VLA2001 expected in 2022 to a third party in order to meet demand or specific customer requirements, and there are additional risks inherent in outsourcing vaccine production, particularly in the context of VLA2001.

Various factors will affect our ability to commercialize VLA2001. Multiple vaccines, including inactivated vaccines, have received regulatory approval and been widely distributed, and other vaccine candidates are undergoing regulatory approval. Several of these vaccines are made by companies that are much larger than we are and have access to larger pools of capital, including government funding, and broader manufacturing infrastructure. The earlier market entry of other vaccines, and their actual or perceived efficacious or success relative to our own, may lead to diversion of funding away from us, additional regulatory scrutiny of risk-benefit of VLA2001 compared to previously approved vaccines and decreased demand for VLA2001 if approved. We may be unable to commercialize VLA2001 and establish a competitive market share before the COVID-19 pandemic is contained or significantly diminished. If our competitors are successful in producing a more efficacious vaccine or other treatments for COVID-19, including for variants of the virus and in the context of boosters, or if our competitors are able to manufacture and distribute any such vaccines or treatments with greater efficiency, there may be a diversion of potential funding and commercial opportunities away from us and toward such other parties. Additionally, we received the biological material that would be used to manufacture certain variant-based vaccines from third parties and would need to acquire a license in order to commercialize any vaccines derived from this material. Finally, pursuant to a provision of the 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, we are required to pay the UK Authority low single-digit percentage royalties in respect of sales of VLA2001 to non-UK customers in an amount not to exceed €100 million. This obligation survived the termination of the UK Supply Agreement discussed elsewhere in these Risk Factors.

All of these factors could substantially impact our ability to complete the development of, commercialize, and profit from our COVID-19 vaccine candidate.

We are contractually obligated to meet specific regulatory approval and product delivery deadlines for VLA2001, and failing to meet these deadlines could negatively impact our business.

As of the date of this Annual Report, we have entered into supply agreements for VLA2001 with the European Commission and other customers. Under the advance purchase agreement with the European Commission, or the EC supply agreement, we are required to use best reasonable efforts to obtain a marketing authorization from the EMA as soon as reasonably possible. The EC may terminate the EC supply agreement if we do not obtain a marketing authorization (including a conditional marketing authorization) by April 30, 2022. In such case, the EC and Participating Member States must notify us within 15 days whether they intend to terminate the agreement on this basis, and we shall have 30 days to obtain a marketing authorization or otherwise propose an acceptable remediation plan. Further, the EC APA provides that, if we do not obtain a marketing authorization covering the entire adult population (adults aged 18 and older) by June 30, 2022, any Participating Member State shall have the right to cancel its purchase of a certain percentage of doses, which would require us to reimburse to such Participating Member State the equivalent percentage of its up-front payment. See “Item 10.C—Material Contracts—EC Advance Purchase Agreement” for further details.

The EC supply agreement also obligates us to manufacture VLA2001 within the European Union and European Economic Area and to deliver doses according to a specified delivery timeline. The EC supply agreement provides that, if delivery of the doses – which is conditioned on obtaining a marketing authorization from the EMA – is delayed by a certain period of time, any participating member state may cancel its purchase of the delayed doses, which would require us to reimburse certain amounts to such participating member state and, in certain circumstances, make us subject to claims for liquidated damages. In addition to the termination provisions mentioned above, the EC may terminate the EC supply agreement if delivery of all doses ordered for 2022 has not taken place by December 31, 2022 or a later date to which we may agree. In the event of a termination for failing to meet the December 31, 2022 deadline, we would be required to repay any unspent and uncommitted amounts of up-front payments received from the participating member states. Numerous factors may influence whether we are able to meet delivery deadlines, including but not limited to our manufacturing capacity and the performance of IDT Biologika, to whom we have outsourced a majority of the production of VLA2001 for 2022. If IDT Biologika is unable to produce the required volume of doses, we may be unable to meet the delivery deadline.

If we are required to repay any or all of the up-front payments we have received, this would have a material adverse effect on our business, prospects, financial condition and results of operations. Additionally, our reputation could be harmed if the EC, or any other customer, chooses to cancel doses or terminate our supply agreement, and this could negatively impact our business and our ability to commercialize VLA2001.

The termination of the UK Supply Agreement has caused disruption to our VLA2001 development plans, and may continue to negatively affect our business.

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. Funding for UK-based clinical trials was agreed to in a separate, linked Clinical Trial Agreement which remains in place.

Following the close of business on September 10, 2021, we received notice of the UK Authority’s decision to terminate the UK Supply Agreement. We had not received any indication from the UK Authority, prior to this time, of the UK Authority’s intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, if the UK Authority were to successfully bring proceedings for damages against Valneva in respect of the alleged anticipatory breach, it could be argued that the applicable contractual cap on our liability under the UK Supply Agreement could be as high as an amount equivalent to the sums paid to us by the UK Authority prior to termination. However, we believe that it is very unlikely that any such claim by the UK Authority will be successful. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination for alleged anticipatory breach nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, 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. A royalty on sales and certain other obligations survive termination for convenience of the UK Supply Agreement.

We are still completing the construction of our new manufacturing facility, Almeida, at our site in Livingston, Scotland. This project was largely funded through certain advance payments made by the UK Authority pursuant to the UK Supply Agreement. While we will receive additional funding from Scottish Enterprise to operationalize the Almeida facility, we are investing our own funds as well, and if we are not able to successfully commercialize our COVID-19 vaccine candidate or repurpose our manufacturing facility for the manufacture of other products, we may not receive a return on this investment. Furthermore, if we fail to comply with the terms of the grant, Scottish Enterprise may stop payments and require repayment of the grant funding paid to date.

The UK Authority's termination of the UK Supply Agreement has substantially disrupted our business and VLA2001 development plans, and the evolving situation regarding a possible settlement or litigation could cause further and substantial harm to our business, financial condition, prospects and results of operations. In addition, 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.

The termination of the UK Supply Agreement was extensively assessed in the context of the preparation of the financial statements as of and for the year ended December 31, 2021. Payments received, where judgement was necessary and we assessed the likelihood of repayment to be remote, totaled €253.3 million and therefore this amount was recognized as revenue in the year ended December 31, 2021. Of this amount, €166.9 million related to uncertain restrictions and repayment obligations and are recognized in refund liabilities.

The final terms of the termination, which we are discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and our future 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, 2021, we had €54.1 million drawn down in two tranches under the Financing Agreement.

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 under the Financing Agreement. 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) bring the minimum liquidity covenant to the amount of €50.0 million in 2021 and 2022 and €35.0 million thereafter and (ii) 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. If our consolidated net revenues (excluding grants) were to fall below these amounts, 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 candidate 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.

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 or will ultimately receive regulatory approval from any or all of the agencies from which we seek such approval. Generally, failure to develop a vaccine that we can successfully commercialize could result in the total loss of our investment in its development.

While we have obtained regulatory approval in major markets for two 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 substantial discretion of the regulatory authorities. While the timeline for receiving conditional approval of VLA2001 may be shorter, long-term approval of VLA2001 will require additional time and expense. We have received an Emergency Use Authorization for VLA2001 from the National Health Regulatory Agency in Bahrain but may not receive approvals from other agencies in a timely manner or at all, and initial approvals such as this Emergency Use Authorization in Bahrain and any conditional marketing authorization that VLA2001 may receive from the EMA or MHRA will require Valneva to provide further information in order to maintain and expand such authorization. A conditional marketing authorization from the EMA or MHRA would be valid for 12 months only, and the Emergency Use Authorization in Bahrain is valid for so long as the declared state of emergency in Bahrain remains. 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 European Economic Area, or 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 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. 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. 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 biologics license application, or 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 also may approve or authorize for marketing 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 or other marketing authorization would delay, inhibit or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the European Commission, FDA or other comparable regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, 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 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. 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. In particular, as discussed further above, success in clinical trials of VLA2001 may not be indicative of VLA2001’s potential efficacy against different strains or when used as a booster in either homologous or heterologous settings.

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 promising 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. 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;
- regulators or institutional review boards and ethics committees may not authorize us or our investigators to commence a clinical trial or conduct 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 good manufacturing practices, or cGMP;
- 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, 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, CTA or 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, such as the possibility of using VLA2001 as part of a booster regimen, which may require new or additional trials;
- evolution of the COVID-19 pandemic, including the emergence or dissipation of different strains of the virus;
- 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, 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;
- 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. 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 comparable foreign authorities have substantial 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, the competent authorities of individual EEA countries, the FDA or another foreign regulatory authority 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 Good Clinical Practice, or GCP, regulations, equivalent regulations in the EEA or other foreign countries that we are exposing participants to unacceptable health risks, or if the competent authorities of individual EEA countries, FDA or another foreign regulatory authority finds deficiencies in our investigational new drug applications, or INDs, or clinical trial applications, or CTAs, respectively, or the conduct of these trials. Moreover, we may not be able to file INDs or CTAs 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 to participate in our clinical trials is critical to our success. We are developing VLA15 for Lyme disease, VLA1553 for chikungunya and VLA2001 for COVID-19, 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 and approval 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 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, as Lyme disease is a seasonal disease. We may 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. 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.

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 is to expand our product pipeline. 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 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 regulatory authorities determine that any side effects experienced by subjects in our clinical trials are being caused by our vaccine candidates, they may require additional testing to confirm these determinations, if they occur.

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 Lyme disease, chikungunya and COVID-19. 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 it was later proven to be safe by an FDA advisory committee. 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.

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 Sanofi's IMOJEV), cholera (such as Emergent's Vaxchora, which is available in the U.S. and has received approval in Europe), and COVID-19, 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, chikungunya and COVID-19. 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 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 and others in the medical community. 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 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 have received 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 regulators for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. 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, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing.

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 or withdraw regulatory approval;
- suspend or vary any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application or any supplements thereto submitted by us or our partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- 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 or have 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. Although our policy is to refrain from statements that could be considered off-label promotion of our products or false or misleading claims, a regulatory agency could disagree with the manner in which we advertise and promote our products. 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, it could request that we modify our promotional materials or training content 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 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, or political instability in particular economies and markets;
- uncertainties related to Brexit, including potential impacts on costs, exchange rates, flow of goods, manufacturing and operations;
- 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 February 2022, Russia invaded Ukraine. In response, NATO has deployed additional military forces to Eastern Europe, including to Lithuania, and the Biden administration announced certain sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the U.S., NATO, and other countries 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 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, Inc., or Pfizer, in connection with VLA15, our Lyme disease vaccine candidate. Pursuant to this agreement, Pfizer will lead late-stage development of the vaccine candidate 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;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- 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 delay 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;
- 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;
- 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 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;
- 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;
- 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 with third-parties, 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 product 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 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 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.

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 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 €40 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. We do not currently have product liability insurance that would cover VLA2001, but we anticipate that we will have such coverage in time for the beginning of deliveries in Europe, if VLA2001 is approved by the EMA. 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;
- the rate of participant enrollment and retention, which is a function of many factors, including 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 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; 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. 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. For example, we expect that the initial conditional approval of VLA2001 by the EMA will be for adults aged 18 to 55 rather than for the entire adult population. 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 EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or 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) and VLA1553 have both received Fast Track designation by the FDA. Fast Track designation may be available to help expedite the development or approval process for a drug that is intended for the treatment of a serious or life-threatening condition and that demonstrates the potential to address an unmet medical need for this condition. Fast Track designation does not change the standards for product approval or ensure that the product will receive marketing approval at all or within any particular timeframe. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. Thus, although VLA15 and VLA1553 have both 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 intend to seek 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.

In the EEA, an innovative biologic medicinal product also benefits from eight years' data exclusivity and 10 years' market exclusivity. 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, which will be expanded beginning in 2022, to require applicable manufacturers to report information regarding payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year; and

- similar healthcare laws and regulations in the EU and other jurisdictions, such as state anti-kickback and false claims laws, including 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, 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.

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, 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 common stock. 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. Thus, the ACA will remain in effect in its current form. 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. It is unclear how any such challenges and the 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 3% 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. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN interim final rule. 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, 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, Congress is considering drug pricing as part of the budget reconciliation process. President Biden may take additional steps to address pharmaceutical product pricing. 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. Congress is considering drug pricing as part of other reform initiatives.

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. For example, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic. 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.

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 product 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. 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could have an adverse effect on demand for our product candidates. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. 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.

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.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business 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 assist the individual or business in obtaining or retaining 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. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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 our compliance with all applicable anti-corruption laws, including the FCPA, the French anti-corruption laws or other 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.

In addition, 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.

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. For example, many patent applications in the SARS-CoV-2 field are still confidential and thus we cannot be sure that we or our licensors were the first to file a patent application relating to any particular aspect of the VLA2001 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 common stock.

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.

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 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 such 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 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, changes in their strategic focus due to the acquisition of competitive products, 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;
- 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;
- 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;

- 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 30% of the development costs for our Lyme disease vaccine. If we cannot maintain enough cash to comply with this obligation, 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.

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 and VLA2001. We also rely on a single source supplier for the adjuvant contained in our COVID-19 vaccine candidate and other vaccine candidates. A loss of our fetal bovine serum supplier or any shortages of this material could adversely affect our ability to produce IXIARO and VLA2001 and significantly raise our cost of producing them. A loss of our adjuvant supplier or any shortages of this could adversely affect our ability to develop our COVID-19 and other vaccine candidates.

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. Any such collaboration, or other strategic transaction, may 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 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 VLA2001 and the adjuvant used in VLA2001 and other vaccine candidates. 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 or withdrawal of approvals, license revocation, seizure or recalls of our products, operating restrictions and legal proceedings. Furthermore, the presence of non-conformities, as detected in regulatory toxicology studies, could result in delays in the development of one or more of our product candidates 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. In particular, a partner's failure to comply with protocols or regulatory constraints, or repeated delays by a partner, could compromise the development of our products or limit its liability. Such events could also inflate the product development 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-party investigators to assist with conducting clinical trials. All clinical trials are subject to strict regulations and quality standards. Should any of these risks materialize, 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 they will face further disruption which 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, particularly our COVID-19 vaccine candidate.

We may be unable to successfully increase our manufacturing capacity to meet demand for VLA2001 or 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 VLA2001 or other 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. Many factors may affect our manufacturing capacity for VLA2001, including but not limited to the virus strains being targeted and whether VLA2001 may be used as a booster. Further, the manufacturing of biological materials is technologically and logistically complex and delicate, particularly because the complexity of biological mechanisms leads to variability in industrial yields, and also because the biological material being manufactured is very vulnerable to contamination. The manufacturing of biological materials is also heavily regulated by the competent authorities of EEA countries, FDA and other regulatory authorities. Failure to comply with strictly enforced good manufacturing practices regulations and similar regulatory standards may result in delays in product approval or withdrawal of an approved product from the market.

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, and this risk is heightened in the context of VLA2001, if approved, because demand is more immediate for our existing customer agreements. We have outsourced a substantial amount of the manufacturing of VLA2001 to a third party, which could result in delays, concerns about manufacturing consistency, or other manufacturing failures. Per the standard industry practice, we rather than the third party provider would bear the risk of such problems. If we, or any third party manufacturing partners, are unable to manufacture sufficient quantities of VLA2001, we may not be able to fulfill our obligations under our existing agreements or may be forced to forego additional partnerships or supply agreements which would be advantageous for our business. Furthermore, our supply agreement with the European Commission for VLA2001 includes, and other supply agreements that we may enter into with governments may include, obligations to refund part or all of any up-front payments received if we are unable to supply the agreed quantities in time. 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.

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 facilities in Livingston, Scotland, and Solna, Sweden, are, and we expect will continue to be, significant factors in growing our revenues from product sales and maintaining control over production costs. Our manufacturing facility in Livingston, Scotland is the sole source of commercial quantities of our Japanese encephalitis vaccine, will be the sole source of clinical materials for our chikungunya vaccine candidate and plays a significant role in the manufacture of clinical materials for VLA2001. Our manufacturing facility in Solna, Sweden, is the sole source of commercial quantities of DUKORAL and will perform the fill-finish of VLA2001. 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 rely upon several 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 the manufacture of a significant portion of VLA2001 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.

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, FDA and other regulatory bodies to ensure compliance with cGMP 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 GMP 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, or may delay or prevent filing or approval of marketing applications for our products.

Failure to comply with applicable regulations 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;
- 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 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. 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.

In addition, if we decide to manufacture VLA2001 in new or different ways, such as to target different strains of the virus or as a booster, we may face unexpected production costs that could ultimately affect profitability. 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. There is some risk that the exchange ratio to be applied could be challenged following the calculation of such safety margins, which could result in a liability for which we have not made specific reserves. 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 March 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 5.31 to our financial statements for the year ended December 31, 2021 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, 2021, we had 762 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 outbreak of the current COVID-19 pandemic and future outbreaks of the disease. The ongoing COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including government orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. As a result, a large part of our workforce has been working remotely since March 2020 and uncertainty remains about whether and to what extent the governments of the countries where we operate will impose further restrictions that will impact our ability to fully reopen our offices. The effects of government-imposed quarantines and our work-from-home policies, including the evolving nature of such policies, may negatively impact productivity and production, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities, or the availability or cost of materials, which would disrupt our supply chain. Since the beginning of the COVID-19 pandemic, two vaccines for COVID-19 have received approval from the FDA and one remains available through Emergency Use Authorization by the FDA. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent legislation outside the United States, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and commercial products, which could lead to delays in these trials and issues with our commercial supply.

In addition, our clinical trials have been affected by the ongoing COVID-19 pandemic. Site initiation and subject enrollment have been and may be further delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some subjects may not be able or willing to comply with clinical trial protocols if quarantines impede subject movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been delayed or disrupted, which has adversely impacted our clinical trial operations. For example, the initiation of the Phase 3 clinical trial for VLA1553 (chikungunya) was delayed due to the impact of COVID-19, and we expect the trial to be completed in 2021. Further delays to our trials may occur, which could have a material adverse impact on our business.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. Additionally, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA’s inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

While the potential economic impact brought by, and the duration of, the ongoing COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting 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 common stock.

The global COVID-19 pandemic continues to rapidly evolve. 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. 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 acquire or invest in other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We have in the past and may in the future 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. The pursuit of potential acquisitions and investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

For example, in 2015 we acquired Crucell Sweden AB and all assets, licenses and privileges related to DUKORAL. 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 stockholders 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.

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, computer viruses, data corruption, cyber-based attacks, natural disasters, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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. 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. The growth in state-sponsored cyber activity, including the increased rate of cyberattacks arising from the Russia-Ukraine armed conflict 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. Additionally, we may be targeted for cyber-attacks as a result of our work on developing a COVID-19 vaccine. On May 13, 2020, the Federal Bureau of Investigation, or FBI, and the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency, or CISA, announced that the FBI was investigating the targeting and compromise of U.S. organizations conducting COVID-19-related research by cyber actors affiliated with the People's Republic of China. On July 16, 2020, the National Security Agency, National Cyber Security Center, Communications Security Establishment and CISA released a joint cybersecurity advisory detailing the targeting by Russian Intelligence Services of organizations involved in COVID-19 vaccine development in the United States, Canada and the United Kingdom. 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 targeting SARS-CoV-2, 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 General Data Protection Regulation, or GDPR. 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 (and our service providers) receive, process, store and use personal information and other data, which subjects us to governmental regulation and other legal obligations, liability and risks related to privacy, security, and data protection, and 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 and regulations 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.

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 May 2018 the European Union General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect in the European Economic Area, or EEA. The GDPR imposes stringent data protection requirements for processing the information of individuals in (i) the EEA and (ii) the United Kingdom as the GDPR continues to form part of law in the United Kingdom, or the UK GDPR, (by virtue of Section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations)), the United Kingdom, and to date, has 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 European Union in certain circumstances. The processing of sensitive personal data, such as health information, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR increases 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 GDPR also provides 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 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 GDPR also confers 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 GDPR.

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the EEA, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. 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." Following this decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on the viability of the Swiss-U.S. Privacy Shield as a future compliance mechanism for Swiss-U.S. data transfers. The CJEU's decision in Schrems II also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe 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 EU-U.S. Privacy Shield and the Standard Contractual Clauses. However, the Court of Justice of the European Union recently invalidated the EU-U.S. Privacy Shield. The decision in Schrems II also affects transfers from the United Kingdom to the United States. As such, if we are unable to implement a valid solution for personal data transfers from Europe, including, for example, obtaining individuals' explicit consent to transfer their personal data from Europe to the United States or other countries, we will face increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to import personal data from the EEA, United Kingdom or Switzerland may also restrict our clinical trials activities in Europe; 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 Europe 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 GDPR or regulatory frameworks of equivalent complexity.

The GDPR applies across the EEA and, by virtue of the UK GDPR in the United Kingdom, in a broadly uniform manner. However, the 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.

Further, the United Kingdom's vote in favor of exiting the European Union, often referred to as Brexit, and ongoing developments in the United Kingdom have created uncertainty with regard to data protection regulation in the United Kingdom. Following the United Kingdom's withdrawal from the European Union on January 31, 2020, pursuant to the transitional arrangements agreed to between the United Kingdom and European Union, the GDPR continued to have effect in law in the United Kingdom, and continued to do so until December 31, 2020 as if the United Kingdom remained a Member State of the European Union for such purposes. Following December 31, 2020, and the expiry of those transitional arrangements, the data protection obligations of the GDPR continue to apply to United Kingdom related to processing of personal data in substantially unvaried form and fashion under the UK GDPR. However, going forward, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and the EEA. 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 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, the European Commission, EMA, FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in Europe, 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, 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 €20.2 million, €8.9 million, and €4.4 million for the years ended December 31, 2021, 2020, and 2019, respectively. Our French Research Tax Credits were €1.8 million, €1.1 million and €1.9 million for the years ended December 31, 2021, 2020, and 2019, 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 by the company 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 €628.3 million, €529.5 million and €457.0 million for the years ended December 31, 2021, 2020, and 2019, 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.

The passage of the Tax Act on December 22, 2017 significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, included changes to U.S. federal tax rates, imposed significant additional limitations on the deductibility of interest and net operating loss carryforwards, allowed for the expensing of capital expenditures, and put into effect the migration from a “worldwide” system of taxation to a territorial system.

Furthermore, as part of Congress’ response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the CARES Act was enacted on March 27, 2020. Both the FFCR Act and the CARES Act contain numerous tax provisions. Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately alter the impact of these laws on our business and financial condition.

In addition, many countries are implementing legislation and other guidance to align their international tax rules with the Organization for Economic Co-operation and Development’s (“OECD”) Base Erosion and Profit Shifting recommendations and action plan that 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 2019 and 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 armed conflict between Russia and Ukraine and the resulting tensions between the European Union, the United States and other European countries including the United Kingdom, 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. However, for so long as we are an "emerging growth company," which may be up to December 31, 2026, we will not be required to assess the effectiveness of our internal controls over financial reporting until the end of the first fiscal year following our initial public offering on the Nasdaq Global Select Market, and no such assessment has been completed. Similarly, our independent registered public accounting firms will not be required to attest to the effectiveness of our internal controls over financial reporting for so long as we are an "emerging growth company," and no audit of our internal control over financial reporting has been performed. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not.

In conjunction with preparing our consolidated financial statements as of and for the years ended December 31, 2020 and 2019, three material weaknesses in our internal control over financial reporting were identified. The material weaknesses related to (i) a lack of formal, documented and implemented processes, controls and review procedures, (ii) insufficient controls on manual journal entries due to insufficient segregation of duties in the finance and accounting function, and (iii) insufficient controls over the accuracy and completeness of information that is being processed and reported by third parties, used to recognize revenue and record inventory. 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.

We have developed and begun to implement a remediation plan to address these material weaknesses and strengthen our controls in these areas. As of December 31, 2021, we had completed remediation of the third material weakness listed above. While we are working to remediate the remaining material weaknesses as quickly and efficiently as possible, we cannot at this time provide the expected timeline in connection with implementing our remediation plan. 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 also cannot guarantee that we will not identify material weaknesses in the course of future assessments of the effectiveness of our internal controls.

The rules governing the standards that will have to be met 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. We have begun the process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation. This process 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 are an "emerging growth company" under the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our ordinary shares ADSs less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

We cannot predict if investors will find the ordinary shares or ADSs less attractive because we may rely on these exemptions. If some investors find the ordinary shares or ADSs less attractive as a result, there may be a less active trading market for the ordinary shares or ADSs and the price of the ordinary shares or ADSs may be more volatile. We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates; (3) the issuance, in any three year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (4) December 31, 2026.

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, 2022. 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, 2021, 15% 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, 2021. 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, 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;
- 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.

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.

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 the ADSs and ordinary shares would 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 the ordinary shares and ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for the ordinary shares and ADSs could decrease, which could cause the price of the 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, 2021, 2020 and 2019 totaled €92.3 million, €18.9 million and €10.5 million, respectively, primarily related to investments in our manufacturing facilities in Scotland and Sweden relating to the production of our COVID-19 vaccine candidate. We expect our capital expenditures in 2022 to be primarily financed from our existing cash and cash equivalents.

B. Business Overview

We are a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our expertise and capabilities both to successfully commercialize two vaccines, IXIARO and DUKORAL, and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

Our 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. VLA15 is a Phase 2 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. VLA1553, targeting the chikungunya virus, is the first and only chikungunya vaccine candidate to report positive Phase 3 data and 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.

We are also advancing VLA2001, a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus that causes COVID-19 in order to address the urgent, global need for billions of doses of vaccines. VLA2001 is currently the only inactivated, adjuvanted vaccine candidate for COVID-19 in clinical development in Europe and has been authorized for emergency use in Bahrain while regulatory reviews in Europe and the United Kingdom are ongoing. We believe that VLA2001, as an inactivated whole virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to previously approved vaccines in territories where it may be approved and could be adapted to offer protection against mutations of the virus. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's Vaxzevria AZD1222 (ChAdOx1-S), in terms of geometric mean titer, or GMT, for neutralizing antibodies, as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. In December 2021, we announced positive homologous booster data showing an excellent immune response after a third dose of VLA2001 was administered seven to eight months following completion of primary vaccination with VLA2001. We expect to report further booster data in the second quarter of 2022 from boosters administered to participants who received either VLA2001 or AZD1222 in our Phase 3 trial, and we also plan to evaluate VLA2001 administered as a booster dose at least six months following administration of the second dose of a licensed mRNA-based vaccine or following natural infection. We also announced in January 2021 that a laboratory study found that a third dose of VLA2001 produced neutralizing antibodies against the Delta and Omicron variants of the virus.

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. We continue to discuss possibilities for other purchase agreements with other countries.

We commenced the regulatory approval process for VLA2001 in August 2021 with our rolling submission to the UK's Medicines & Healthcare products Regulatory Agency, or MHRA. We commenced the rolling submission process with the European Medicines Agency, or EMA, and with the National Health Regulatory Authority, or NHRA, in Bahrain in December 2021. We received an Emergency Use Authorization from the NHRA at the end of February 2022, and we expect that we could receive conditional marketing authorization for VLA2001 from the EMA in April of 2022. Further submissions to other regulatory agencies may also take place in 2022.

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 ETEC, the leading causes of travelers' diarrhea.

Our advanced clinical portfolio is supported by our significant development, manufacturing and commercial capabilities. We have a robust manufacturing and laboratory platform in place with facilities across Europe to meet our clinical and commercial needs, including BioSafety Level 3 manufacturing and R&D facilities. Additionally, sales of our proprietary products, IXIARO and DUKORAL, as well as products that we commercialize on behalf of third parties have given us the ability to reinvest in our research and development programs and to build the necessary infrastructure to support manufacturing of our product candidates.

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 executive team has extensive combined experience spent working at industry leaders such as Novartis, Chiron, GlaxoSmithKline and Daiichi Sankyo.

Our Portfolio and Pipeline

We have a broad portfolio that consists of assets at all stages of development including late and early stage clinical assets, pre-clinical assets and commercial assets. Each of the assets in our portfolio are differentiated products that either target diseases currently lacking a preventative and effective therapeutic treatment option or that we believe may have meaningful therapeutic advantages relative to other existing vaccine and treatment options.

Our pipeline and key assets are summarized below:

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

Our clinical pipeline includes:

- **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 vaccine undergoing clinical trials against Lyme disease. We have completed recruitment and reported initial results for three Phase 2 clinical trials of VLA15 in over 900 healthy adults, in which we observed high levels of antibodies against all six strains. In April 2020, we announced a collaboration with Pfizer pursuant to which Pfizer will lead late phase development of VLA15 and, if approved, Pfizer will have sole control over its commercialization and we will be eligible to receive milestone and royalty payments. As part of this collaboration, in December 2020, we announced that we had accelerated the development of VLA15 for pediatric use with an additional Phase 2 clinical trial initiated in March 2021. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of $10 million. We announced positive data from this additional Phase 2 clinical trial in February 2022. Together with Pfizer, we expect that our Phase 3 pivotal, placebo-controlled field efficacy trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the 2023 tick season. Initial data, based on the first tick season of the trial, may be reported by the end of 2023. If the results from these clinical trials are positive, we expect Pfizer to submit a biologics license application, or BLA, and marketing authorization application, or MAA. VLA15 has received Fast Track designation from the FDA.

- **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 has reported positive Phase 3 data. 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 positive topline results in August 2021 and final results, including six-month follow-up data, in March 2022. In the pivotal Phase 3 trial, we observed a very high seroprotection level of 98.9% 28 days after receiving the single administration, and this immunogenicity profile was maintained over time, with 96.3% of participants showing protective CHIKV neutralizing antibodies one month after receiving a single vaccination. VLA1553 has received Fast Track and Breakthrough Therapy designation from the FDA and PRIME designation from the EMA. We have also received confirmation for our proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, we plan to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA and the EMA that is reasonably likely to predict protection from chikungunya infection, rather than executing a time- and cost-intensive field trial that observes natural rates of infection between trial participants receiving our vaccine and the placebo. The seroprotection rate of 98.5% observed in the pivotal Phase 3 trial exceeds the 70% surrogate of protection threshold 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 Priority Review Voucher, or PRV.

- **VLA2001** – a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 in terms of GMT for neutralizing antibodies, as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. In December 2021, we announced positive homologous booster data showing an excellent immune response after a third dose of VLA2001 was administered seven to eight months following completion of primary vaccination with VLA2001, and in January 2021, we announced data from a laboratory study showing that a third dose of VLA2001 produced neutralizing antibodies against the Delta and Omicron variants of the virus. 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 and 2023, and the Bahraini NHRA granted an Emergency Use Authorization for VLA2001 at the end of February 2022. We have regulatory review processes ongoing with the EMA and MHRA and expect that we could receive a conditional marketing authorization for VLA2001 from the EMA in April 2022. Although vaccines against SARS-CoV-2 have already been approved and deployed, given the potential advantages often associated with inactivated whole virus vaccines, we believe our vaccine can be incorporated into the current and future portfolio of SARS-CoV-2 vaccines to address the global need for billions of doses of vaccines to prevent further spread of the virus.

In addition to our clinical-stage assets, we are advancing 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. Specifically, our pre-clinical portfolio is composed of three assets, including VLA1554, a vaccine candidate targeting human metapneumovirus, or hMPV, a respiratory pathogen that causes acute upper and lower respiratory tract infection that primarily impacts children and immunocompromised adults; a program targeting parvovirus B19, which can cause a range of symptoms, from rash to severe anemia; and a program targeting norovirus, the leading cause of acute viral gastroenteritis in all age groups in the United States.

Our commercial portfolio includes two vaccines, both of which are marketed to travelers to regions where the targeted diseases are endemic:

- **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 €45.1 million, €48.5 million and €94.1 million in the years ended December 31, 2021, 2020 and 2019, 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 contemplate 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 exercised the first option year of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is now 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option of 250,000 doses, which remains unchanged.

- **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 €2.4 million, €13.3 million and €31.5 million of revenues in the years ended December 31, 2021, 2020 and 2019, respectively. Sales in 2020 and 2021 were significantly impacted by the COVID-related decline in travel. 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.

Our Strategy

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 robust commercial portfolio. We are focused on utilizing our proven and validated product development capabilities to rapidly advance our late-stage clinical programs to regulatory approval 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, we are pursuing the following near-term goals:

- **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 have completed recruitment and reported initial results for three Phase 2 clinical trials of VLA15 in Europe and the United States which together administered VLA15 to over 900 healthy adults and in which we observed that VLA15 was generally well tolerated and led to the generation of antibodies to six serotypes of Borrelia. Together with Pfizer, we announced the acceleration of the pediatric development of VLA15 with an additional Phase 2 clinical trial in approximately 600 participants between 5-65 years of age that began in March 2021. We announced further positive Phase 2 results, including a booster response, in September 2021 and January 2022. We intend to advance VLA15 into Phase 3 clinical trials in 2022 in adults, adolescents and children, with the potential to submit a BLA and a MAA in the second half of 2024. The dosing of the first subject in the Phase 3 clinical trial will trigger a milestone payment from Pfizer of $25 million.

- **Seek regulatory approval for, and commercialize, VLA1553 as a prophylactic vaccine candidate against chikungunya virus.** Based on data from Phase 1 clinical trials in which we observed that VLA1553 led to the development of antibodies to chikungunya in 100% of the 120 healthy trial participants, we advanced VLA1553 directly into various Phase 3 clinical trials. We reported positive topline results of our pivotal Phase 3 trial involving over 4,000 healthy adults in August 2021 and reported final results, including six-month follow-up data, in March 2022. These final results confirmed a very high level of seroprotection, with 98.9% of participants achieving protective levels of CHIKV neutralizing antibodies one month after receiving a single vaccination, and 96.3% of participants showed protective CHIKV neutralizing antibody titers six months after this single vaccination. These reported seroprotection levels far exceeded the 70% threshold (for non-acceptance) based on a surrogate of protection agreed with the FDA under the accelerated approval pathway. We intend to prepare a BLA and MAA to submit to the regulatory agencies for approval, beginning with the FDA. As the first company to complete a Phase 3 clinical trial 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 approved by the FDA, we would target commercialization in the United States as early as 2023, with submissions to other regulatory agencies, including the EMA, to follow.

- **Advance VLA2001 through clinical development for the prevention of COVID-19.** VLA2001 is developed from an inactivated whole virus, which is a type of vaccine that has proven effective against other viruses, including influenza. In its pivotal Phase 3 clinical trial, VLA2001 met both co-primary endpoints by demonstrating superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of GMT for neutralizing antibodies, as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination. VLA2001 received an Emergency Use Authorization from the NHRA in Bahrain in February 2022, and review processes are ongoing with the EMA and MHRA. We have also announced positive homologous booster data from our Phase 1/2 study, the launch of further trials to collect homologous and heterologous booster data from our Phase 3 trial participants and plans for a further heterologous booster study. Additionally, we announced in January 2021 that a laboratory study found that a third dose of VLA2001 produced neutralizing antibodies against the Delta and Omicron variants of the virus. Given the fact that VLA2001 is an inactivated whole virus vaccine, an approach with a well-proven and established profile, we believe our vaccine could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to previously approved vaccines in territories where it may be approved and could be adapted to offer protection against mutations of the virus. We have already scaled our manufacturing capabilities and commenced initial production to address the projected commercial demand for VLA2001 and plan to begin delivering purchased doses of the vaccine to Bahrain and, if approved, to the European Commission. We will also continue to pursue opportunities to provide VLA2001 in other countries.

- **Drive sales through our established commercial infrastructure and continue to fund our research and development pipeline and manufacturing platform.** To date, sales of our proprietary products, IXIARO and DUKORAL, as well as products that we commercialize for third parties, such as RABIPUR and ENCEPUR on behalf of Bavarian Nordic, have provided revenues which we have been able to reinvest in our research and development programs and use to build necessary infrastructure to support manufacturing of our vaccine candidates.

- **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.

- **Deepen 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 initiated or are considering initiating pre-clinical programs focusing on human metapneumovirus (hMPV), parvovirus B19, Epstein Bar Virus (EBV), Campylobacter and norovirus.

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 four 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 vaccine against Japanese encephalitis and our SARS–CoV-2 vaccine candidate 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.

Additionally, there are companies pursuing novel technologies such as RNA or mRNA vaccines, which are composed of the nucleic acid RNA and packaged within a vector such as lipid nanoparticles; 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 treatment or effective therapeutic 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 (potassium aluminum sulphate) and other types of aluminum salts. 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 adjuvants in a number of our clinical stage vaccine candidates, including VLA15 and VLA2001.

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

- ***Seroprotection*** — 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 Development Pipeline

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 completed recruitment and reported initial results of three Phase 2 clinical trials of VLA15 in over 900 healthy adults and interim analysis has demonstrated the presence of high titers of antibodies against all six strains. 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. Pursuant to our agreement with Pfizer, we are eligible to receive up to $35 million upon the achievement of potential development milestones, up to $143 million upon the achievement of early commercialization milestones and tiered royalties starting at 19% based on future sales. Under the terms of the agreement, Pfizer will fund 70% of all development costs through completion of the development program. Pfizer will lead late-stage development and have sole control over commercialization. See "Item 10.C—Material Contracts—Pfizer License Agreement" for more details. Together with Pfizer, we expect that our Phase 3 clinical trial will start in the third quarter of 2022 to ensure vaccination with VLA15 in time for the 2023 tick season. Initial data, based on the first tick season of the trial, may be reported by the end of 2023. If the results from this Phase 3 trial are positive, we expect Pfizer to submit a BLA and MAA. The dosing of the first subject in the Phase 3 clinical trial will trigger a milestone payment from Pfizer of $25 million. VLA15 has received Fast Track designation from the FDA and is the only vaccine undergoing clinical trials against Lyme disease.

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

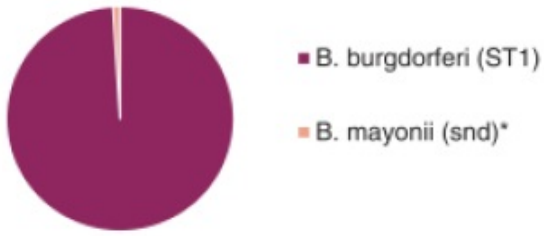
VLA15 provides a potential prophylactic solution to Lyme disease by generating antibodies that target the OspA protein on the surface of Borrelia, killing the bacteria before it can be transmitted from the infected tick to the human host. Third-party studies have shown that antibodies against OspA, which 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 as can be seen in the figure below:

Europe

United States



* *B. spielmanii* and *B. mayonii* are novel species and their serotype is not determined.

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, as illustrated in the figure below.

Phase 1 Clinical Trial and Results

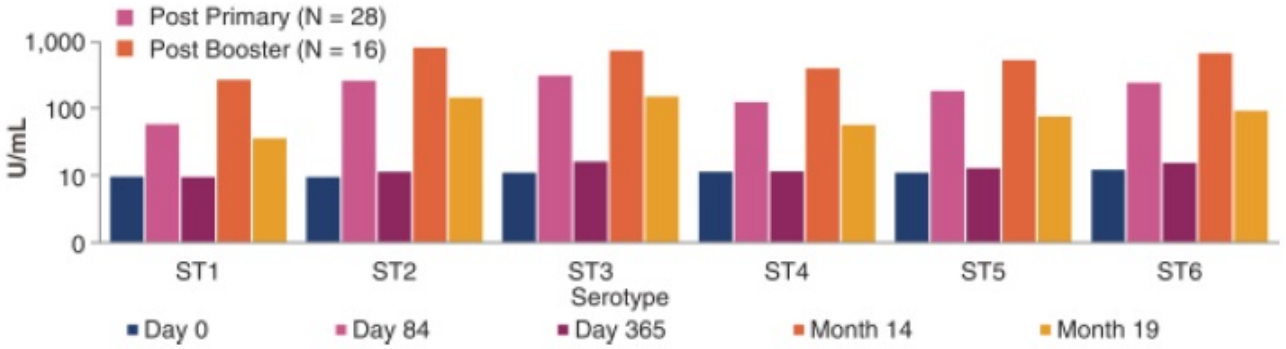
We evaluated VLA15 in a partially randomized, multi-center dose escalation Phase 1 clinical trial conducted in Belgium and the United States in 179 healthy adults below 40 years of age. The first 24 subjects were included in an open-label trial in which they participated in a staggered dose escalation 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 at month 14. 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 against all six OspA variants can be observed in the figure below. Additional data about a booster dose follow in the Phase 2 discussion below.

lgG Geometric Mean Titers (GMT) by Serotype Over Time: 90 µg w/ alum



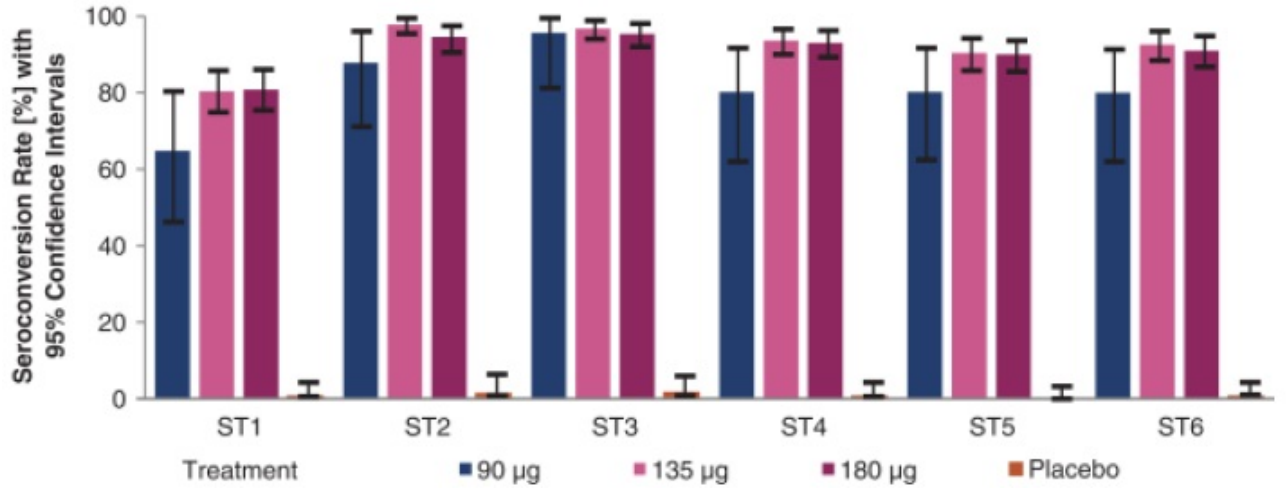
Phase 2 Clinical Trials and Results

We have evaluated the safety and immunogenicity of VLA15 at different dosage levels and schedules in two Phase 2 clinical trials in Europe and the United States. Together, these trials enrolled 818 healthy adults of 18 to 65 years of age. We also commenced a third Phase 2 clinical trial in the United States in March 2021 as part of our collaboration with Pfizer. This trial incorporates a shorter dosing schedule and includes pediatric participants.

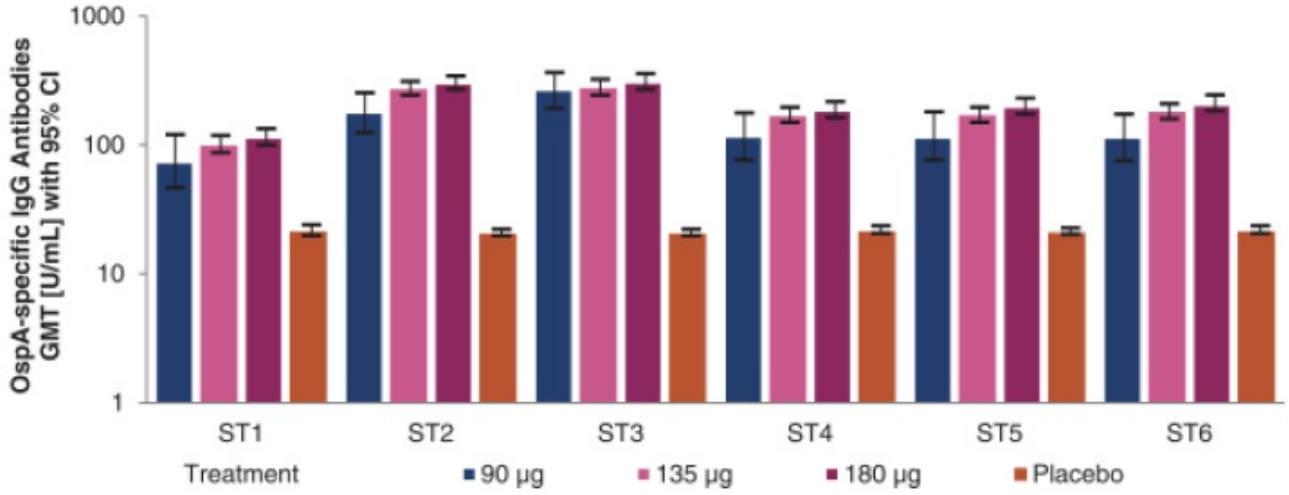
VLA15-201 Clinical Trial and Results

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. GMT calculates the average antibody across a set of subjects. Secondary endpoints examined SCR, geometric mean fold rise, or GMFR, and occurrence of adverse events.

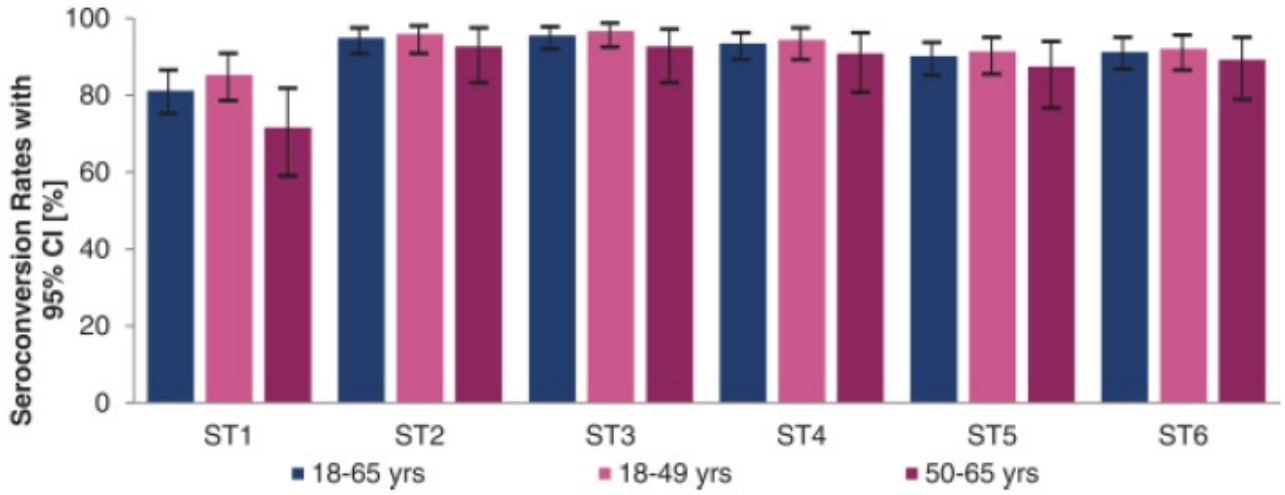
In July 2020, we announced statistically significant results from our Phase 2 clinical trial of VLA15-201 in which we observed VLA15 was immunogenic across all dose groups tested. Compared to results from the Phase 1 clinical trial, the higher doses used in our Phase 2 clinical trial elicited higher antibody responses across all serotypes than those observed after the primary dose in the Phase 1 clinical trial. SCR in the highest dose ranged from 81.5% (ST1) to 95.8% (ST2) on Day 85, as can be seen in the figure below:



The figure below shows VLA15 201 GMT for OspA-specific IgG for Serotypes 1-6 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. The figure below shows SCRs measured at Day 85 of VLA15-201 for OspA-specific IgG antibodies per serotype and age group.

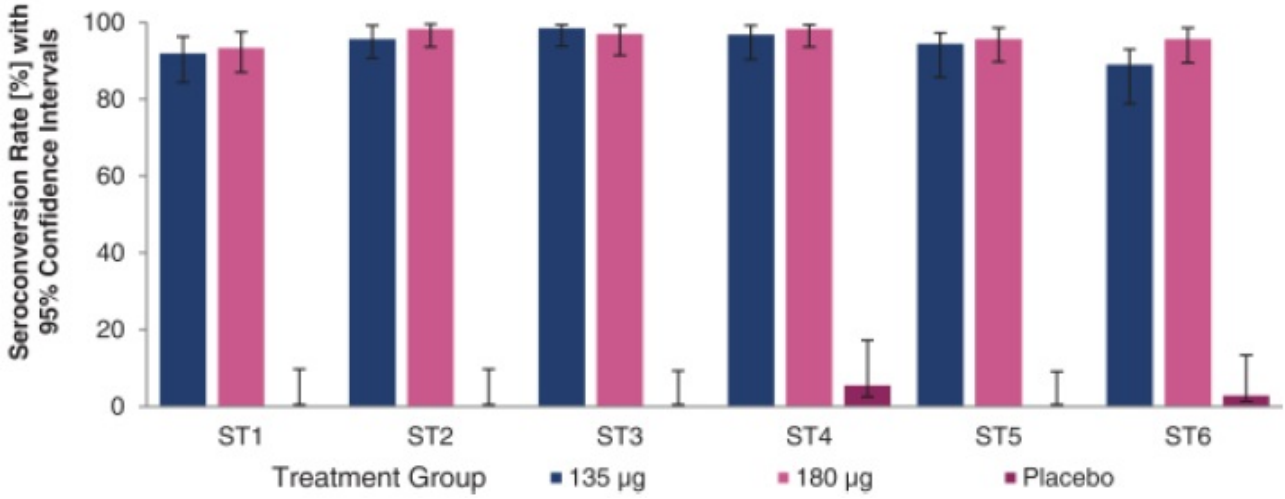


VLA15 was generally well tolerated across all dose and age groups tested. No serious adverse events related to VLA15 were observed in any treatment group. The most common solicited local adverse events were injection site pain (68.4%) and tenderness (76.6%), whereas the most common solicited systemic 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

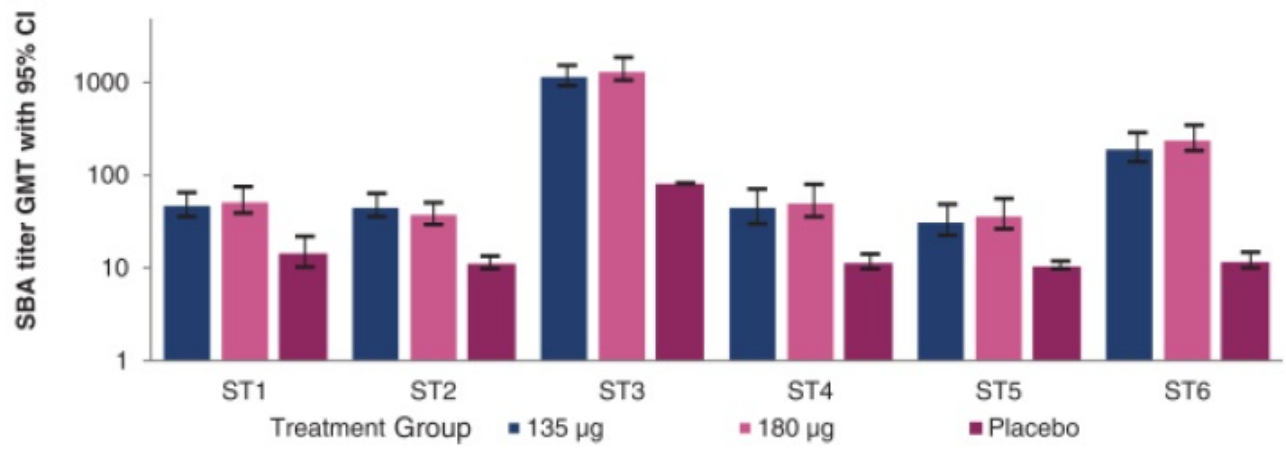
Our second Phase 2 clinical trial, VLA15-202, is a randomized, observer-blind, placebo-controlled multi-center Phase 2 clinical trial conducted in the United States with 246 healthy volunteers aged 18-65. The subjects were randomized 2:2:1 to receive either VLA15 with alum (either 135 µg or 180 µg) or 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 statistically significant 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 illustrated in the figure below, which shows SCRs as of Day 208.



Antibody responses were comparable in the two dose groups tested. 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. The figure below shows the GMT for OspA-specific SBA Titer, per serotype at day 208.



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 (Figure 1). All participants seroconverted to anti-OspA IgG after the booster dose, meaning SCRs were 100% for all OspA serotypes (Figure 2). 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.

Figure 1. Geometric Mean Titer (GMT) for OspA Serotypes 1-6 (measured by ELISA) over time for Group 180 µg w/B, Booster PP Population

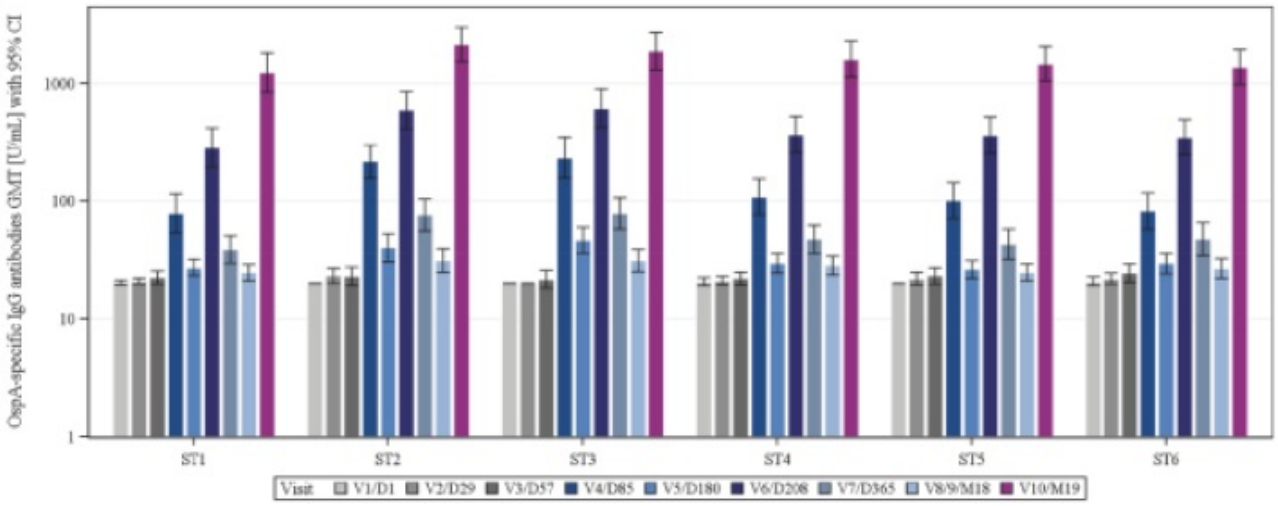
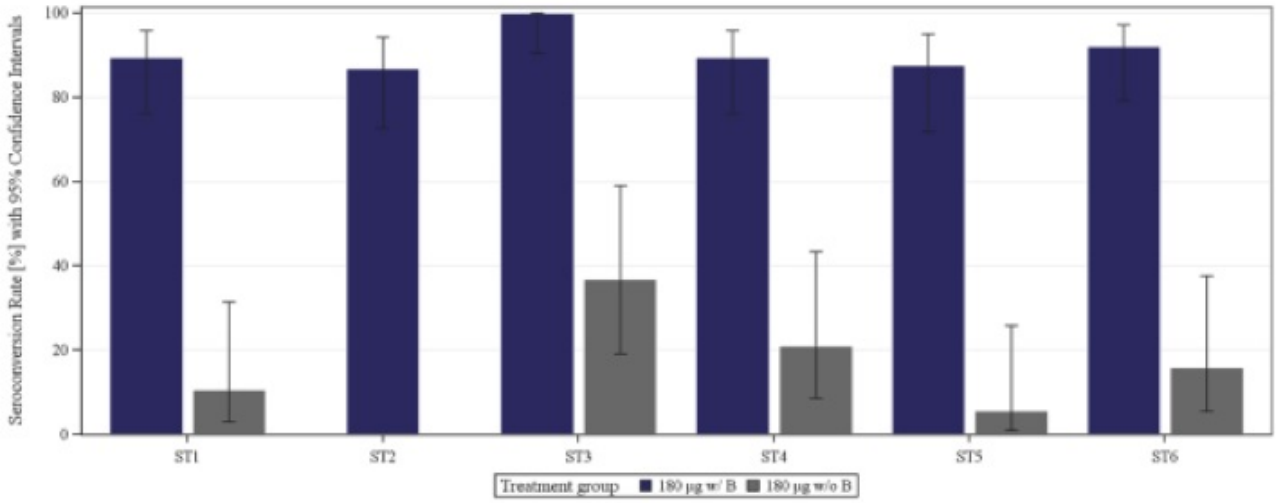


Figure 2. Seroconversion Rate (SCR)* for OspA-specific SBA Titer, per Serotype, at Month 19 (Booster PP Population)



Note: No bar is shown if there is no seroconverted subject for a serotype in the respective treatment group.

* *SCR (Seroconversion Rate) is defined as rate of subjects that change from seronegative to seropositive (SB titer above the quantitation limit of 20 for ST1, 2,3,4, 5 and 6 and 160 for ST3) or as a > 4-fold rise in IgG antibody titer from Visit 1 for subjects that are seropositive at Visit 1 (baseline).*

VLA15-221 Clinical Trial

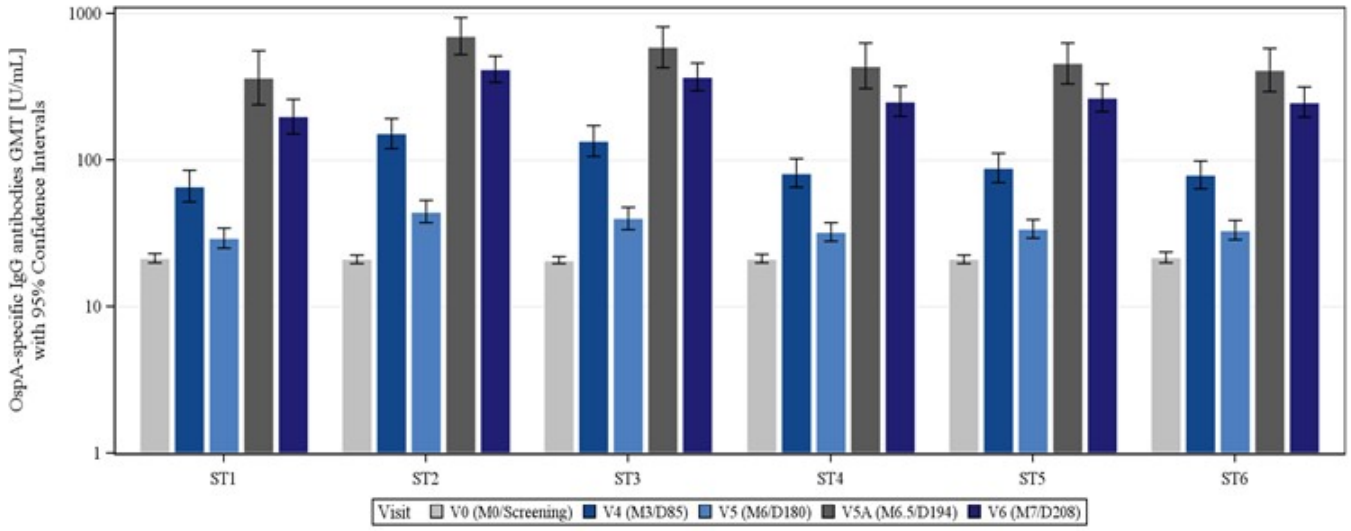
On December 2, 2020, we announced the acceleration of the pediatric development of VLA15. The Phase 2 clinical trial VLA15-221, which commenced in March 2021, is the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old. We announced completion of recruitment 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.

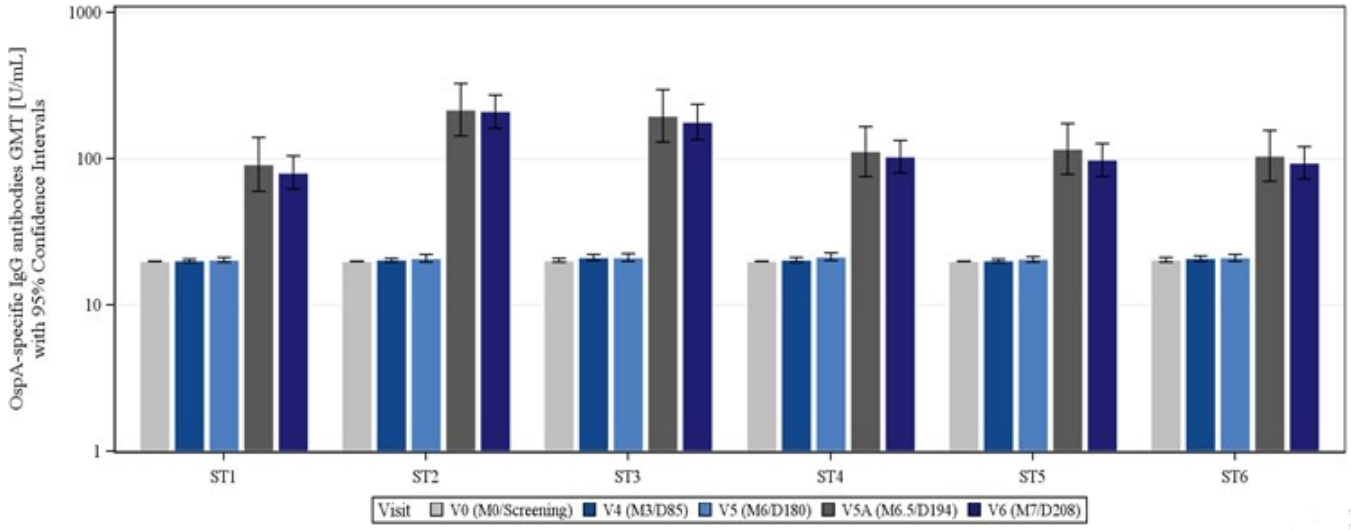
The main safety and immunogenicity readout was performed approximately one month after completion of the primary vaccination schedule (i.e. at Month 7), when peak antibody titers were anticipated. A subset of participants will receive a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and 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 dose, 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, as shown in the first graph below, compared to those who received the two-dose primary series, as shown in the second graph below. Based on these results, we and Pfizer plan to proceed with a three-dose primary series vaccination schedule in the planned 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.

GMTs for OspA STs 1-6 over time, Study Group 2 (adults aged 18-65) (Month 0-6, Per-Protocol Analysis Set)



GMTs for OspA STs 1-6 over time, Study Group 2 (adults aged 18-65) (Month 0-6, Per-Protocol Analysis Set)



The VLA15-221 trial is ongoing to assess the safety and immunogenicity of VLA15 in 5-17 year old participants. Initial pediatric data from VLA15-221 are expected in the first half of 2022.

Phase 3 Trial

We are working closely with Pfizer on a large-scale efficacy trial which will be conducted in the United States, Canada and countries in the European Union. The pivotal field efficacy trial will evaluate the ability of a VLA15 vaccine regimen to prevent Lyme disease compared to a placebo regimen. We anticipate that this trial will start in the third quarter of 2022, subject to feedback from regulatory authorities. Initial data, based on the first tick season of the trial, may be reported by the end of 2023. If the results from this Phase 3 trial are positive, we expect Pfizer to submit a BLA and MAA.

The planned Phase 3 field efficacy trial is expected to be a fully randomized, placebo-controlled clinical trial in which participants will be randomized to receive either VLA15 180µg, with alum, or placebo, with a three-dose primary immunization schedule (0-1-6 month). A booster vaccination will be given to all participants 12 months after receiving the last dose of the primary vaccinations. The planned primary endpoint for the Phase 3 clinical trial will be the efficacy of VLA15 compared to placebo in preventing confirmed Lyme disease during the first tick season after completing the primary series vaccination (i.e., April to October 2023). In case this endpoint is not met after the first tick season, efficacy of VLA15 in preventing confirmed Lyme disease in the second Lyme disease season after participants also receive the 12-month booster dose (i.e., April to October 2024) will be the basis for potential vaccine licensure. Enrollment in this trial is expected to begin in the third quarter of 2022 and primary vaccinations are expected to be completed by March 2023, prior to start of the tick season.

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. VLA1553 has received Fast Track and Breakthrough

Therapy designation from the FDA and PRIME designation from the EMA. We have also received confirmation for our proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, we plan to seek licensure of VLA 1553 based on a surrogate of protection agreed with the FDA and the EMA. The surrogate of protection is an immune response that predicts protection against clinical endpoints and 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. The rates of infection are observed and compared at various points in time across each of the various trial groups. The final Phase 3 clinical trial data that we announced in March 2022 indicated a seroprotection rate of 98.9% compared to the 70% threshold surrogate of protection (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. We reported positive topline results of our pivotal Phase 3 trial involving over 4,000 healthy adults in August 2021 and reported final results, including six-month follow-up data, in March 2022. These final results confirmed a very high level of seroprotection, with 98.9% of participants achieving protective levels of CHIKV neutralizing antibodies one month after receiving a single vaccination, and 96.3% of participants showed protective CHIKV neutralizing antibody titers six months after this single vaccination. These reported seroprotection levels far exceeded the 70% threshold (for non-acceptance) based on a surrogate of protection agreed with the FDA under the accelerated approval pathway. 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 750 healthy volunteers in Brazil in 2022, which has been approved by the local regulatory agency, ANVISA, and will be sponsored by Instituto Butantan. We have been awarded up to $23.4 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.

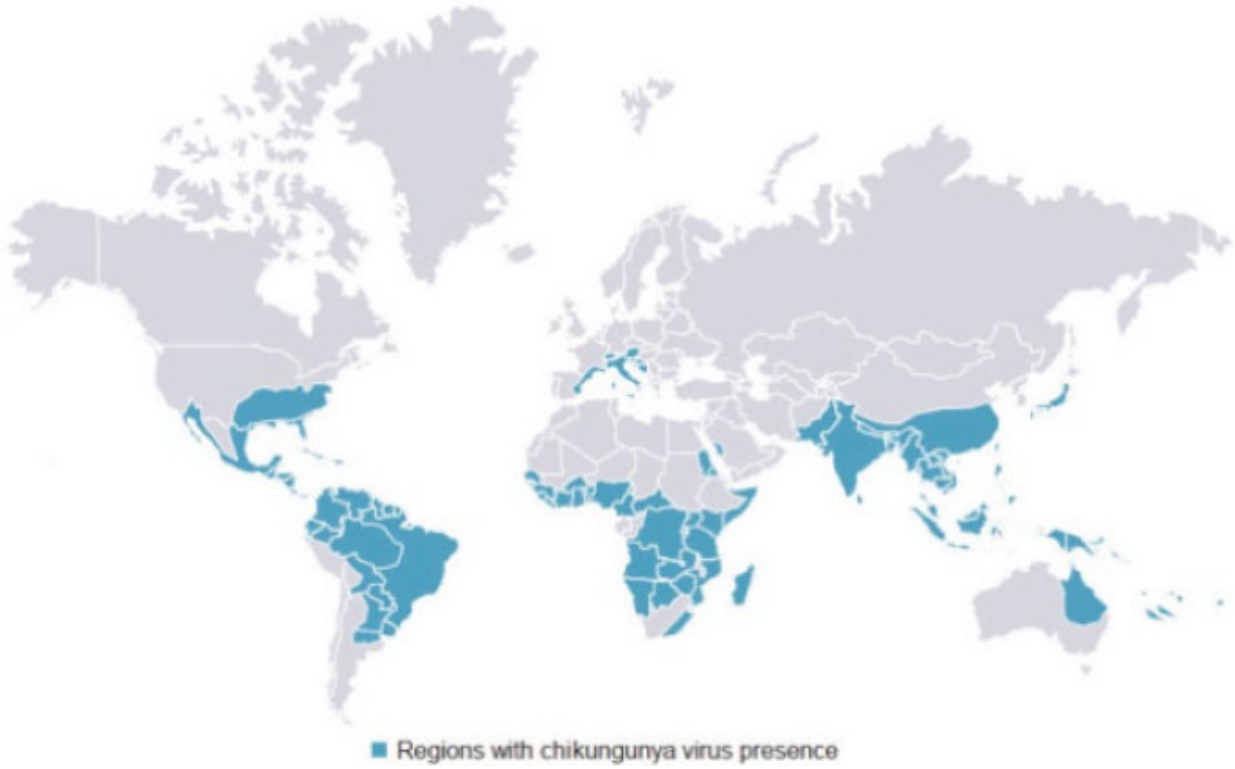
Overview of the chikungunya virus

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 the spread of the virus across the globe as of 2019 following various regional outbreaks:



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 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 three third-party advanced chikungunya vaccine candidates. The first is a measles-vectored vaccine candidate developed by Merck, which has completed Phase 2 clinical testing with positive results, but has not publicly announced initiation of Phase 3 clinical trials. The second is an inactivated vaccine candidate manufactured by Bharat Biotech of India, which has initiated a seamless Phase 2/3 clinical trial. The third 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, Merck's and potentially Emergent BioSolution's 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 ESCA, 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.

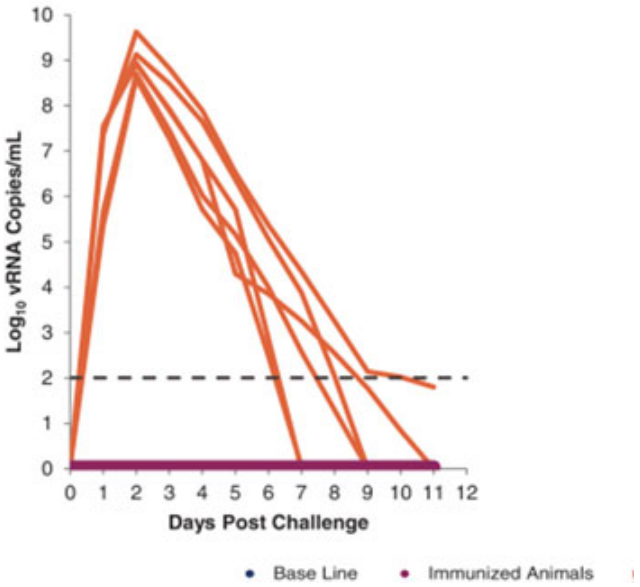
Pre-Clinical Data

A comprehensive pre-clinical assessment of VLA1553 evaluating this VLA1553 for advancing to clinical trials as a single administration observed the following:

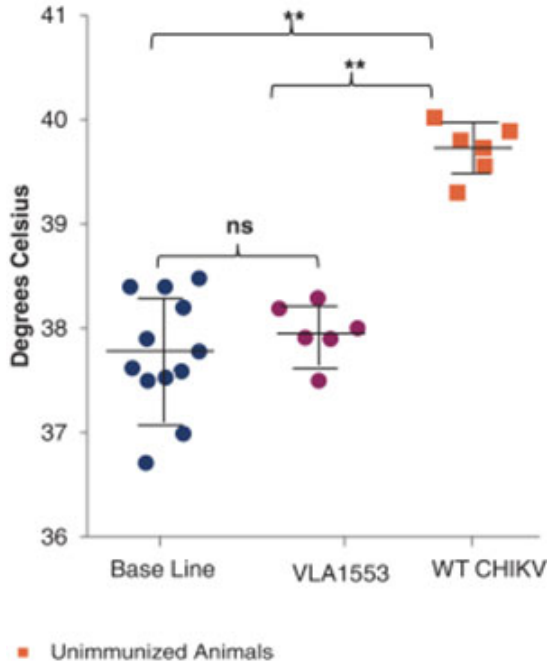
- It was highly immunogenic and induced a strong and long-lasting neutralizing antibody response in non-human primates, or NHPs, models after a single administration.
- It was protective in NHPs that received a high-dose of wild-type, or WT, chikungunya virus after vaccination.
- It was not observed to cause any of the clinical manifestations such as viremia, fever and rash that NHPs typically develop after infection with the WT chikungunya virus, and caused lower and delayed virus titers compared to an infection with the WT virus.

To assess the ability of VLA1553 to prevent chikungunya infection in NHPs, immunized animals were challenged with a dose of chikungunya that was 100-fold higher than the dose typically required to induce viremia in 50% of the animals. The figures below show the results of this study:

Viremia Post Challenge of Individual Animals



Comparison of Temperature between Day 0 and Day 2 Post Infection

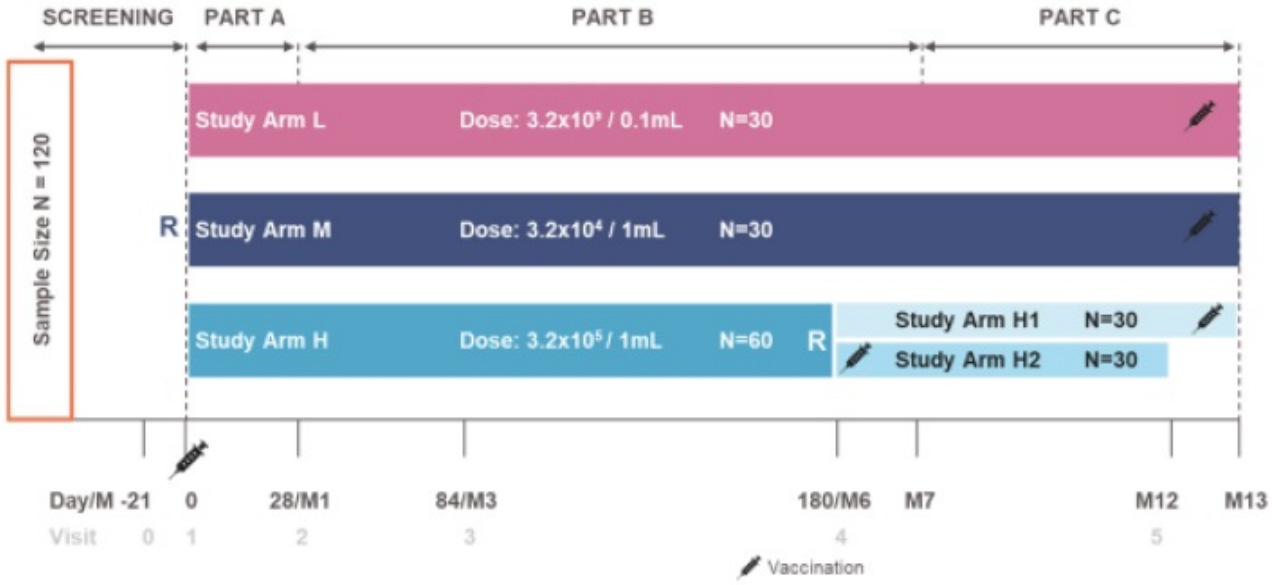


** denotes statistically significant difference ($p<0.01$)

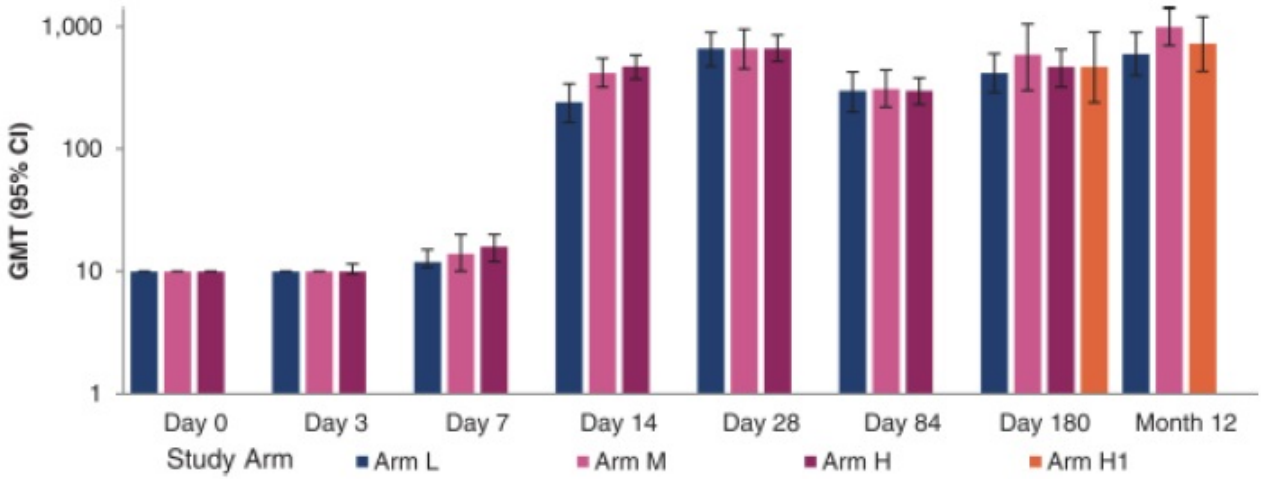
The above left figure shows that whereas unimmunized animals showed a rapid increase in viral load within one day of the challenge, as depicted by the orange lines, there was no detectable viremia in any of the immunized animals, as depicted in the purple line on the x-axis. The dotted line represents maximum level of viremia present in immunized NHPs for which the vaccine would have been considered effective. The above right figure shows that there was no increase in body temperature in immunized animals upon chikungunya challenge compared to unchallenged controls.

Phase 1 Clinical Trial and Results

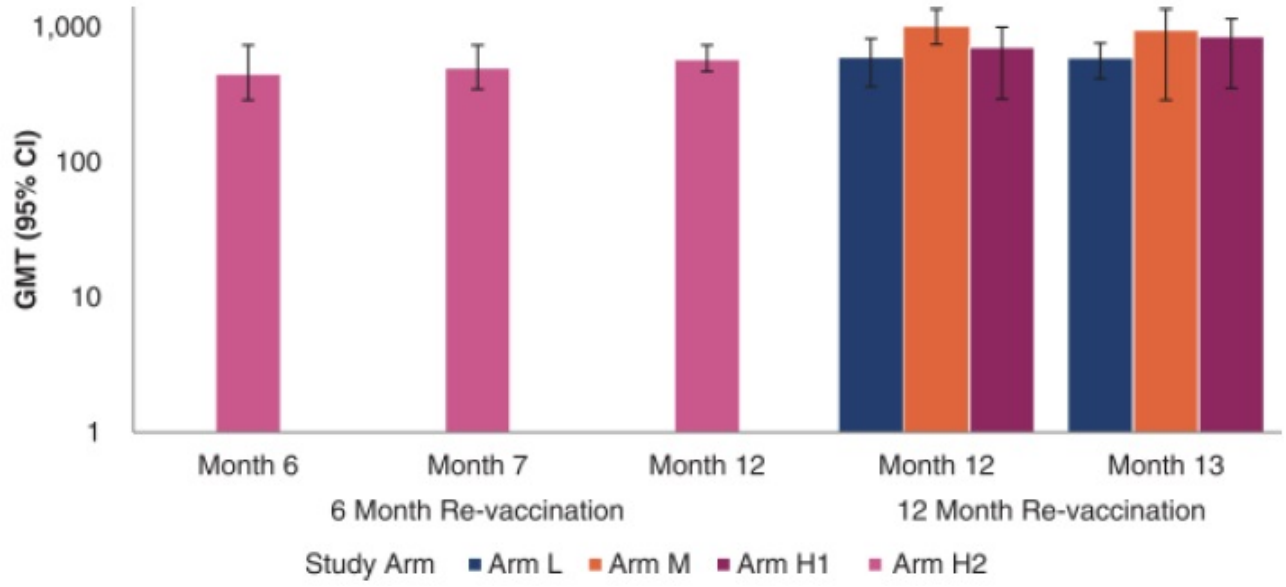
We conducted a single blind, randomized dose-escalation Phase 1 clinical trial of VLA1553 in 120 adults, at multiple centers in the United States, the results of which were published in Lancet in 2020. In this trial we examined three doses of VLA1553: a low dose having a viral titer of 3.2 x 10^3, a medium dose of 3.2 x 10^4, and a high dose of 3.2 x 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. A summary of our Phase 1 trial design is depicted in the figure below:



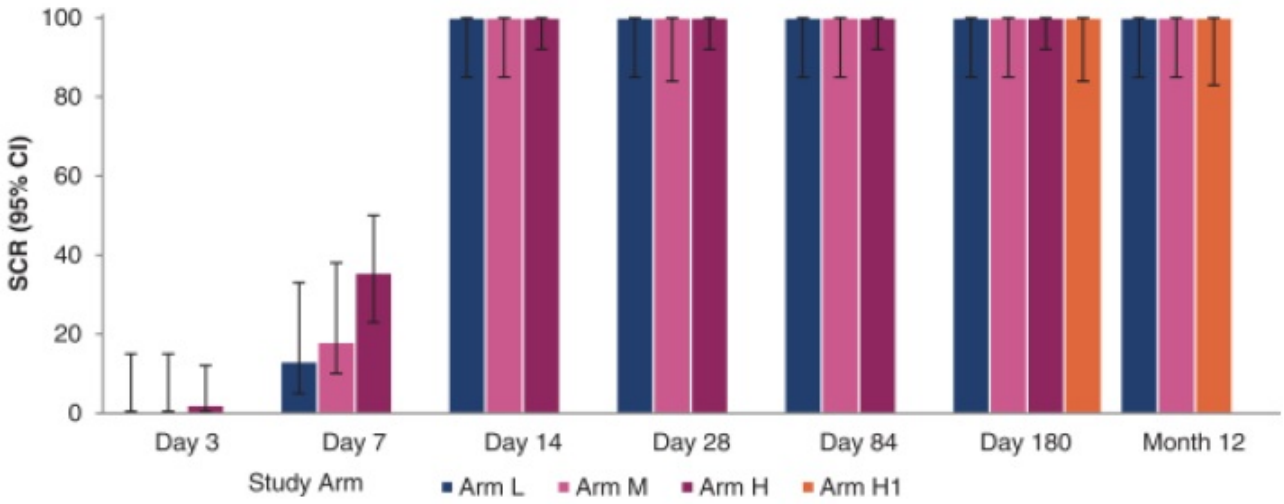
Chikungunya virus neutralizing antibodies were observed in 100% of patients for 12 months at all three of the doses evaluated as can be observed in the figure below. A single vaccination was sufficient to induce sustaining high-titer neutralizing antibodies at twelve months post vaccination.



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, as is illustrated in the below figure. This result suggests that a single dose of VLA1553 could offer sufficient protection with no additional booster required.

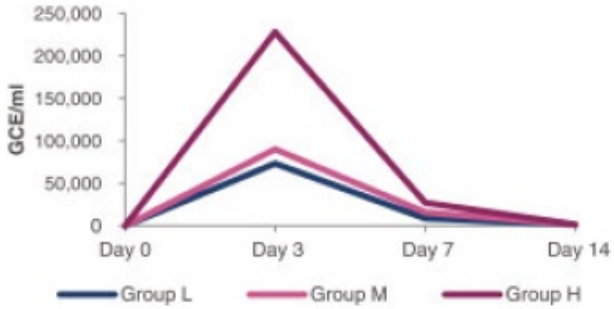


The titer of these neutralizing antibodies was assessed by determining how far the antibodies in the plasma could be diluted and still reduce *in vitro* viral infection by 50%, a commonly used parameter referred to as the neutralization titer or NT_{50}. Seroconversion was defined as having an NT_{50} 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 as can be observed in the figure below:

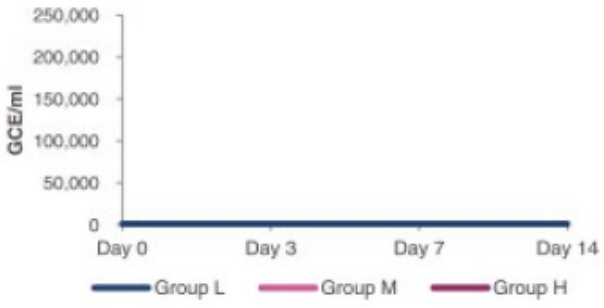


Plasma of the trial volunteers was screened for viremia, which peaked at day three in all groups and was lower in the low-dose and medium-dose groups. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

Viremia after Single Vaccination



Viremia After Re-Vaccination with VLA1553



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.

We have received concurrence from the FDA on our proposal to utilize the accelerated approval pathway, which will enable us to potentially submit a BLA for this candidate based on clinical trial data on an immunological surrogate of protection, rather than observing natural rates of infection between trial participants receiving our vaccine and the placebo. 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 and rates of infection are observed and compared at various points in time across each of the various trial groups. As part of the accelerated approval pathway, we will be required to conduct a confirmatory trial.

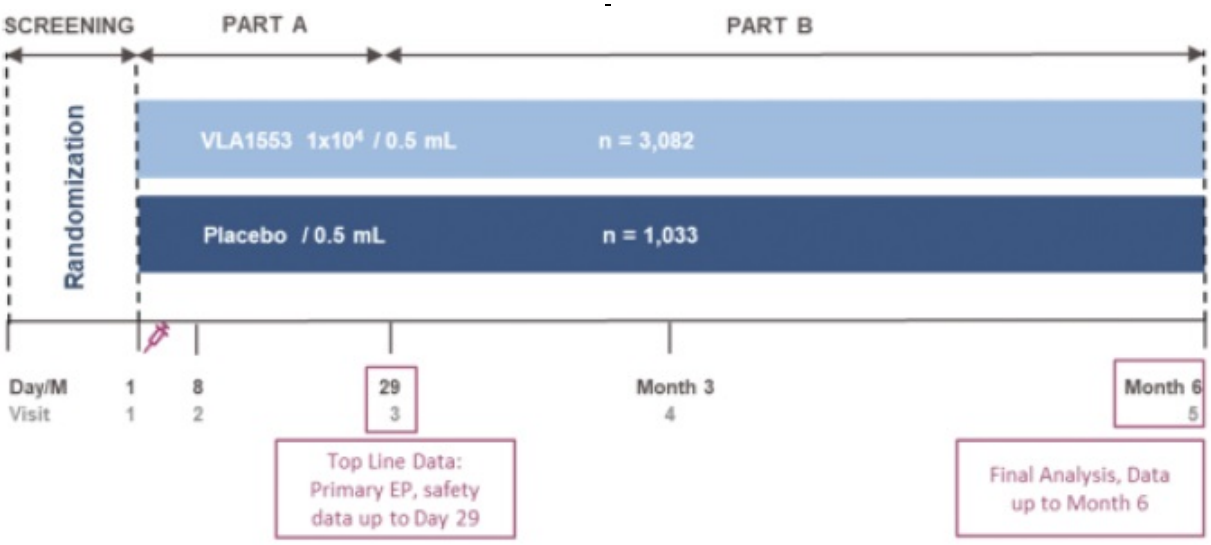
Phase 3 Clinical Trials

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 graphic below shows the design of the Phase 3 clinical trial.

Design of the VLA1553 Phase 3 Trial



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 seroprotection rate result of 98.9% exceeded the 70% threshold (for non-acceptance) agreed with the FDA (Figure 3). The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission for approval of VLA1553 under the accelerated approval pathway. 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 (Figure 4).

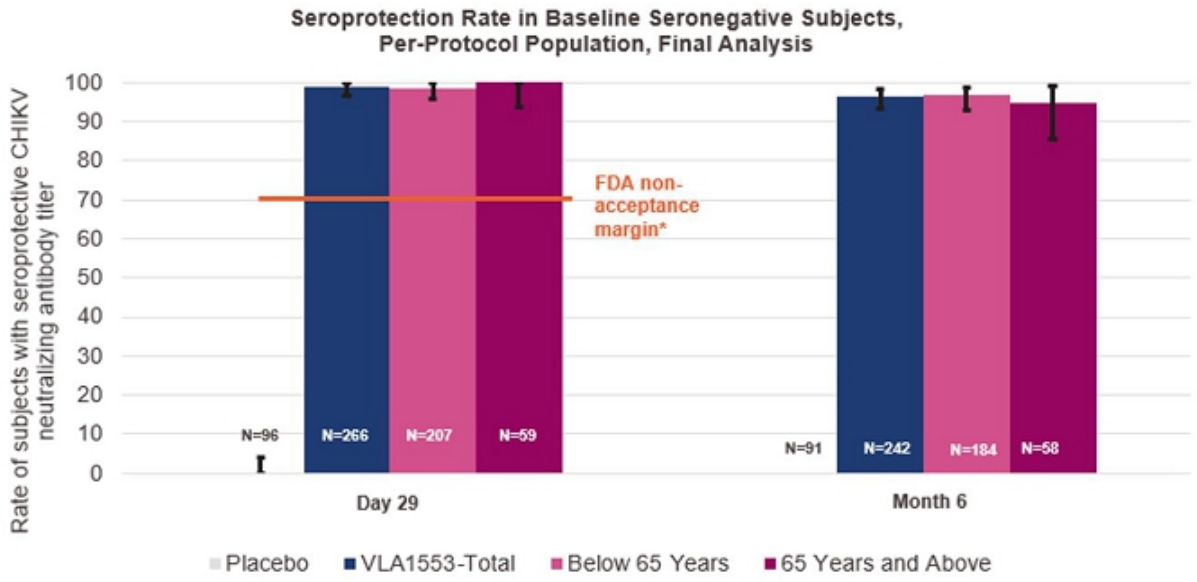


Figure 3. Seroprotection Rate at Day 29 and Month 6 in Baseline Seronegative Subjects, PP Population, for All Immunogenicity Subset Subjects Receiving VLA1553 Combined and Stratified by Age Group.

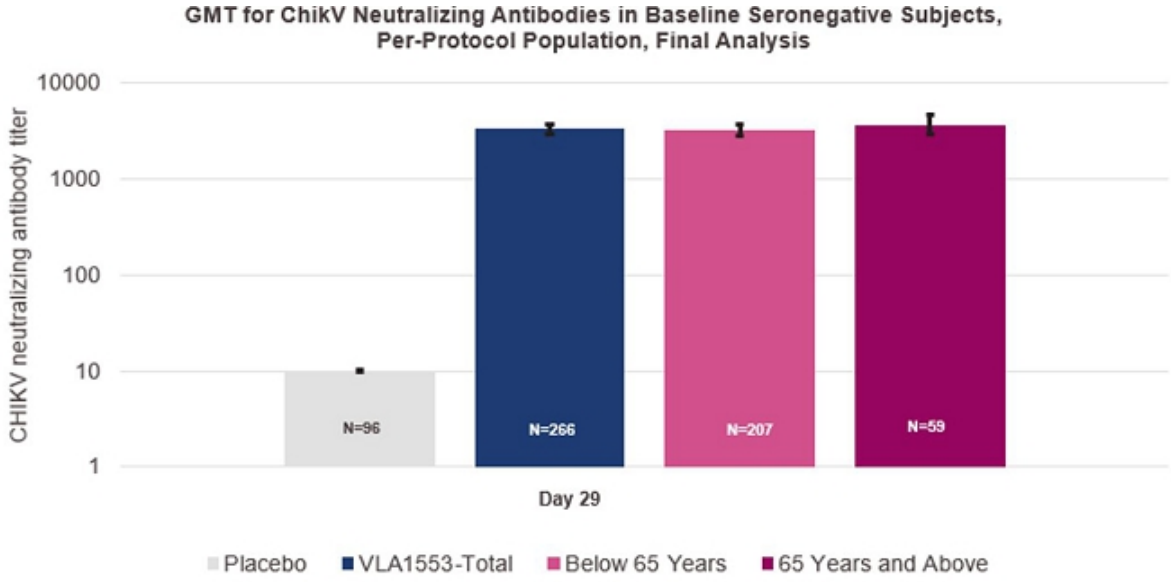


Figure 4. Geometric Mean Titers for CHIKV Neutralizing Antibodies at Day 29 in Baseline Seronegative Subjects, PP Population, for All Immunogenicity Subset Subjects Receiving VLA1553 Combined and Stratified by Age Group.

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 topline 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 seroprotection rates and neutralizing antibody titers over time as younger adults.

A dedicated antibody persistence trial, VLA1553-303, will monitor a subset of VLA1553-301 study participants for a period of at least five years to confirm the anticipated long-term protection after a single vaccination.

VLA1553-302 Clinical Trial

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

VLA1553-302 is a prospective, multicenter, randomized, pivotal Phase 3 clinical trial. Participants in the VLA1553-302 trial were randomized and will be followed for a total of six months. The objective of the trial is 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 are administered as a single intramuscular immunization. Equivalence of immune responses will be determined based on neutralizing antibody titers. The primary objective of the trial is 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.

VLA1553-302 will continue to run in parallel to VLA1553-301. Final trial results of the lot-to-lot trial are expected in the second quarter of 2022. The lot-to-lot data will be part of our submission to the FDA planned for later in 2022.

VLA1553-303 Clinical Trial

In April 2021, we initiated an antibody persistence trial that will follow 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.

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. 750 adolescents from 12 to 17 years old will be 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.

VLA2001—Our vaccine candidate targeting COVID-19

We are developing VLA2001 as a vaccine against SARS-CoV-2, the virus that causes COVID-19. We have taken advantage of the viral production infrastructure which we assembled to manufacture IXIARO to rapidly generate an inactivated SARS-CoV-2 vaccine candidate. We initiated a pivotal Phase 3 clinical trial of VLA2001, Cov-Compare, in April 2021 and reported positive topline data from this trial in October 2021. In this trial, we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of GMT for neutralizing antibodies, as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. Additionally, we reported positive homologous booster data in December 2021 and announced initiation of further booster studies in January 2022. We also announced in January 2022 that a laboratory study had confirmed that VLA2001 produced neutralizing antibodies against both the Delta and Omicron variants of the SARS-CoV-2 virus.

The results of the Cov-Compare clinical trial have been submitted as part of our regulatory review processes with the MHRA in the United Kingdom, the EMA, and the Bahraini NHRA. VLA2001 received an Emergency Use Authorization from the NHRA in February 2022, and we believe that we may expect a potential conditional marketing authorization from the EMA in April of 2022. Further submissions to other regulatory agencies may take place in 2022.

While a number of vaccines against COVID-19 have already been approved for use and multiple candidates remain in late stage development, VLA2001 currently is the only inactivated, whole virus vaccine candidate in clinical trials in Europe. We believe VLA2001 could potentially offer clear benefits in terms of safety, cost, ease of manufacture and distribution compared to previously approved vaccines in territories where it may be approved and could also be adapted to offer protection against mutations of the virus.

Overview of COVID-19

COVID-19 is a disease caused by infection with SARS-CoV-2, a strain of coronavirus. Respiratory illness is the most common symptom associated with COVID-19, with a severity ranging from mild disease to life-threatening acute respiratory distress syndrome. Patients with advanced age, comorbidities such as obesity, diabetes and cardiovascular disease, or an immunocompromised state are at increased risk for poor outcomes. COVID-19 has been declared a pandemic by the World Health Organization, or WHO. As of March 1, 2022, there have been more than 434 million confirmed cases of COVID-19, including nearly six million deaths, reported to the WHO. As of March 1, 2022, more than 10 billion vaccine doses have been administered worldwide.

Several therapies are currently being investigated or have been approved or authorized to treat or prevent COVID-19. These include therapies being developed to directly target SARS-CoV-2 such as small molecules, oral antiviral, and monoclonal antibody therapies. For example, the FDA has granted emergency use authorization to Gilead's Veklury (remdesivir) and Regeneron and Eli Lilly's monoclonal antibody therapies for the treatment of hospitalized patients with suspected or laboratory-confirmed COVID-19 and has approved remdesivir for a subset of this population. In addition to treatments directed at the virus, there are immunomodulatory therapies such as interleukin-6 inhibitors, steroids, JAK inhibitors, and anti-tumor necrosis factor antibodies which are being developed to treat the host inflammatory response to the disease.

Biopharmaceutical companies and academic centers have now developed prophylactic vaccines based on several platforms including mRNA, adenoviral vectors and recombinant proteins. As of March 1, 2022, five vaccines have been approved by US or European regulatory authorities. Although there have been preliminary data released on the ability of some of these vaccines to generate neutralizing antibodies that can prevent severe COVID-19 disease, no data on their potential to prevent mild or asymptomatic infection or the transmission of the virus to others have been publicly presented. We believe that the worldwide need for an effective vaccine to prevent COVID-19 will not be adequately addressed by first-wave vaccines and product candidates alone as governments must take into consideration safety, cost, ease of manufacture and distribution and indications for specific populations of each vaccine while trying to vaccinate as many people as possible.

VLA2001 Approach

We are developing VLA2001, an inactivated, whole virus SARS-CoV-2 vaccine candidate based on our platform and technical capabilities derived from our marketed IXIARO vaccine. We believe there is an opportunity, particularly among competitors based in the United States and Europe, to commercialize a vaccine based on an inactivated whole virus, a technology that has been well-validated in the clinic and commercial market for other viral diseases. We have seen that inactivated SARS-CoV-2 vaccines have shown efficacy and safety comparable to other types of vaccines against SARS-CoV-2. When taking safety into account, we believe that VLA2001 may offer advantages compared to vaccines using other technologies. The inactivated whole SARS-CoV-2 virus cannot replicate inside human cells and therefore cannot cause illness. For example, the novel mRNA vaccines tend to be more reactogenic (causing adverse effects) than traditional inactivated vaccines. An inactivated virus vaccine may also offer advantages in manufacturing, storage and distribution. For example, we expect VLA2001 to be stable at 2 to 8 degrees Celsius, the temperature of a standard refrigerator, and to have a longer shelf life than current mRNA vaccines. In addition to these advantages, we believe our flexible approach to the clinical and manufacturing development of VLA2001 will facilitate our ability to meet the needs of future customers, including playing a key role in providing supply for any potential booster programs.

We have entered into a collaboration with Dynavax Technologies for the use of their adjuvant CpG 1018, a component of their FDA- and EMA-approved hepatitis B vaccine, in VLA2001. See “Item 10.C—Material Contracts—Dynavax Supply Agreement” for more information about this collaboration. Clinical trials with hepatitis B vaccination consistently demonstrated more pronounced induction of protective antibody titers with CpG 1018 compared to alum. We believe that the use of alum and CpG 1018 could further enhance the broader immune response that we expect from VLA2001 as an inactivated whole virus vaccine.

VLA2001 is produced from SARS-CoV-2 grown on Vero cells, the same cells used to produce IXIARO. The highly purified whole virus is then inactivated using ß-propiolactone.

We commenced manufacturing of VLA2001 at our facility in Livingston that has been producing FDA/EMA/MHRA approved commercial-grade travel vaccines for more than a decade. We began expanding our Livingston facility in 2020 in order to accommodate manufacturing of VLA2001, and we anticipate completing that expansion in 2022. We are targeting an annual manufacturing capacity of 100 million doses of VLA2001, including the production we have outsourced to IDT Biologika in Germany.

We commenced in-human clinical trials for VLA2001 in December 2020 and announced initial positive results from our Phase 1/2 clinical trial in April 2021. We initiated our pivotal Phase 3 clinical trial shortly thereafter and announced positive topline Phase 3 data in October 2021, in which VLA2001 met both of the co-primary endpoints of the trial. We received an Emergency Use Authorization from the NHRA in Bahrain in February 2022 and have rolling review processes ongoing with the MHRA and EMA. We expect that we may receive a conditional marketing authorization from the EMA in April 2022.

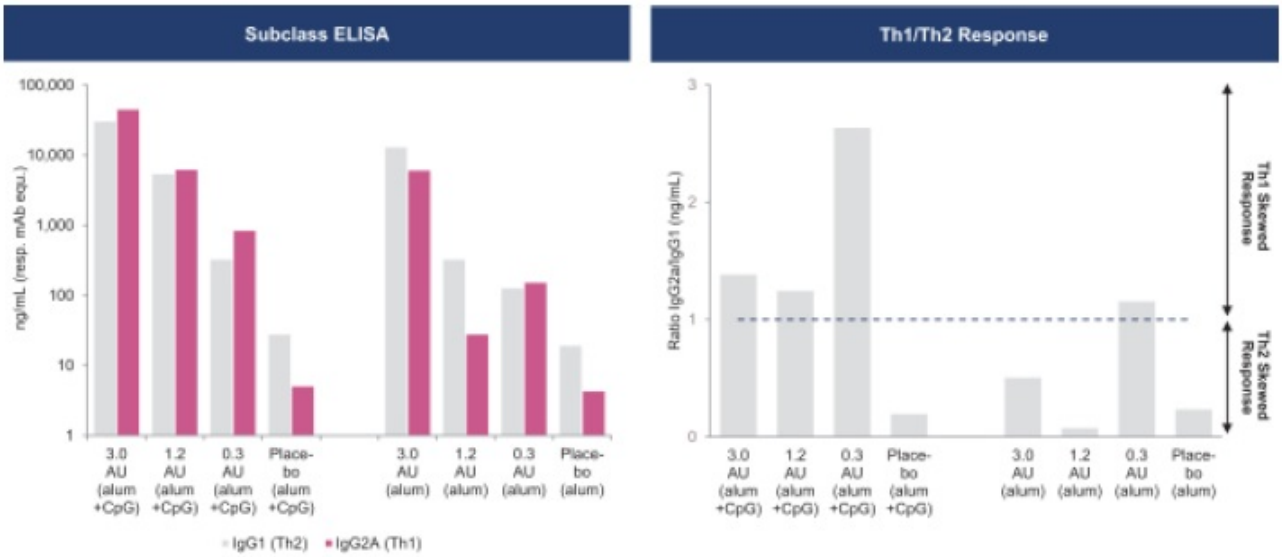
Pre-clinical Trial and Results

In our pre-clinical experiments, we evaluated the immunogenicity of VLA2001 using female BALB/c-strain mice. We immunized mice two times subcutaneously with a dose of 100 µL VLA2001 vaccine on days 0 and 21. The mice were dosed in three groups, one that received a placebo (buffer with alum adjuvant only or buffer with alum and CpG 1018 only), one that received VLA2001 with alum in 3 different dose levels, and one that received VLA2001 with alum and CpG 1018 in the same three different dose levels.

Blood samples were collected from the mice on days 14, 28 and 35 and immune responses were measured as follows: ELISA (enzyme-linked immunosorbent assay) titers for total IgG and antibody neutralization titers by PRNT (plaque reduction neutralization test). The Th1 (IgG2a)/Th2 (IgG1) response was determined in a subclass ELISA. IgG2a is associated with a Th1 response. IgG1 is associated with a Th2 response. A strong Th1 response is important to minimize potential risks for vaccine mediated enhanced respiratory disease (VAED) or antibody disease enhancement (ADE) upon infection, as one potential cause for VAED or ADE may be a strong Th2 response.

We have also observed that the alum+CpG 1018 adjuvant formulation of VLA2001 consistently induced higher IgG antibody titers in mice than the alum-only formulation. With regards to the functional antibody response, sera from BALB/c mice immunized with VLA2001 plus alum+CpG 1018 showed neutralization titers close to the ones present in serum from human convalescent COVID-19 patients.

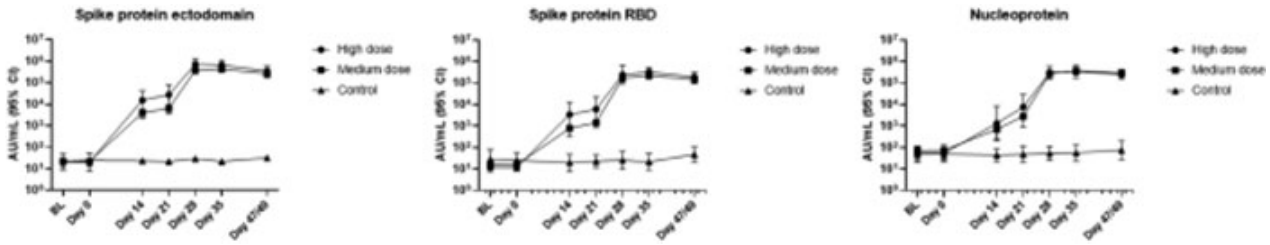
When determining the ratio for IgG subclasses (amount of IgG2a/ amount of IgG1), we observed that the addition of CpG 1018 led to a significant shift of the immune response towards a Th1 response (ratio >1), as shown below, whereas VLA 2001 formulated with alum only induced a Th2-skewed immune response.



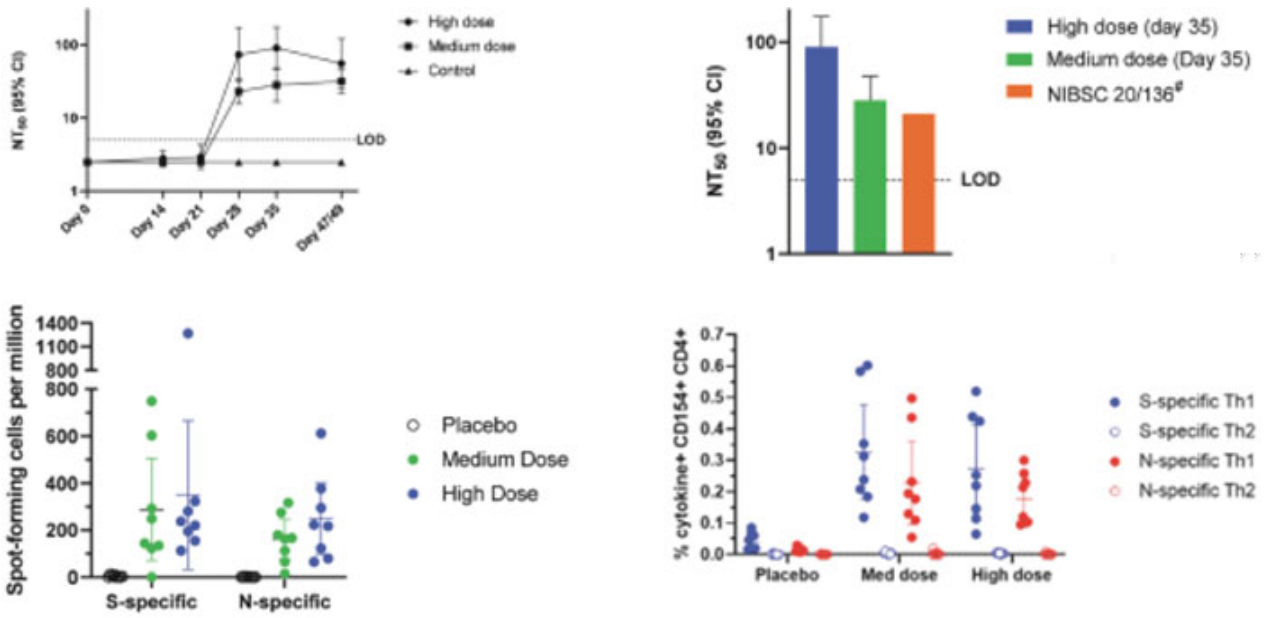
These pre-clinical results supported the advancement of our clinical development program and initiation of our first in human study of our VLA2001 vaccine candidate.

Immunogenicity and efficacy of VLA2001 in non-human primates

To investigate the immunogenicity and efficacy of VLA2001in non-human primates, groups of eight cynomolgus macaques were vaccinated twice with placebo, a medium dose of VLA2001 (7 antigen units, AU), or a high dose of VLA2001 (35 AU). The vaccinations were administered on day 0 and 21 of the study and the animals were subsequently challenged on day 47 or 49 with 105 PFU of SARS-CoV-2 (strain BetaCoV/France/IDF/0372/2020) through simultaneous intranasal and intratracheal infection. Sera were collected at several time points during the study and analyzed for the presence of antibodies that bind SARS-CoV-2 antigens by ELISA. As shown below, significant levels of antibodies that bind the spike glycoprotein (left), the receptor-binding domain of the spike protein (middle), and the nucleoprotein (right) were seen after the first vaccination with both the medium and high dose. The second vaccination on day 21 clearly boosted the magnitude of the antibody responses against all three antigens. There was not a significant difference between the medium and high dose in this assay.



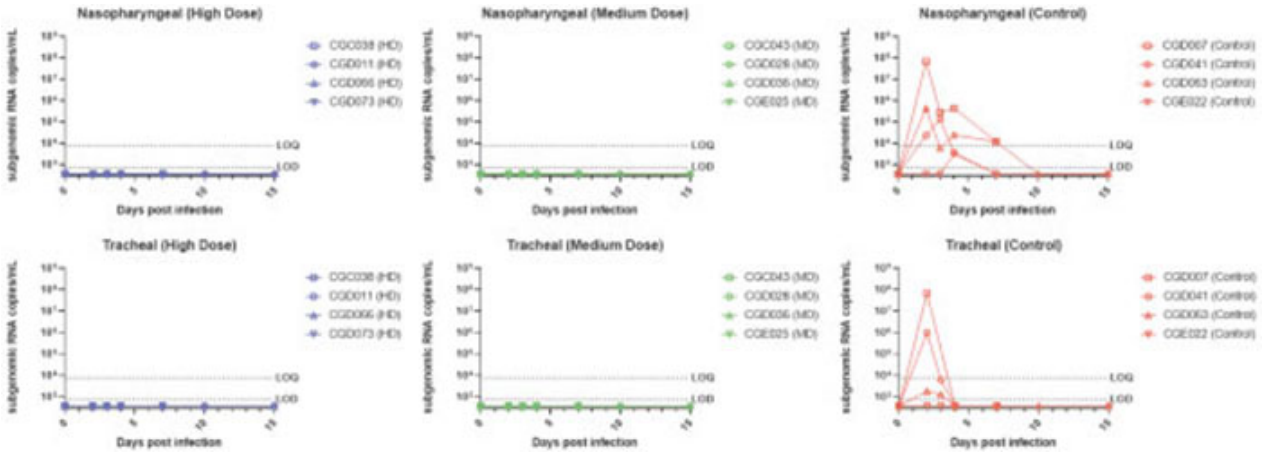
The sera were also used to assess virus-neutralizing responses using a cytopathic-effect based microneutralization assay. The line graph below shows that two vaccinations were required to induce a significantly neutralizing response compared to control animals. Further, the high dose elicited a significantly stronger neutralizing response than the medium dose (P=0.0119). Sera taken at the peak of the immune response from vaccinated animals was also compared in the same neutralization assay to a WHO standard serum preparation (NIBSC 20/136). As seen in the bar graph below, the responses in vaccinated animals were at least as strong as this international standard.



Peripheral blood mononuclear cells (PBMCs) were isolated from each animal 14 days after the second vaccination and analyzed by IFN ELISpot. PBMCs were restimulated with peptide pools for the spike (S) protein and the nucleoprotein (N). As seen in the top panel on the left, both the medium and high dose of the vaccine elicited cellular immune responses.

The PBMCs were further characterized using intracellular cytokine staining to assess the Th1/Th2 bias of the response. Cells were restimulated as below and stained with antibodies specific for different cellular markers (e.g. CD4) and cytokines. For this analysis, the cytokines IFN, TNF, and IL-2 were considered representative of a Th1 response and IL-13 of a Th2 response. The bottom graph to the left shows that whereas cells expressing IFN, TNF, or IL-2 were abundant, cells expressing IL-13 were practically not detectable. Thus, consistent with our observations in mice, the non-human primate response to VLA2001 vaccination was heavily Th1-biased.

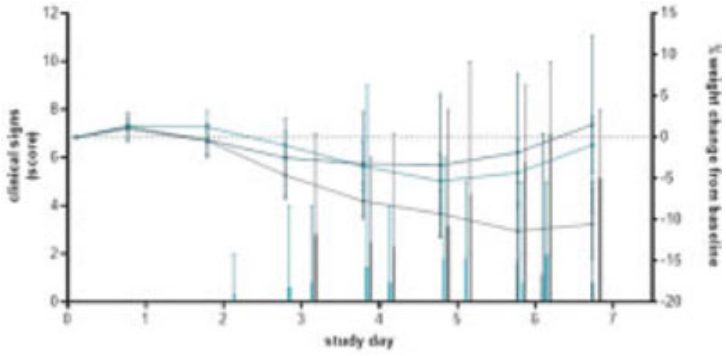
Following challenge, tracheal and nasopharyngeal swabs were taken from the animals to monitor the presence of viral subgenomic RNA using RT-qPCR. As seen below, while several of the control animals (right) showed signs of viral replication, i.e. presence of viral RNA, none of the vaccinated animals (right, high dose; middle, medium dose) had detectable viral RNA at any time point.



The non-human primate study demonstrated that VLA2001 elicits both spike- and nucleoprotein-binding antibodies, a potently neutralizing serological response, and a Th1-biased cellular response. The immune response induced by vaccination prevented evident viral replication, measured using sub-genomic viral RNA as a surrogate, in the upper respiratory tract.

Passive transfer data for VLA2001

To investigate whether antibodies elicited by vaccination of human subjects with VLA2001 can neutralize SARS-CoV-2 infection, we passively transferred pooled sera from participants in the phase 1/phase 2 trial of VLA2001 to Syrian gold hamsters. The study was performed by Public Health England. Three different serum pools were used either neat or diluted to achieve a range of neutralizing activities transferred to 7 different groups of hamsters. Negative human serum was used as a control. The hamsters were challenged intranasally one day after serum transfer with 5×104 PFU of the Victoria/1/2020 strain of SARS-CoV-2. The body weights of the animals was recorded once daily and clinical signs twice daily for 7 days post challenge. As shown below, animals in group 1 that received the highest dose of passively transferred antibodies (50% neutralizing dose of 1,699) were significantly protected against weight loss (line graphs and right y-axis, P=0.0344 on day 7). Hamsters in other groups were protected against weight loss to an extent that approximately correlated with the dose of transferred neutralizing antibodies. There was also a trend of protection against clinical signs of distress (bar graphs and left y-axis).



ND50s of transferred sera
Group 1: 1,699
Group 2: 521

Group 8: 29 (negative control)
(Groups 3-7 not shown to avoid cluttering, received serum pools with ND50s between 152 and 834 and showed intermediate levels of protection.)

This passive transfer experiment demonstrated that vaccination of humans with VLA2001 elicits neutralizing serological responses that can prevent clinical manifestations of SARS-CoV-2 infection in a passive transfer hamster model.

Cross-Neutralization Studies

We are in the process of evaluating the ability of VLA2001 to neutralize variants of the SARS-CoV-2 virus.

In January 2022, we announced results from an initial laboratory study in which we observed that serum antibodies induced by three doses of VLA2001 neutralized the Delta and Omicron variants of the SARS-CoV-2 virus.

Sera from 30 participants in the Phase 1/2 trial VLA2001-201 were used in a pseudovirus assay to analyze neutralization of the ancestral SARS-CoV-2 virus as well as the Delta and Omicron variants. To assess neutralization, pseudoviruses expressing the spike (S) protein from either the ancestral SARS-CoV-2 virus, the Delta variant, or the Omicron variant were pre-incubated with serial dilutions of individual serum samples and then used to infect target cells. Neutralization was calculated from the reduction of infection efficiency at different serum dilutions compared to a no serum control.

All 30 samples (100%) presented neutralizing antibodies against the ancestral virus and Delta variant, and 26 samples (87%) presented neutralizing antibodies against the Omicron variant. The mean fold reduction of neutralization relative to the ancestral virus was 2.7-fold for Delta and 16.7-fold for Omicron.

VLA 2001 Phase 1/2 Clinical Trial and Results

VLA2001-201 (Primary Vaccination)

We initiated VLA2001-201, our Phase 1/2 randomized, dose-finding trial to evaluate the safety, tolerability and immunogenicity of our inactivated, adjuvanted VLA2001 vaccine candidate in healthy subjects, in December 2020. In January 2021, we announced full enrollment in the trial; a total of 153 healthy adults between 18 and 55 years of age were recruited. We have commenced the Phase 2 portion of the trial.

The trial design consists of a randomized, dose-escalation, multi-center trial with three dose groups (low, medium and high dose), each with 51 subjects who received intramuscular injections three weeks apart. The study is being conducted in two parts: Part A (Day 1 to Day 36) and Part B (Day 37 to Day 208). Part A was divided into an open-label, staggered recruitment for the first 15 subjects and a blinded, randomized part of the study for all remaining 135 subjects. Part B has been initiated following our announcement of immunogenicity and tolerability data from Part A.

The primary safety endpoint of the trial was the frequency and severity of solicited adverse events, or AEs, within seven days after each vaccination. Secondary safety endpoints included frequency and severity of any unsolicited AE, any vaccine-related AE, any serious AE and any AE of special interest. Additionally, the trial included various immunogenicity endpoints: immune response as measured by neutralizing antibody titers against SARS-CoV-2; proportion of participants with seroconversion (in participants negative for SARS-CoV-2 at screening); fold increase of SARS-CoV-2 neutralizing antibody titers compared with baseline; GMTs for IgG against SARS-CoV-2, determined by ELISA; proportion of subjects with seroconversion in terms of IgG antibodies against SARS-CoV-2 as determined by ELISA; and exploratory endpoints on cellular immune response parameters (e.g. T-cell responses against S-, M- and N- antigens of SARS-CoV-2).

For safety reasons, the first 15 subjects were included into the trial in an open-label, not randomized manner following a staggered dose escalation of VLA2001. Dose escalation was done at a single site to ensure permanent oversight on safety data by one principal investigator during the recruitment of the 15 sentinel subjects. A DSMB reviewed the accrued safety data at Day 4 of all 15 sentinel subjects.

The remaining 138 subjects were enrolled, screened and randomized in a 1:1:1 fashion to the three dose groups in the blinded part of the trial. Subjects were observed for 30 minutes post-vaccination on Day 1. An unscheduled safety telephone call was performed in case a Grade 3 AE or serious AE was reported by the subject via eDiary. All subjects were followed by eDiary for seven days post vaccination, starting on the day of vaccination. Subjects returned to the study site on Day 8 (visit 2). After approximately 20 subjects per dose group had been randomized and followed up with seven days post first vaccination, the DSMB reviewed the accrued safety data and continued to review such data periodically up to Day 36 for all randomized subjects. All subjects received their second vaccination on Day 22 (visit 3) and received follow-ups on Day 36 (visit 4), 14 days after the second vaccination. The DSMB reviewed safety and immunogenicity data up to Day 36. In Part B, participants will be invited for on-site visits on Day 106 (visit 5) and Day 208 (visit 6), six months after the second vaccination.

VLA2001 was observed to be highly immunogenic, with more than 90% of all trial participants developing significant levels of antibodies to the SARS-CoV-2 virus spike protein compared to baseline across all dose groups tested. Seroconversion rates for S-protein binding IgG antibodies were 89.8% in the medium dose and 100% in the high dose group. Two weeks after completion of the two dose schedule, GMFR from baseline were 26 in the medium dose and 86 in the high dose group.

The IgG antibody response was highly correlated with neutralization titers in a micro-neutralization assay (MNA50) ($r=0.79$, $p<0.001$). VLA2001 induced a dose-dependent response with statistically significant higher GMTs for both IgG and neutralizing antibodies in the high dose group compared to the low and medium dose groups on Day 36. In the high dose group, the GMT of neutralizing antibody titers measured two weeks after completion of the two-dose schedule was at or above levels for a panel of convalescent sera (GMT 530.4 (95% CI: 421.49, 667.52)). The ratio of antibodies, measured by GMT, produced by VLA2001 compared to those present in convalescent sera was greater than or equal to 1, which suggests that VLA2001 induced antibodies that have a better neutralization capacity than the antibodies in those individuals who were infected naturally. Other COVID-19 vaccines that have reported 80% efficacy or higher have achieved a similar ratio.

VLA2001 also induced broad T-cell responses across participants with antigen-specific IFN-gamma producing T-cells against the S-protein, M-protein and N-protein detected in 75.6 %, 35.6% and 48.9% of trial participants, respectively.

VLA2001 was generally well tolerated across all dose groups tested, with no safety concerns identified by the DSMB. There were no statistically significant differences between dose groups and no differences between first and second vaccinations in terms of reactogenicity. Overall, 85% of participants experienced an AE and 81.7% of AEs were solicited. The most frequent solicited systemic AEs were headache (46.4%), fatigue (39.2%) and muscle pain (32.7%). The majority of AEs were mild or moderate and only two subjects reported severe solicited AEs (headache and fatigue). All solicited AEs were transient. Only 17.6% of unsolicited AEs up to Day 36 were considered related to the vaccine and no severe unsolicited AEs were reported. One AE of special interest was observed (chilblains) but was determined by the investigator to be unrelated to the vaccination. No serious related AEs were reported.

In Part B of the trial, which is ongoing as of the date of this Annual Report, all subjects will be further followed up on Day 106 (visit 5) and Day 208 (visit 6), six months after the second vaccination.

VLA2001-201 (Booster Extension)

The original VLA2001-201 protocol was amended to include study participants who have completed the primary immunization schedule (two vaccinations) and were invited to participate in a Booster Phase of the trial to investigate the immunogenicity and safety of a booster dose of VLA2001 administered at least six months after completing the primary immunization schedule. This expansion will support future clinical development strategies and allow for potential approval and label expansions. We announced in September 2021 that we had started to provide boosters to the volunteers, and in December 2021, we reported initial results confirming that VLA2001 significantly boosted immunity in participants who had received VLA2001 as a primary vaccination.

In this booster study, 77 of the 153 original Phase 1/2 study participants, aged 18-55, received a booster dose of VLA2001 seven to eight months after completion of their primary immunization with either a low, medium or high dose of VLA2001. All participants received a single booster vaccination with VLA2001 at the same (high) dose level used in the pivotal Phase 3 trial. IgG antibody titers (spike protein-based) were measured at the time of the booster as well as two weeks after the booster dose.

A third dose of VLA2001 elicited an excellent anamnestic response, with similar antibody levels observed whether participants were initially vaccinated with a low, medium or high dose (GMT 9,699.3 (95% CI: 8,497.76, 11,070.71)). This represents a strong boosting effect, increasing levels of antibodies against the Wuhan virus 42- to 106-fold, depending on the pre-boosting levels of antibodies. Antibody levels measured two weeks after the booster dose were approximately four-fold higher compared to those observed two weeks after primary immunization.

45 of the 77 boosted participants were included in the final analysis. 27 of the excluded participants had also received another COVID-19 vaccine, and five experienced a COVID-19 infection during the study.

We are undertaking a further homologous booster study as part of our Phase 3 trial, as described further below.

Phase 3 Clinical Trials

VLA2001-301 (Cov-Compare) Clinical Trial

Trial Design

Based on the initial data from VLA2001-201, in April 2021, we commenced a pivotal, comparative immunogenicity Phase 3 clinical trial, Cov-Compare. This Phase 3 clinical trial used the high dose treatment from VLA2001-201 and we reported topline results in October 2021.

Cov-Compare is a randomized, observer-blind, controlled, comparative immunogenicity trial in 4,012 adults. The two co-primary endpoints are to demonstrate the superiority of VLA2001 compared to AstraZeneca's AZD1222, administered in a two dose immunization schedule four weeks apart, in terms of superiority of GMT as well as non-inferiority of the seroconversion rate with regards to neutralizing antibodies at two weeks after the second vaccination (i.e., Day 43) in adults aged 30 years and older. It will also evaluate the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults aged 18 years and older. The trial is being conducted at approximately 26 sites in the UK. 2,972 participants 30 years of age and older (through age 71 in the enrolled population) were randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=1,977) or AZD1222 (n=995) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from 990 participants (VLA2001: n=492, AZD1222: n=498) who tested sero-negative for SARS-CoV-2 at screening were analyzed. 1,040 participants that were under 30 years of age were placed in a non-randomized treatment group and received VLA2001 28 days apart.

Topline Results

In October 2021, we announced positive Phase 3 topline results in which VLA2001 met both of the co-primary endpoints of the trial. The trial recruited a total of 4,012 participants aged 18 years and above across 26 trial sites in the United Kingdom. VLA2001 demonstrated superiority against AZD1222 in terms of GMT for neutralizing antibodies as measured on Day 43 (GMT ratio=1.39, $p<0.0001$), with VLA2001 having GMT of 803.5 in adults aged 30 years and above (95% CI: 748.48, 862.59) and AZD1222 having GMT of 576.6 (95% CI: 543.59, 611.66). VLA2001 also achieved non-inferiority in terms of SCR on Day 43, with each treatment group achieving SCR above 95% at two weeks after the second vaccination in adults aged 30 years and older (VLA2001: 97.4%, AZD1222: 98.9% in the per protocol population).

A key secondary endpoint was assessment of T-cell responses in a subset of patients. In this trial, VLA2001 induced broad antigen-specific IFN-gamma producing T-cells reactive against the S- (74.3%), N- (45.9%) and M- (20.3%) protein, compared to AZD1222 S- (86.5%), N- (1.4%) and M- (0%) protein.

VLA2001 was generally well tolerated and its tolerability profile was more favorable compared to AZD1222. Participants aged 30 and older reported significantly fewer solicited adverse events up to seven days after vaccination, both with regards to injection site reactions (73.2% VLA2001 compared to 91.1% AZD1222, $p<0.0001$) and systemic reactions (70.3% VLA2001 compared to 91.3% AZD1222, $p<0.0001$). Statistically significantly less participants experienced any unsolicited adverse event with VLA2001 (27.9% in the VLA2001 aged 30 and older group compared to 32.7% in the AZD1222 group, $p=0.0075$). Rates of participants with unsolicited serious adverse events (0.3% for VLA2001 compared to 0.2% for AZD1222) or medically attended unsolicited adverse events (7.2% for VLA2001 compared to 6.5% for AZD1222) were comparable between the adults aged 30 years and older who received VLA2001 and the participants who received AZD1222. No unsolicited treatment-related serious adverse events have been reported. Less than 1% reported an adverse event of special interest in both treatment groups, and the majority of solicited and unsolicited adverse events were mild or moderate. Participants under 30 years old who were vaccinated with VLA2001 showed an overall safety profile comparable to the group aged 30 years and older.

The rates of occurrence of COVID-19 cases, an exploratory endpoint, were similar between treatment groups (VLA2001: 0.3% after the first dose and 3.5% after the second dose; AZD1222: 0.2% after the first dose and 2.4% after the second dose). The complete absence of any severe COVID-19 cases may suggest that both VLA2001 and AZD1222 prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta).

Adolescent Recruitment

Additionally, we announced in September 2021 that recruitment of adolescents for participation in the VLA2001-301 clinical trial had begun in the United Kingdom and Mexico. Adolescents, aged 12 to 17 years, were enrolled in an open label, non-randomized format. Subject to safety review, remaining participants were randomized to receive two doses of either VLA2001 or a placebo 28 days apart, followed by a booster dose seven months after enrolling into the trial. Approximately 660 participants were recruited for this trial. Participants randomized to the placebo arm will have the opportunity to receive a course of VLA2001 following the initial safety assessment. We also intend a further expansion of the clinical development to include volunteers younger than 12 years old, subject to data from the adolescent group.

Booster Extension

In January 2022, we announced the start of booster vaccinations in adult participants from the Cov-Compare trial. This booster extension is intended to provide both homologous and first heterologous booster data to complement the results of the booster extension from the Phase 1/2 trial described above.

The trial extension will evaluate a booster dose of VLA2001 in adults, aged 18 and above, who received primary vaccination with two doses of VLA2001, as well as participants, aged 30 and above, who received two doses of AZD1222. All participants in the Cov-Compare trial were offered a third vaccination, except those who already received a licensed COVID-19 vaccine outside of the study. The VLA2001 booster vaccination will be given at least seven months after completion of the primary vaccination series. Follow-up visits will be performed 14 days and six months after the booster vaccination. In addition to evaluating tolerability of a VLA2001 booster dose, blood samples will be taken for immunogenicity analysis from a subset of adults who received primary vaccination with two doses of VLA2001, as well as from a subset of participants who received two doses of AZD1222 for primary immunization.

The trial is currently ongoing in the UK and is expected to provide topline data during the second quarter of 2022.

VLA2001-304 Clinical Trial

In August 2021, we announced the initiation of a further Phase 3 clinical trial, VLA2001-304. This clinical trial will enroll two cohorts of participants and be conducted at approximately 10 trial sites in New Zealand. In both cohorts, vaccinations will be administered in a 2-dose immunization schedule 28 days apart. Data from VLA2001-304 are expected to complement ongoing clinical trials and support additional regulatory submissions.

Cohort 1 has fully recruited approximately 306 volunteers aged 56 years and older who have received two vaccination 28-days apart in an open-label manner in order to generate safety and immunogenicity data for this age group. We announced the completion of recruitment for Cohort 1 in September 2021 and expect to announce topline data from this cohort in early in the second quarter of 2022.

Additional Planned Clinical Trials

We are in the planning stage for additional clinical trials of VLA2001.

We are also planning to continue our evaluation of VLA2001 in the pediatric population with a Phase 3 clinical trial (VLA2001-321) in approximately 2,200 children aged 2 years through 11 years, including dose-finding in children aged 2 years to 5 years and a full dose of VLA2001 in children aged 5 years and above.

We may also explore development of new versions of VLA2001 to address variants.

VLA1601—Our Zika virus development program that remains on hold

We have developed VLA1601, a highly purified inactivated vaccine candidate which we developed using the same manufacturing platform as IXIARO, our approved Japanese encephalitis vaccine. We have concluded the Phase 1 trial and the results obtained will allow us to design a Phase 2 clinical trial if we choose to continue this program. We currently have this program on hold, as cases of Zika have significantly declined since 2016. We have chosen to prioritize our development programs to focus on viruses that are currently a greater health crisis, but 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 against *Clostridium difficile*, a leading cause of life-threatening, healthcare-associated infections worldwide. We completed Phase 2 development of VLA84 and 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 portfolio, we are advancing a series of pre-clinical assets. Each of the assets included in our pre-clinical pipeline aligns with our strategy of leveraging our vaccine development expertise and capabilities to develop prophylactic solutions for diseases with high unmet need and limited available preventative and effective therapeutic treatment options.

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 our platform and technology could support development of a vaccine for that disease.

VLA1554—Our vaccine candidate targeting Human MetaPneumoVirus (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 worldwide morbidity and mortality in immunocompromised patients and older adults. Repeated infections occur often, demonstrating a heavy medical burden. However, there is currently no hMPV-specific prevention treatment.

We are currently in pre-clinical proof of concept studies and we received first readouts in the fourth quarter of 2021. We are currently analyzing these results and additional data are expected in the second half of 2022 in order to proceed towards a proof of concept. We are also considering developing a potential combination vaccine that would protect against both hMPV and respiratory syncytial virus, or RSV. Despite the high frequency of pneumoviral infections and over 50 years of research in this field, no licensed vaccine against hMPV or RSV is currently available. This lack of effective vaccine candidates against hMPV can be explained by the recent discovery of the virus, but also by the lack of a successful vaccine against closely related RSV that could serve as a base for vaccine design.

Epstein-Barr Virus (EBV) program

Epstein-Barr virus (EBV), also known as human herpesvirus 4, is a member of the herpes virus family. It is one of the most common human viruses. EBV is found all over the world. Most people get infected with EBV at some point in their lives. EBV spreads most commonly through bodily fluids, primarily saliva. EBV can cause infectious mononucleosis, also called mono, and other illnesses. We are currently in an evaluation phase and working closely with external scientific experts to define next steps.

Campylobacter program

Campylobacter is a Zoonotic Gram negative bacteria and the two main species responsible for human cases are *C. jejuni* (90%) and *C. coli* (10%). Foodborne transmission can occur via ingestion of uncooked meat (especially poultry), contaminated water or milk. The onset of disease symptoms usually occurs 2 to 5 days after infection with the bacteria, but can range from 1 to 10 days. The most common clinical symptoms of Campylobacter infections include diarrhea (frequently bloody), abdominal pain, fever, headache, nausea, and/or vomiting. Death from campylobacteriosis is rare and is usually confined to very young children or elderly patients, or to those already suffering from another serious disease such as AIDS. Complications such as bacteraemia (presence of bacteria in the blood), hepatitis, pancreatitis (infections of liver and pancreas, respectively), and miscarriage have been reported with various degrees of frequency. Post-infection complications may include reactive arthritis (painful inflammation of the joints which can last for several months) and neurological disorders such as Guillain-Barré syndrome, a polio-like form of paralysis that can result in respiratory and severe neurological dysfunction in a small number of cases. We are currently in an evaluation phase and working closely with external scientific experts to define next steps.

Parvovirus B19 program

Parvovirus B19 is a virus that infects humans with a range of symptoms depending on age and overall health. About two out of 10 people who get infected with this virus will be asymptomatic or display no symptoms. Others may have only mild, rash illness. Parvovirus B19 most commonly causes fifth disease, a mild rash illness that usually affects children and adults. Less common symptoms of parvovirus B19 infection include painful or swollen joints (polyarthropathy syndrome), which is more common in adults, and severe anemia (a condition in which the body does not have enough healthy red blood cells). In rare cases, some of these symptoms can persist for several years. We are currently in an evaluation phase and working closely with external scientific experts to define next steps.

Norovirus program

Norovirus is the leading cause of acute viral gastroenteritis in all age groups in the U.S. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis and leads to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, vomiting, diarrhea with abdominal cramps and nausea. In a study conducted by the University of Pittsburgh and the U.S. Centers for Disease Control and Prevention in 2012, the total economic burden of norovirus in the U.S. was estimated at $5.5 billion. We are currently in an evaluation phase and working closely with external scientific experts to define next steps.

Our Commercial Portfolio

Our commercial portfolio is composed of two vaccines both of which are marketed as traveler vaccines in that they are targeted to people traveling to the regions where the diseases they prevent are endemic. Our vaccines serve a wide range of potential travelers, from business and leisure travelers to government and military personnel traveling on behalf of their government. These vaccines 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 deployed U.S. military personnel. 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. IXIARO sales were €45.1 million, €48.5 million and €94.1 million in the years ended December 31, 2021, 2020 and 2019, respectively. Sales in 2020 and 2021 were significantly impacted by the COVID-19 pandemic and the related decline in travel. In September 2020, DLA awarded us a new contract for the supply of IXIARO. The terms of the agreement contemplate 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 exercised the first option year of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is now 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option of 250,000 doses, which remains unchanged. See "—Material Agreements—Department of Defense Contracts" for more information about this agreement.

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.

Other than IXIARO, there is currently no other treatment for Japanese encephalitis except symptomatic support. In 2017, approximately 30 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. IXIARO has also been commercialized in a number of other key travel markets into Canada, Australia, Israel, Switzerland and Singapore. The U.S. Department of Defense represented approximately half of IXIARO global sales in 2019 (prior to the COVID-19 pandemic) due to large deployment of troops and their dependents to JEV-endemic areas. The remainder of sales are generated through vaccination of leisure and business travelers.

Sales in 2021 continued to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its November 2021 report, the UNWTO noted that despite improvement in the rate of international travel in the third quarter of 2021, as measured by international arrivals, the pace of recovery remains slow and uneven across the world. Rising concerns over the Delta variant of the virus have led several countries to re-impose restrictive measures. In addition, the volatility and lack of clear information on entry requirements could continue to affect the resumption of international travel. However, vaccination programs worldwide, together with softer restrictions for vaccinated travelers and the use of digital tools such as the EU Digital COVID Certificate, are contributing to the gradual normalization of travel. The recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to recover to 2019 demand levels between mid-2023 to end of 2024. There can be no assurances that travel demand will recover at all or to forecasted rates due to the evolving nature of the COVID-19 pandemic.

DUKORAL—Our vaccine for 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 Jansen Pharmaceuticals as part of its strategic vision to extend its 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 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 €2.4 million, €13.3 million and €31.5 million in the years ended December 31, 2021, 2020 and 2019, respectively, of which Canada represented €0.6 million, €6.8 million and €18.3 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 continued to be significantly impacted by ongoing COVID-19 travel restrictions.

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. Recently 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 diseases target 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 US, Canada and European countries.

Given the large population in the Japanese encephalitis endemic region, consisting of over 3 billion people, and the inclusion of the Japanese encephalitis vaccine in many national immunization programs, the competitive landscape in the endemic region is more crowded. Many of the first generation, locally manufactured mouse-brain derived vaccines have been phased out over the past 5-10 years, making way for the introduction of second-generation technologies. This includes companies such as Biken and Kaketsuken (Japan), both with inactivated vero-cell based vaccines, Chengdu (China and GAVI/UNICEF markets) with a live-attenuated vaccine, and Sanofi's live-attenuated chimeric vaccine, IMOJEV (Australia/some Asian territories). None of these vaccines are currently approved for sale in the European Union, Canada or the United States. Therefore, there is currently no direct competitor to IXIARO in those markets, which represented over 95% of total IXIARO revenues in 2021.

The only country where our Japanese encephalitis vaccine currently faces direct competition is Australia, where it splits market share with Sanofi's IMOJEV.

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 57% of DUKORAL sales in 2021, with Canada alone representing over 25%. 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 371.5 million travelers to Asia, South America and Africa in 2017.

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.

U.S. company PaxVax (now owned by Emergent BioSolutions) has developed, with the support of public grants, an oral cholera vaccine, Vaxchora, that 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. It has not yet been commercially launched in Europe.

Competition related to our product pipeline

Lyme disease

Companies such as GlaxoSmithKline, Sanofi and Baxter had clinical programs that advanced thorough pre-clinical all the way to market. 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.

Chikungunya

We are aware of companies such as Merck, NIAID, Emergent, Barath Biotech, Moderna Therapeutics, Inovio, DRDE, Indian Immunological, UAB 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.

COVID-19

A number of companies are actively advancing COVID-19 vaccines through the clinic. As of March 1, 2022, COVID-19 vaccines from five companies were already approved for use in the European Union or the United Kingdom: Pfizer-BioNTech, Moderna Therapeutics, AstraZeneca, Johnson & Johnson and Novavax. The vaccines from Pfizer-BioNTech and Moderna are based on mRNA technology. The vaccines from AstraZeneca and Johnson & Johnson use a viral vector technology. Novavax's vaccine is based on recombinant protein technology. In addition to VLA2001, the following vaccines were under rolling review by the EMA as of March 1, 2022: Sputnik V from the Gamaleya Institute (based on viral vector technology), Sinovac's vero cell inactivated vaccine and Vidprevtyn from Sanofi Pasteur (based on recombinant protein technology). Additionally, a number of companies such as CanSino Biologics, Bharat Biotech, Inovio Pharmaceuticals and Clover are currently developing vaccine candidates into Phase 2 and Phase 3 clinical stage development. Developers of COVID-19 vaccines are also investigating adaptions of their vaccines to protect against new variants of the virus.

Sales and Marketing

We have a specialist commercial capability comprising approximately 40 employees for the distribution of our travelers' vaccines, IXIARO and DUKORAL.

We have established our own commercial operations in certain travel vaccine markets including the United States, Canada, the United Kingdom, Sweden, France and Austria. We are currently establishing commercial operations in 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 (GSK), Eastern Europe (IMED), Israel (Kamada) and Australia and New Zealand (Seqirus/CSL).

Commercial operations in key markets

Based on 2021 product sales, we manage approximately 96% of our global product sales revenues through our own commercial operations. Local operations include expertise in Sales, Marketing, Medical Affairs, Governmental Affairs (US), 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. Through our partnership with Seqirus, we commercialize two differentiated vaccines in Austria. We entered into a marketing and distribution partnership with Bavarian Nordic in 2020 to commercialize their Rabipur and Encepur brands in Austria, the UK, France, Belgium, The Netherlands and Canada.

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 10 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 250 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, currently dedicated to the commercial production of our COVID vaccine candidate VLA2001.

In addition, and as part of our COVID vaccine program, the Livingston site is currently being expanded to include two additional production units.

We have also outsourced a significant portion of the manufacturing of VLA2001 to IDT Biologika in Germany.

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 200 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 vaccine business we are currently expanding our existing fill-finish capacity by fitting out a nearby site for formulation, filling and packaging of our COVID vaccine candidate, VLA2001. The 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, 2021, we had a portfolio of 398 issued patents, including 73 granted in Germany, France, United Kingdom, Spain and Italy, 34 issued in the United States, and 149 pending patent applications, including 21 pending in Europe and 10 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 marketed 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 one granted European patent with claims directed to compositions comprising IXIARO and methods for preparing IXIARO, and two pending European patent applications. This patent family also includes 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 and the appeal procedure is currently pending following an oral hearing on March 13, 2022. The appeal procedure could ultimately result in a revocation, narrower or broader scope of protection being upheld compared to that maintained by the opposition division, or a withdrawal of the patent. 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 PCT application with claims covering the manufacturing processes of IXIARO. Patent applications claiming the benefit of this PCT application, 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 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 claiming priority to this 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. 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. We also own a further U.S. patent application directed to the use of the cholera bacteria used in DUKORAL in the treatment or prevention of cancer. Patent applications claiming the benefit of this U.S. patent 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, 2021, we own a patent family which includes three issued U.S. patents and two European patents as well as 21 foreign patents and 7 patent applications with claims covering the composition of matter of VLA15. We further own a second patent family which includes two issued U.S. patents and one granted European patent as well as 15 foreign patents and 6 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, 2021, we also own three International patent applications with claims directed to compositions comprising OspA fusion proteins including uses thereof and to improved methods for producing a vaccine. 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, 2021, we own two patent families that include three 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 over 20 pending patent applications in such jurisdictions as the U.S., Europe, Australia, Canada, China, India, Japan, and Mexico. 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, 2021, we also own two pending PCT applications with claims covering formulations and manufacturing processes of VLA1553. Patent applications claiming the benefit of these PCT 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.

VLA2001—SARS-CoV-2 vaccine candidate

In regards to our SARS-CoV-2 vaccine candidate, VLA2001, as of December 31, 2021, we own one International patent application and 8 foreign patent applications with claims relating to the antigen and processes preparing the antigen of VLA2001, furthermore we co-own together with Dynavax two International patents and three 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, 2021, we own a patent family with three granted U.S. patents with claims covering the composition of matter of VLA84 and methods of use thereof, two pending U.S. patent applications, 10 granted foreign patents in such jurisdictions as Australia, China, and Japan, and three pending foreign patent applications. This patent family also includes a granted European patent validated in over 35 countries that has been opposed and appealed. The European Patent Office maintained our European patent in amended form, which still covers VLA84. A second European patent has not been opposed. 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 VLA84 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 VLA84 candidate. The European Patent Office has revoked this patent, and the appeal period is currently pending.

VLA1601—Zika vaccine candidate

In regards to our Zika vaccine candidate VLA1601, as of December 31, 2021, 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. 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 pending U.S. patent applications 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.

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, 2021 are shown in the table below.

Trademarks	Number of registrations or applications
IXIARO®, IXIARO logo	136
JESPECT®	19
DUKORAL®	55
EB66®	11
IC31®	8
Valneva®, Valneva logos	78
SBL trademarks	20
IXCHIQ	13

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.

"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 DUCORA 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

At December 31, 2021, we hold 97 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 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, or MA, 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 a further two, 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. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the United Kingdom, however this period ended on December 31, 2020. Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from EU regulations, Brexit has materially impacted, and could further materially impact, the regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as United Kingdom legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long-term. 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 ("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 MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time.

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;

- State and foreign laws that are analogous to each of the above federal laws, 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; and

- 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, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers; state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state and local laws that require the registration of pharmaceutical sales representatives; 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; and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

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. Thus, the ACA will remain in effect in its current form. 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. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects.

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 3% 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.

For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN interim final rule. 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, 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, Congress is considering drug pricing as part of other health reform initiatives.

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.

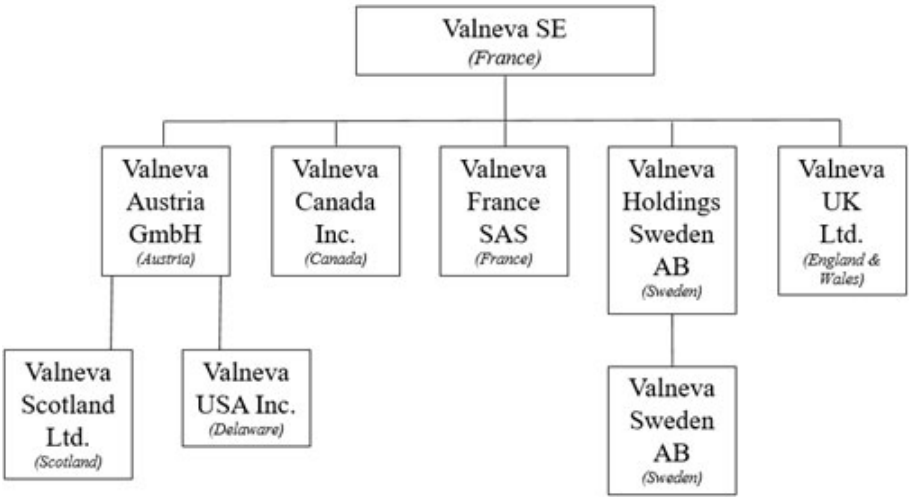
Third-party payors decide which therapies they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment 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").

C. Organizational Structure

The chart below presents our significant subsidiaries as of December 31, 2021. 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 127.5 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 is being expanded. Upon conclusion of the construction, the site will be approximately 5,000 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 315 square meters located 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 5,500 square meters of combined office warehouse space across six 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

- 353 square meters of offices in Gaithersburg, 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 December 31, 2021 and 2020 and the three years ended December 31, 2021 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. The audit report from Deloitte & Associés and PricewaterhouseCoopers Audit on the consolidated financial statements includes an explanatory paragraph referring to the adoption of IFRS 16 Leases.

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 and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

Our 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. Our lead program, VLA15, is a Phase 2 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. Our clinical portfolio also includes VLA1553, targeting the chikungunya virus, which has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. VLA1553 is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data and 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.

We are also advancing VLA2001, a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus that causes COVID-19 in order to address the urgent, global need for billions of doses of vaccines. VLA2001 is currently the only inactivated, adjuvanted vaccine candidate for COVID-19 in clinical development in Europe and has been authorized for emergency use in Bahrain while regulatory reviews in Europe and the United Kingdom are ongoing. We believe that VLA2001, as an inactivated whole virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to previously approved vaccines in territories where it may be approved and could be adapted to offer protection against mutations of the virus.

In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S), in terms of geometric mean titer, or GMT, for neutralizing antibodies, as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. In December 2021, we announced positive homologous booster data showing an excellent immune response after a third dose of VLA2001 was administered seven to eight months following completion of primary vaccination with VLA2001. We expect to report further booster data in the second quarter of 2022 from boosters administered to participants who received either VLA2001 or AZD1222 in our Phase 3 trial, and we plan to launch a heterologous booster trial that will evaluate VLA2001 administered as a booster dose at least six months following administration of the second dose of a licensed mRNA-based vaccine or following natural infection. We also announced in January 2021 that a laboratory study found that a third dose of VLA2001 produced neutralizing antibodies against the Delta and Omicron variants of the virus. 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. We continue to discuss possibilities for other purchase agreements with other countries.

We commenced the regulatory approval process for VLA2001 in August 2021 with our rolling submission to the UK's Medicines & Healthcare products Regulatory Agency, or MHRA. We commenced the rolling submission process with the European Medicines Agency, or EMA, and with the National Health Regulatory Authority, or NHRA, in Bahrain in December 2021. We received an Emergency Use Authorization from the NHRA at the end of February 2022, and we expect that we could receive conditional marketing authorization for VLA2001 from the EMA in April 2022. Further submissions to other regulatory agencies may also take place in 2022.

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. All references to IXIARO in this Item 5 include both IXIARO and JESPECT, unless stated otherwise.

We are led by a highly dedicated international Management Board under the supervision of a Supervisory Board that helps guide business strategies and the direction of our business. To receive guidance and expertise with respect to research and development, we formed a Scientific Advisory Board in 2019.

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 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 executive team has more than 100 years of combined experience spent working at industry leaders such as Novartis, Chiron, Acambis, 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, 2021, we had €346.7 million in cash and cash equivalents.

Our operating losses were €61.4 million, €55.1 million and €0.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. Our net losses were €73.4 million, €64.4 million and €1.7 million for the years ended December 31, 2021, 2020 and 2019, 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, DUKORAL and IXIARO, in their respective markets and from the sale of third-party products. We also derive revenues from partnerships related to our vaccine candidates, as well as from collaborations, services and licensing agreement 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 and Third-party Products

Product sales of IXIARO and DUKORAL represented in aggregate 75.5%, 56.0% and 99.5% of our revenues for the years ended December 31, 2021, 2020 and 2019, respectively. In 2019, total revenue included a negative revenue of €10.7 million related to the June 2019 mutual agreement to terminate our Strategic Alliance Agreement, or SAA, with GlaxoSmithKline Biologicals SA, or GSK, originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively) as further discussed below. We primarily sell IXIARO in the United States, Canada and Germany and DUKORAL in Canada.

In addition, we generate revenues by leveraging our existing sales and marketing infrastructure to sell third-party products. Revenues from sales of third-party products represented 24.4%, 3.8% and 3.1% of our revenues for the years ended December 31, 2021, 2020 and 2019, respectively.

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. This agreement had no material financial impact on the consolidated financial statement as of and for the year ended December 31, 2020. In the year ended December 31, 2021, we recognized €8.2 million of revenue from sales of Bavarian Nordic’s vaccines.

Sales trends in travel vaccines are primarily driven by travel volume to endemic regions, national travel advisories, awareness about the 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. According to the United Nations World Tourism Organization or UNWTO, Asia and the Pacific, the first region to suffer the impact of the pandemic and the region with the highest level of travel restrictions still in place to date, experienced an 84% decrease in arrivals from international flights from January to December 2020.

While COVID-19 has adversely affected sales of our travel vaccines to the general public, sales of IXIARO to the U.S. Government Department of Defense, or DLA, which purchases our 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 contemplate 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 exercised the first year option of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option which remains unchanged, compared to a minimum value of $135 million in the initial agreement. For the years ended December 31, 2021, 2020 and 2019, 60.5%, 52.6% and 37.0%, 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 with Pfizer Inc., entered into in April 2020, to co-develop and commercialize our Lyme 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. Under the terms of the agreement, 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 19% on net sales of licensed products, subject to specified offsets and reductions. As of December 31, 2021 and 2020, we have recognized €79.6 million and €81.9 million, respectively, as discounted refund liabilities. In addition, €14.3 million and €31.6 million was recognized as other revenues during the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and December 31, 2020, €3.0 million and €2.8 million, respectively, in contract costs were included in other assets, and €0.9 million and €0, 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. Funding for UK-based clinical trials was agreed to in a separate, linked Clinical Trial Agreement. This Clinical Trial Agreement has not been terminated and we reported positive topline Phase 3 clinical trial results on October 18, 2021.

Following the close of business on September 10, 2021, we received notice of the UK Authority’s decision to terminate the UK Supply Agreement. We had not received any indication from the UK Authority, prior to this time, of the UK Authority’s intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority’s purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, if the UK Authority were to successfully bring proceedings for damages against Valneva in respect of the alleged anticipatory breach, it could be argued that the applicable contractual cap on our liability under the UK Supply Agreement could be as high as an amount equivalent to the sums paid to us by the UK Authority prior to termination. However, we believe that it is very unlikely that any such claim by the UK Authority will be successful. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination for alleged anticipatory breach nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, 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. A royalty on sales and certain other obligations, as described below, survive termination of the UK Supply Agreement.

The termination of the UK Supply Agreement was extensively assessed in the context of the preparation of the financial statements as of and for the year ended December 31, 2021. Payments received, where judgement was necessary and we assessed the likelihood of repayment to be remote, totaled €253.3 million and therefore this amount was recognized as revenue in the year ended December 31, 2021. Of this amount, €166.9 million related to uncertain restrictions and repayment obligations and were recognized in refund liabilities.

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 €173.3 million, €84.5 million and €38.0 million for the years ended December 31, 2021, 2020 and 2019, 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 increased research and development costs in 2021 as we have invested in development of our COVID-19 vaccine candidate (VLA2001), continued our Phase 3 clinical trial for our chikungunya vaccine (VLA1553) and commenced our Phase 3 clinical trial for our Lyme vaccine candidate (VLA15). Under our agreement with Pfizer, we are obligated to contribute 30% of all ongoing and future Lyme vaccine candidate development costs through completion of the development program expected in 2025.

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.

During the COVID-19 outbreak, including through 2021, travel costs for our sales team have significantly decreased, and we have implemented a variety of cost containment measures such as reducing the advertising and promotional spend as well as reducing staffing across most of our commercial entities. We believe that ultimately, our investment in commercial infrastructure will yield higher revenues compared to outsourcing commercialization.

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 candidate will be manufactured at our facility in Livingston, Scotland and by IDT Biologika in Germany, and fill-finishing activities will take place at our facilities in Solna, Sweden. As part of our broader COVID-19 response, we have invested in both our Livingston and Solna manufacturing facilities, including through an expansion of the Livingston facility financed by the UK Supply Agreement.

General and Administrative Expenses

General and administrative expenses have increased as we have become a more complex organization, requiring more corporate support. We have also seen an increase in stock-based compensation expense as we have increased our headcount and the issuance of share based compensation to employees and the Management Board. Furthermore, stock-based compensation related social security expenses are driven by the development of our company's 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, increased from €17.6 million for the year ended December 31, 2020 to €23.6 million for the year ended December 31, 2021, mainly due to increased research and development tax credits but partly offset by the recognition of €1.1 million of negative grant income in 2021 related to our funding agreement with the Coalition for Epidemic Preparedness Innovations, or CEPI. Grant income, including research and development tax credits, increased from €8.2 million for the year ended December 31, 2019 to €17.6 million for the year ended December 31, 2020. 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 the 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. 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 the Swedish Krona, or SEK, and proceeds in USD from our Nasdaq offerings in May and October 2021, 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 candidate and announced a COVID-19 vaccine partnership with the UK Government. However, COVID-19 has adversely impacted sales of our travel vaccines to the general public, with travel to endemic areas significantly reduced compared to 2019 and our sales and marketing team unable to travel. DUKORAL and IXIARO are aimed at diseases that primarily threaten travelers to particular regions. As a result, sales of these vaccines have decreased significantly, adversely impacting our financial results. We expect to remain impacted by the significant reduction in international travel following the onset of the global COVID-19 pandemic. Therefore, as a result of COVID-19, 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. As a result of a related manufacturing stoppage for IXIARO and DUKORAL in the third quarter of 2020, idle capacity costs were not capitalized.

Sales in 2021 continued to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic, and this impact is expected to continue into 2022. In its November 2021 report, the UNWTO noted that despite improvement in the rate of international travel in the third quarter of 2021, as measured by international arrivals, the pace of recovery remains slow and uneven across the world. Rising concerns over the Delta variant of the virus have led several countries to re-impose restrictive measures. However, vaccination programs worldwide, together with softer restrictions for vaccinated travelers and the use of digital tools such as the EU Digital COVID Certificate, contribute to the gradual normalization of travel. The recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to recover to 2019 demand levels between mid-2023 to end of 2024. If international travel does not resume as quickly or as much as expected, our revenues will continue to be severely affected, and we may not be able to complete the development of our vaccine candidates without additional financing. Site initiation and subject enrollment have been and may be further delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some subjects may not be able or willing to comply with clinical trial protocols if quarantines impede subject movement or interrupt healthcare services. The initiation of Phase 3 clinical trial for VLA 1553 (chikungunya) was delayed due to the impact of COVID-19. We continue to closely monitor how the pandemic and related response measures are affecting our business.

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 candidate, 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 candidate, VLA2001.
- “**Technologies and services**” — services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements.

Prior to January 1, 2021, we reported in three segments—commercialized products, vaccine candidates and technologies and services. 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.

As of January 1, 2021, given the materiality of our COVID-19 business in 2021, we introduced a “COVID” segment covering all activities related to the development, manufacturing and distribution of our COVID-19 vaccine candidate, VLA2001. The presentation of 2020 was adjusted to allow a better comparison.

As of January 1, 2021, we changed our internal reporting process and amended the following allocation rule: general and administrative costs previously reported under “corporate overhead” have been fully allocated to the four operational segments based on three criteria (each equally weighted): (1) revenues, (2) research and development spend and (3) full-time equivalent personnel. The allocation of local general and administrative costs is based on the above criteria measured on the local level, whereas the allocation of global functional general and administrative costs is based on global key criteria. We also monitor our general and administrative expenses dedicated to corporate projects. Any project which (1) is material in spend, (2) is one-time in nature and (3) supports the entire business remains reported under Corporate Overhead. In 2021, the major item included in Corporate Overhead was costs related to our Nasdaq offerings. Segment reporting information for earlier periods have been amended to conform to these changes. The change in segments had no impact on our historical consolidated financial position, results of operations or cash flows, as reflected in the reissued consolidated financial statements. The annual financial statements were restated only for the change in segment.

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 (primarily to U.S. military personnel being deployed to endemic areas), Canada and Germany. We primarily sell DUKORAL in Canada.

Our other revenue (from collaboration, licensing and services) consists of milestone payments, upfront licensing payments and reimbursement of development expenses. 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, 2021 and 2020 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 September 2020, we entered into the UK Supply Agreement, pursuant to which Valneva was obligated to develop, manufacture and supply SARS-CoV-2 vaccines to the UK Authority. In September 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. 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 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, 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;
- clinical development efforts for our 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, 2021, 2020 and 2019, such as for CROs, and other contracted research and development activities, as well as for raw materials, relate to our COVID-19 vaccine candidate (VLA2001) (in 2020 and 2021), our chikungunya vaccine candidate (VLA1553), and our Lyme vaccine candidate (VLA15). 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 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. As of December 31, 2021 and 2020, we had capitalized research and development expenses recorded as intangible assets in an aggregate amount of €1.9 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 as we grow our support functions for the expected increase in our research and development and manufacturing activities. 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). 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.

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

We hold a 48.9% equity interest in BliNK Biomedical SAS, or BliNK, a private company not listed on a stock exchange. While we intend to retain a substantial ownership interest in the entity, 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, and therefore the investment is recorded using the equity method according to IAS 28.

Income Tax

Income tax income or expense reflects our current income tax, as well as our deferred tax income (expense).

Item 5A. Operating Results

Results of Operations

Overview

Results of Operations—Consolidated

Our results of operations for the years ended December 31, 2021, 2020 and 2019 are summarized in the table below.

€ in thousands	**Year ended December 31,**		
	2021	**2020**	**2019**
Product sales	62,984	65,938	129,511
Other revenues	285,101	44,383	(3,315)
Total revenues	**348,086**	**110,321**	**126,196**
Cost of goods and services	(187,920)	(54,302)	(52,781)
Research and development expenses	(173,283)	(84,454)	(38,022)
Marketing and distribution expenses	(23,643)	(18,264)	(24,145)
General and administrative expenses	(47,606)	(27,539)	(18,398)
Other income and expenses, net	22,976	19,117	6,338
Operating profit (loss)	**(61,390)**	**(55,120)**	**(811)**
Finance income	8,379	689	1,449
Finance expenses	(16,964)	(10,738)	(3,082)
Result from investments in associates	(5)	(133)	1,574
Profit (loss) before income tax	**(69,979)**	**(65,302)**	**(870)**
Income tax income (expense)	(3,446)	909	(874)
Profit (loss) for the period	**(73,425)**	**(64,393)**	**(1,744)**

Results of Operations—By Segment

The following table presents our results of operations by segment for the years ended December 31, 2021, 2020 and 2019:

	Commercialized products			COVID			Vaccine candidates			Technologies and services			Corporate overhead			Total		
€ in thousands	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**	**2021**	**2020**	**2019**
Product sales	62,984	65,938	129,511	—	—	—	—	—	—	—	—	—	—	—	—	62,984	65,938	129,511
Other Revenue	18	1	163	253,314	—	—	3,257	31,604	(10,516)	28,512	12,779	7,038	—	—	—	285,101	44,383	(3,315)
Revenues	**63,002**	**65,939**	**129,674**	**253,314**	—	—	**3,257**	**31,604**	**(10,516)**	28,512	**12,779**	**7,038**	—	**—**	**—**	**348,086**	**110,321**	**126,196**
Cost of goods and services	(40,017)	(41,830)	(47,789)	(122,843)	—	—	—	(3,305)	(1)	(25,061)	(9,167)	(4,991)	—	—	—	(187,920)	(54,302)	(52,781)
Research and development expenses	(2,094)	(2,711)	(3,928)	(113,907)	(18,962)	—	(53,181)	(62,140)	(32,864)	(4,101)	(640)	(1,229)	—	—	—	(173,283)	(84,454)	(38,022)
Marketing and distribution expenses	(18,455)	(17,554)	(22,930)	(1,182)	—	—	(3,811)	(638)	(895)	(194)	(72)	(261)	—	—	(59)	(23,642)	(18,264)	(24,145)
General and administrative expenses	(6,102)	(13,412)	(10,161)	(23,003)	(2,374)	—	(8,323)	(7,781)	(7,124)	(5,495)	(2,274)	(795)	(4,684)	(1,697)	(318)	(47,606)	(27,539)	(18,398)
Other income and expenses, net[(1)]	2,196	1,101	7	11,546	1,578	—	7,033	14,073	7,709	2,458	117	484	(257)	2,248	(1,861)	22,976	19,117	6,338
Operating profit (loss)	**(1,469)**	**(8,466)**	**44,873**	**3,927**	**(19,759)**	**—**	**(55,025)**	**(28,189)**	**(43,691)**	**(3,881)**	**743**	**245**	**(4,941)**	**551**	**(2,238)**	**(61,390)**	**(55,120)**	**(811)**

(1) 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. For the year ended December 31, 2019, our other income expenses, net in other corporate overhead of €1.9 million mainly related to the provision related to the merger litigation.

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:

€ in thousands	**Year ended December 31,**	
	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

€ in thousands	**Year ended December 31,**	
	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.

€ in thousands	**Year ended December 31,**	
	2021	**2020**
United States (military)	38,048	34,659
United States (non-military)	2,291	1,755
Canada	4,226	8,965
Austria	9,341	3,333
United Kingdom	2,707	1,847
Nordics	2,436	2,866
Germany	726	7,060
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.

€ in thousands	**Year ended December 31,**	
	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 COGS related to cost of services was €25.1 million. The increase in COGS related to cost of services from €12.2 million to €25.1 million was mainly due to the fact that the Lyme vaccine candidate had been out-licensed to Pfizer by the end of 2020. COGS from the Lyme 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 COGS related to 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:

€ in thousands	Year ended December 31,	
	2021	2020
COVID-19 (VLA2001)	(113,907)	(18,962)
Chikungunya (VLA1553)	(43,975)	(31,746)
Lyme (VLA15)	(3,761)	(25,948)
hmPV	(2,111)	(1,327)
IXIARO	(1,125)	(1,373)
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:

€ in thousands	**Year ended December 31,**	
	2021	**2020**
Employee benefit expense other than share-based compensation[(1)]	(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)
Supply, office and IT-costs	(7,409)	(3,333)
License fees and royalties	(4,865)	(4,384)
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)**

(1) 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:

€ in thousands	Year ended December 31,	
	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:

€ in thousands	Year ended December 31,	
	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)
	(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.

Comparisons for the Years Ended December 31, 2020 and 2019

Revenue

Consolidated Revenue

Revenue decreased by €15.9 million, or 12.6%, to €110.3 million for the year ended December 31, 2020 compared to €126.2 million for the year ended December 31, 2019. The decrease was primarily due to a significant decrease in sales due to the impact of COVID-19 on the travel industry, offset in part by an increase in other revenues related to entering into our collaboration with Pfizer. Our total revenues for the year ended December 31, 2019 included a negative revenue of €10.7 million related to the June 2019 mutual agreement to terminate our SAA with GSK, which included recognition of negative revenues related to both current and future payment obligations. We paid €9.0 million to GSK immediately and will pay up to a further €7.0 million upon the achievement of milestones related to marketing approvals of our Lyme vaccine candidate.

The breakdown of revenue by operating segment is as follows:

€ in thousands	**Year ended December 31,**	
	2020	**2019**
Commercialized products[(1)]	65,939	129,674
Vaccine candidates	31,604	(10,516)
Technologies and services	12,779	7,038
Total revenues	**110,321**	**126,196**

(1) Commercial products revenues consisted of €129.5 million of product sales and €0.2 million of other revenues for the year ended December 31, 2019. For the year ended December 31, 2020, the full amount of €65.9 million related to product sales.

Product Sales

€ in thousands	**Year ended December 31,**	
	2020	**2019**
IXIARO	48,480	94,144
DUKORAL	13,300	31,471
Third-party products	4,158	3,896
Total product sales	**65,939**	**129,511**

Product sales decreased by €63.6 million, or 49.1%, from €129.5 million in the year ended December 31, 2019 to €65.9 million in the year ended December 31, 2020.

In the year ended December 31, 2020, IXIARO product sales were €48.5 million, a decrease of €45.7 million, or 48.5%, compared to €94.1 million in the year ended December 31, 2019. In the year ended December 31, 2020, 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, 2019, IXIARO product sales were driven by demand in the U.S. private market as well. Although we experienced significantly reduced demand in the U.S. market in 2020 due to the COVID-19 pandemic and travel restrictions, our revenue from continued sales of IXIARO to the U.S. military partially mitigated this significant decrease between the 2019 and 2020 periods.

For DUKORAL, in the year ended December 31, 2020, product sales decreased to €13.3 million, a decrease of €18.2 million, or 57.7%, compared to €31.5 million in the year ended December 31, 2019. In the year ended December 31, 2020, DUKORAL product sales were driven by demand in Canada, and, to a lesser extent, product sales to European countries. In the year ended December 31, 2019, DUKORAL product sales were driven by strong sales performance in Canada, and, to a lesser extent, product sales to European countries.

Sales of IXIARO and DUKORAL decreased primarily in 2020 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, 2020, third-party product sales increased to €4.2 million, an increase of €0.3 million, or 6.7%, compared to €3.9 million in the year ended December 31, 2019. This increase was primarily due to increased sales of influenza vaccines, partly offset by significantly reduced demand for one of the third-party travel vaccine we sell, Vivotif, as a result of the COVID-19 pandemic and travel restrictions.

Product Sales—By Geography

We also monitor product sales generated in the countries and regions where we operate. The following table presents product sales by geography and is based on the final location where our distribution partner sells the product or where the customer or partner is located.

€ in thousands	**Year ended December 31,**	
	2020	**2019**
United States (military)	34,659	47,975
United States (non-military)	1,755	15,725
Canada	8,965	24,396
Germany	7,060	10,345
Nordics	2,866	11,027
Austria	3,333	2,668
United Kingdom	1,847	8,594
Other Europe	2,068	4,961
Rest of world	3,384	3,819
Total product sales	**65,938**	**129,511**

Total product sales in the United States decreased by €27.3 million, or 42.8%, from €63.7 million in the year ended December 31, 2019 to €36.4 million in the year ended December 31, 2020. Sales in the United States decreased primarily as a result of the COVID-19 pandemic, as travel restrictions significantly reduced demand for travel vaccines. The decreased demand for travel vaccines was partially mitigated by continued sales of IXIARO to the U.S. military. Product sales in Canada decreased by €15.4 million, or 63.3%, from €24.4 million in the year ended December 31, 2019 to €9.0 million in the year ended December 31, 2020. Sales in Canada decreased primarily as a result of the COVID-19 pandemic, partially mitigated by strong sales of DUKORAL in the first quarter of 2020. Typically DUKORAL sales are strongest in the first and the fourth quarter of the year, which is the main travel season for Canadians.

Other revenues

The following table presents our other revenues, by segment, for the years ended December 31, 2020 and 2019.

€ in thousands	Year ended December 31,	
	2020	2019
Commercialized products	1	163
COVID		
Vaccine candidates	31,604	(10,516)
Technologies and services	12,779	7,038
Total other revenues	**44,383**	**(3,315)**

In the year ended December 31, 2020, total revenue from collaborations, licensing and services were €44.4 million, an increase of €47.7 million compared to the prior year period in which we recognized negative revenue of €3.3 million. In the year ended December 31, 2020, our revenue from collaborations, licensing and services included €31.6 million related to our Lyme research and development collaboration with Pfizer, which we entered into in April 2020. Technologies and services revenues increased from €7.0 million in the year ended December 31, 2019 to €12.8 million in the year ended December 31, 2020, primarily resulting from increases in service revenues from our Solna facility and contract manufacturing we perform for third parties. In the year ended December 31, 2019, our negative revenue from collaborations, licensing and services was primarily driven by the effect of €10.7 million negative revenue related to the June 2019 mutual agreement to terminate our SAA with GSK, which included recognition of negative revenue related to both current and future payment obligations. We paid €9.0 million to GSK immediately and will pay up to a further €7.0 million upon the achievement of milestones related to marketing approvals of our Lyme vaccine candidate. Further information is shown in the table below and explained in Note 5.1 of to our consolidated financial statements as of and for the year ended December 31, 2020 included elsewhere in this Annual Report.

During the year ended December 31, 2019, the net effect of the SAA termination consisted of:

€ in thousands	
Settlement fee (fixed)	(9,000)
Settlement fee (variable; excluding financing component)	(5,987)
Release of SAA related contract liabilities	4,274
Net effect of SAA termination	**(10,714)**

Operating Income and Expenses

Cost of Goods and Services

Cost of goods and services, or COGS, increased by €1.5 million, or 2.9%, to €54.3 million with a gross margin on product sales of 36.6% for the year ended December 31, 2020, as compared to COGS of €52.8 million and gross margin on product sales of 63.1% for the year ended December 31, 2019. The increase in COGS was primarily due to write-offs of excess stock driven by reduced demand resulting from the COVID-19 pandemic, idle capacity costs in both of our manufacturing sites and increased costs associated with our collaboration and manufacturing agreements with Hookipa Pharma Inc. and Batavia Biosciences. The increase in COGS was partially offset by a decrease in license fees and royalties due to lower sales and a reduction in raw materials and consumables used.

COGS was €54.3 million, or 32.8% of our total operating income (expenses), for the year ended December 31, 2020, of which €24.8 million related to IXIARO sales, yielding a product gross margin of 48.9%, and of which €14.3 million related to DUKORAL sales, yielding a product gross margin of minus 7.3%. Gross margin 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 2020, COGS related to the third-party product distribution business was €2.8 million, and COGS related to cost of services was €12.5 million. COGS was €52.8 million, or 41.6% of our total operating income (expenses), for the year ended December 31, 2019, of which €31.1 million related to IXIARO sales, yielding a product gross margin of 67.1%. €14.0 million of COGS related to DUKORAL sales, yielding a product gross margin of 55.6%. Of the remaining COGS for the year ended December 31, 2020, €2.8 million related to the third-party product distribution business and €5.0 million related to cost of services.

Research and Development Expenses

Research and development expenses increased by €46.4 million, or 122.1%, to €84.5 million for the year ended December 31, 2020 from €38.0 million in the year ended December 31, 2019. Research and development expenses were 51.0% of our total operating income (expenses) for the year ended December 31, 2020, as compared to 29.9% of our total operating income (expenses) for the year ended December 31, 2019. This increase was driven primarily by investments in our clinical stage vaccine candidates, notably our Lyme, chikungunya and COVID-19 vaccine candidates, which resulted in an increase in consulting and other purchased services, employee benefit expense and raw materials and consumables used. Reclassifications mainly consisted of quality release services provided by the research and development organization, which were re-classified into COGS.

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. For the year ended December 31, 2019, these expenses consisted primarily of €13.7 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 function, of €16.2 million external research and development services and €2.2 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:

€ in thousands	**Year ended December 31,**	
	2020	**2019**
Chikungunya (VLA1553)	(31,746)	(14,460)
Lyme (VLA15)	(25,948)	(14,783)
COVID-19 (VLA2001)	(18,962)	—
IXIARO	(1,373)	(1,904)
hmPV	(1,327)	(2,052)
DUKORAL	(1,338)	(2,023)
Other research projects	(3,760)	(2,799)
Total research and development expenses	**(84,454)**	**(38,022)**

VLA1553. Our research and development expenses related to our chikungunya vaccine candidate program increased by €17.3 million, or 119.5%, to €31.7 million in the year ended December 31, 2020 from €14.5 million in the prior year period. This increase was primarily driven by increased expenses related to our Phase 3 clinical trial.

VLA15. Our research and development expenses related to our Lyme vaccine candidate program increased by €11.2 million, or 75.5%, to €25.9 million in the year ended December 31, 2020 from €14.8 million in the prior year period. This increase was primarily driven by the advancement of VLA15 in our Phase 2 clinical trial.

VLA2001. We began our COVID-19 vaccine candidate program in 2020 and, accordingly, have no comparative expenses in the 2019 period. Our research and development expenses related to our COVID-19 vaccine candidate program amounted to €19.0 million in the year ended December 31, 2020.

Our research and development expenses related to our commercial products and the rest of our development pipeline decreased by €1.0 million, or 11.2%, to €7.8 million in the year ended December 31, 2020 as we chose to focus our research and development efforts on our clinical-stage programs.

Marketing and Distribution Expenses

Marketing and distribution expenses decreased by €5.9 million, or 24.4%, to €18.3 million in the year ended December 31, 2020 from €24.1 million in the year ended December 31, 2019. Marketing and distribution expenses comprised 11.0% of our total operating income (expenses) for the year ended December 31, 2020, compared to 19.0% of our total operating income (expenses) for the year ended December 31, 2019. The decrease in the 2020 period was primarily the result of lower marketing and distribution spend across all our direct markets due to reduced sales activity as a result of the COVID-19 pandemic.

These expenses in both 2019 and 2020 were a result of continued investments in our key markets, the United States and Canada. 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. For the year ended December 31, 2019, marketing and distribution expenses consisted of €7.2 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €6.8 million of advertising expenses, including media and public relations expenses, €3.0 million of warehousing and distribution costs and €2.2 million of costs related to third-party services.

General and Administrative Expenses

General and administrative expenses increased by €9.1 million, or 49.7%, to €27.5 million for the year ended December 31, 2020 from €18.4 million for the year ended December 31, 2019. General and administrative expenses comprised 16.6% of our total operating income (expenses) for the year ended December 31, 2020 compared to 14.5% of our total operating income (expenses) for the year ended December 31, 2019. This increase was primarily driven by increased costs to support corporate transactions and projects, costs related to our share-based compensation programs and one-time termination of employment costs for two of our Management Board members.

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. For the year ended December 31, 2019, general and administrative expenses consisted of €11.0 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 €5.0 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:

€ in thousands	**Year ended December 31,**	
	2020	**2019**
Employee benefit expense other than share-based compensation[(1)]	(58,264)	(46,219)
Share-based compensation expense	(6,328)	(2,552)
Consulting and other purchased services	(65,212)	(29,840)
Raw materials and consumables used	(12,434)	(9,844)
Cost of services and change in inventory	(10,778)	(5,320)
Depreciation and amortization & impairment	(9,939)	(8,607)

€ in thousands	Year ended December 31,	
	2020	2019
Building and energy costs	(8,140)	(6,995)
License fees and royalties	(4,384)	(7,553)
Supply, office and IT-costs	(3,333)	(3,281)
Advertising costs	(2,496)	(6,801)
Warehousing and distribution costs	(1,898)	(3,013)
Travel and transportation costs	(529)	(1,921)
Other expenses	(822)	(1,399)
Operating expenses	**(184,558)**	**(133,345)**

(1) As of December 31, 2020, the position "employee benefit expense other than share-based compensations" includes a provision in the amount of €7.4 million of employer contribution fees, which are payable at the exercise of the IFRS 2 programs (December 31, 2019: nil).

The increase in operating expenses of €51.2 million mainly resulted from the increased research and development expenses.

Other Income (Expenses)

The table below summarizes the other operating income (expenses) for the years ended December 31, 2020 and 2019:

€ in thousands	Year ended December 31,	
	2020	2019
Research and development tax credit	9,937	6,314
Grant income	7,680	1,886
Profit/(loss) on disposal of fixed assets and intangible assets, net	(10)	(92)
Profit/(loss) from revaluation of lease agreements	1,584	—
Taxes, duties, fees, charges, other than income tax	(168)	(146)
Miscellaneous income/(expenses), net	95	(1,623)
Total other operating income (expenses), net	**19,117**	**6,338**

Other operating income and expenses increased by €12.8 million, or 201.6%, to €19.1 million for the year ended December 31, 2020 from €6.3 million for the year ended December 31, 2019. This increase was primarily due to the CEPI grants and COVID-19 pandemic related grants in the period ended December 31, 2020, as well as higher research and development tax credits resulting from increased qualifying research and development expenses. CEPI grants were €5.8 million and €1.8 million for the year ended December 31, 2020 and 2019, respectively. COVID-19-pandemic related grants amounted to €0.8 million in the period ended December 31, 2020. Research and development tax credits from Austria were €8.9 million and €4.4 million for the year ended December 31, 2020 and 2019, respectively. The CIR from France totaled €1.1 million and €1.9 million for the year ended December 31, 2020 and 2019, respectively. €1.6 million of income is derived from an early termination of a rental contract in Sweden.

In the year ended December 31, 2019, these amounts were partly offset by other expenses of €1.9 million, primarily related to a potential settlement of litigation related to the Vivalis-Intercell merger in 2013. See Note 5.30 to our consolidated financial statements included elsewhere in this Annual Report for more information about this litigation.

Financial Income (Expense)

The table below summarizes our financial income (expense) for the years ended December 31, 2020 and 2019:

€ in thousands	Year ended December 31,	
	2020	**2019**
Finance income		
Interest income from other parties	119	199
Fair value gains on derivative financial instruments	397	—
Foreign exchange gains, net	173	1,250
	689	**1,449**
Finance expense		
Interest expenses on loans	(6,162)	(1,588)
Interest expense on refund liabilities	(3,640)	(89)
Interest expenses on lease liabilities	(907)	(926)
Other interest expense	(30)	(30)
Fair value losses on derivative financial instruments	—	(449)
	(10,738)	**(3,082)**
Finance income/(expenses), net	**(10,049)**	**(1,633)**

Finance expense, net was €10.0 million for the year ended December 31, 2020 compared to €1.6 million for the year ended December 31, 2019. This increase in finance expense, net was mainly due to higher borrowings and the increase in non-current refund liabilities.

Income Tax

We recorded €0.9 million of income tax benefit for the year ended December 31, 2020 compared to an income tax expense of €0.9 million for the year ended December 31, 2019. This change in income tax benefit (expense) was primarily driven by effect from eliminated inter-company profits especially on the level of inventory held in the United States.

Profit/(Loss) for the Period

Our loss for the period for the year ended December 31, 2020 was €64.4 million, increased from a loss of €1.7 million in the year ended December 31, 2019. The increased loss in the 2020 period was primarily driven by decreased revenue from commercialized product sales and increased research and development expenses for our vaccine candidate programs.

Item 5B. Liquidity and Capital Resources.

Overview

Since our inception, we have financed our operations primarily through the issuance of equity and secured debt. As of December 31, 2021, we had €346.7 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, 2021 will fund our current operating plans through at least September 2023.

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 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.

As of December 31, 2021, we had borrowings and lease liabilities of €114.7 million, of which €57.8 million were other loans and €56.8 million were lease liabilities.

In July 2016, we entered into a €25.0 million term loan facility with the European Investment Bank, or EIB, as part of the European Horizon 2020 initiative. The EU through the EIB piloted a European Innovation Council, which aimed at generating market-creating innovation that can assist with rapid scale-up of European enterprises, in particular Small and Medium-sized Enterprises. Subject to the fulfillment of certain conditions precedent, the loan could be drawn in one or several tranches within a 36-month period. Each tranche was repayable at the end of a five-year period starting from the date of first draw-down on the loan. The loan was secured by the assets of our material subsidiaries, generally subordinate to security interests linked to our existing indebtedness. Furthermore, the loan agreement contained covenants, including that we maintain a positive EBITDA and a minimum cash balance of €3.0 million at all times. In the year ended December 31, 2017, two €5.0 million tranches were drawn under the loan facility with no commitment fee and subject to variable interest on amounts drawn. In July 2019, a €10.0 million tranche was drawn following the same conditions as the last two tranches of this loan. This loan was fully terminated and repaid early in the first quarter of 2020.

In February 2020, we entered into a debt financing agreement with Deerfield and OrbiMed. The intended use of proceeds was to repay existing borrowings from the EIB and allow us to continue to advance our Lyme and chikungunya development programs in the short term. Amortization payments will start in April 2023, while the loan will mature in February 2026. 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 loan is secured by substantially all of our assets, including our intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. Furthermore, the loan 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. To avoid a breach of covenants due to the decline in revenues caused by the COVID-19 pandemic, the initial agreement was amended in July 2020, to postpone the application of the minimum revenue covenant until December 31, 2020 (included) in exchange for a minimum liquidity covenant of €75.0 million (instead of €35.0 million) during that period. On January 15, 2021, a new amendment was executed to (i) bring the minimum liquidity covenant to the amount of €50.0 million in 2021 and 2022 and €35.0 million thereafter and (ii) 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, €103.8 million in 2022 and €115.0 million thereafter. 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 financing agreement with Deerfield and OrbiMed, 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 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. As of December 31, 2021, $56.3 million (€49.7 million) was outstanding under our debt financing agreement with Deerfield and OrbiMed.

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 candidate and our other vaccine candidates. The funds under these grants will be received over three years, beginning in March 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, 2021 and 2020

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

€ in thousands	**Year ended December 31,**	
	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 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.

Comparisons for the Years Ended December 31, 2020 and 2019

The table below summarizes our cash flows for the years ended December 31, 2020 and 2019:

€ in thousands	**Year ended December 31,**	
	2020	**2019**
Net cash generated from operating activities	137,738	5,529
Net cash used in investing activities	(19,340)	(10,685)
Net cash generated from/(used in) financing activities	21,740	(7,696)
Net change in cash and cash equivalents	**140,138**	**(12,852)**

Operating Activities

Net cash generated from operating activities for the year ended December 31, 2020 was €137.7 million compared to €5.5 million for the year ended December 31, 2019.

Net cash generated from operating activities for the year ended December 31, 2020 was €137.7 million, primarily derived by the $130.0 million (€116.9 million) 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 our agreement to develop and provide an inactivated COVID-19 vaccine and was reflected in working capital.

Net cash generated from operating activities was €5.5 million for the year ended December 31, 2019. The major adjustments to reconcile our net loss to net cash generated from operating activities consisted of non-cash expenses, such as depreciation and amortization, accrued expenses and share-based payments, partly offset by cash outflows from working capital and income tax paid.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was €19.3 million, compared to €10.7 million for the year ended December 31, 2019 and was comprised primarily of equipment purchases in both periods. More recently, the purchases have been driven by our manufacturing facilities expanding to support our COVID-19 vaccine candidate development activities.

Financing Activities

Net cash generated from financing activities was €21.7 million for the year ended December 31, 2020 compared to €7.7 million used in financing activities for the year ended December 31, 2019. The increase was primarily due to the impact of borrowing activities. Net cash 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.

Net cash used in financing activities was €7.7 million for the year ended December 31, 2019, driven primarily by the repayment of the Pharmakon Loan of €9.6 million in January 2019, offset by a €10.0 million tranche drawn against the €25.0 million term loan facility with the EIB. Payment of lease liabilities, interest paid and proceeds from issuance of common stock comprised the remainder of the financing activities.

Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. As of December 31, 2021 and 2020, we had accumulated a net loss of €307.0 million and €233.5 million, respectively. Our net loss was €73.4 million, €64.4 million and €1.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. We expect to incur significant expenses and 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 VLA2001 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;
- the number of potential new product candidates we identify and decide to develop;
- our ability to establish and maintain collaborations in 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 vaccine, 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, 2021 will be sufficient to fund our operations through at least September 2023.

Contractual Obligations

The following table discloses aggregate information about our material long-term contractual obligations as of December 31, 2021 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 thousands	**Less than 1 year**	**Between 1 and 3 years**	**Between 3 and 5 years**	**Over 5 years**	**Total**
Borrowings	7,121	48,560	20,534	1,765	77,980
Lease liabilities	4,060	29,011	5,761	24,631	63,464
Refund liabilities	101,070	132,355	55,000	12,720	301,145
Total	**112,252**	**209,927**	**81,295**	**39,115**	**442,589**

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

Borrowings

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 loan agreement with Deerfield and OrbiMed. The repayments will start in 2023, while the loan will mature in 2026. 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 €4.7 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 loan 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.

As of December 31, 2019, the outstanding amount of bank borrowings and other loans was €26.3 million. This amount consisted of a loan agreement with EIB of €19.8 million with a variable interest rate and planned repayments between 2021 and 2024, and other borrowings totaled €6.6 million and mainly related to financing of research and development expenses, fixed assets and CIR (research and development tax credit in France) and have various conditions (interest rates) and terms (maturities).

Lease Liabilities

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, which we expect will terminate in 2031 and 2037, respectively. Base rent will increase based on an inflation index. €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).

As of December 31, 2020, the outstanding, discounted amount of lease liabilities was €52.1 million. Of this, €26.2 million related to the lease agreement for premises in Sweden, which we expect will terminate in 2037. Base rent will increase based on an inflation index. €24.9 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 €1.1 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of December 31, 2019, the outstanding, discounted amount of lease liabilities was €58.9 million. Of this, €31.9 million was related to the lease agreement for premises in Solna, Sweden, which we expect will terminate in 2037. Base rent will increase based on an inflation index. €25.6 million was related to lease agreement for to the premises in Vienna, Austria. We expect that these leases will terminate in 2023 and that we will incur a final payment to buy the leased assets. Regular installments payments are variable and based on EURIBOR. Other lease liabilities of €1.4 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

Refund Liabilities

As of December 31, 2021, the carrying amount of refund liabilities was €254.6 million. Of this, €166.9 million (thereof €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, Inc., as we will 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 (thereof €70.0 million non-current) related to the collaboration with Pfizer Inc. for development of our Lyme disease vaccine, as we are 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.

As of December 31, 2019, the carrying amount of refund liabilities was €6.6 million (thereof €6.1 million non-current). This primarily comprised the expected payment to GSK related to the termination of the SAA and €0.5 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 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 judgment and estimates on the following critical accounting topics:

Revenue Recognition of Other Revenue

Management’s judgment 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 judgment 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 hard to value intangible assets, so various valuation techniques are used. In addition, management’s judgment is required on 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 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. As we are obligated to contribute 30% of all ongoing and future development costs through completion of the development program, as of December 31, 2021 and 2020, €79.6 million and €81.9 million, respectively, have been recognized as discounted refund liabilities to reflect the requirement to pay 30% of Pfizer’s research and development costs. The transaction price was determined taking into account our refund obligation and was modified during 2021. 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. Judgment 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, 2021 and 2020, €14.3 million and €31.6 million, respectively, was recognized as other revenue (from collaboration, licensing and services). The amount recognized in the year ended December 31, 2021 included an adjustment of revenues recognized in 2020 due to a modification of the agreements. €3.0 million and €2.8 million of costs to obtain a contract are included in other assets as of December 31, 2021 and 2020, respectively. Key assumptions applied by management included the allocation of cost that related directly to the contract, as well as the recoverability of these costs (mainly projected future cash flows generated by the contract with the customer). In case the refund liability varies from the estimates, the revenue will be adjusted in the period where the estimate is updated.

For additional details regarding the financial impact, see Note 5.1 to our consolidated financial statements, “General information and significant events of the period–Significant agreements signed in the periods presented”, included in this Annual Report.

In September 2020, we announced a collaboration with the UK government for our COVID-19 vaccine candidate, 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 is the delivery of 60 million doses, second is 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.

Following the close of business on September 10, 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us. First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective on October 10, 2021. The termination of the UK Supply Agreement was extensively assessed in 2021. We assessed the likelihood of repayment to be remote, resulting in €253.3 million being 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).

With regards to refund liabilities for royalties, the UK Authority's termination of the UK Supply Agreement has significantly changed the facts and circumstances underlying the initial estimate for the refund liability so that a revised estimate was made by management at the termination date. Key assumptions that were revised involved the location of customers (inside and outside the UK), market structure (presumed persistency of the SARS-CoV-2 virus with implications on pricing), as well as interest rates used in discounting of refund obligations.

For additional details regarding the financial impact, see Note 5.1 to our consolidated financial statements, "General information and significant events of the period–Significant agreements signed in the periods presented", included in this Annual Report.

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 an NGO partly funded by 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 WHO 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. Judgment 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, 2021 €3.5 million was recognized as revenue from collaboration, licensing and services and included €1.3 million from CEPI pursuant to the CEPI grant, where Instituto Butantan is the beneficiary.

Valuation of Intangibles and Tangibles / Impairment tests

As of December 31, 2021, impairment tests were performed on the IXIARO, DUKORAL and COVID cash-generating units (CGUs). For the first time, an impairment test has been performed for the COVID CGU, where the termination of the UK Supply Agreement represented a triggering event ("loss of a major customer"). The impairment tests resulted in no impairment charges being taken.

Our impairment calculations contain uncertainties as management is required to make assumptions and apply judgment to estimate future cash flows and asset fair values.

Key assumptions used in estimating future cash flows and asset fair values include projected revenue growth and operating expenses including the growth rate applied to the calculation of the terminal value, as well as forecasting asset useful lives and the determination of capital expenditure and working capital requirements.

These estimates are subjective and our ability to realize future cash flows and asset fair values is affected by factors such as ongoing maintenance and improvement of the assets, changes in economic conditions, as well the evolution of the COVID-19 related pandemic.

Management estimates are applied on several assumptions including on the WACC and the long range business plan.

For additional details regarding the financial impact, see Note 5.16 to our consolidated financial statements, "Impairment testing", included in this Annual Report.

Valuation of Inventories

Key assumptions used with regards to limited shelf life of finished goods include obsolescence assumptions based on aging of inventory, and the likelihood of obtaining extensions of shelf life from key suppliers.

Our impairment calculations contain uncertainties as management is required to make assumptions and apply judgment to estimate sales expectations and limited shelf life of finished goods.

Key assumptions used in estimating sales expectations include estimated selling prices based on forecasted demand, and the analysis of industry and market data which may suggest that there is a change in future demand.

For additional details regarding the financial impact, see Note 5.18 to our consolidated financial statements, "Inventories", included in this Annual Report.

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 €153.8 million, and €126.3 million as of December 31, 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.

Our calculation of deferred tax assets contain uncertainties as management is required to make assumptions and apply judgment to estimate the future availability of adequate taxable profits against which the unused tax lossen can be utilized.

Projections of future taxable profits (including revenues and assumed growth rates, projected capital expenditure and working capital requirements), assumptions with regard to tax planning opportunities and the timing of reversal of temporary differences in the future are associated with uncertainties that management are facing.

For additional details regarding the financial impact, see Note 5.10.2 to our consolidated financial statements, "Deferred tax", included in this Annual Report.

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.

Our assessment of contingencies and calculation of loss provision contain uncertainties as management is required to make assumptions and apply judgment with regards to the probability and amount of cash outflows, which is often based on information quoted in legal opinions or expert opinons by subject matter experts, as well as on information concerning the historical outcome of legal claims.

For additional details regarding the financial impact, see Note 5.1 to our consolidated financial statements, "General information and significant events of the period–Significant agreements signed in the periods presented", included in this Annual Report.

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, 2021 and 2020 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 2021 was €24.50, therefore the provision taken as of December 31, 2021 amounted to €26.5 million, whereas the latest share price in 2020 was €7.75 and the respective provision amounted to €7.4 million as of December 31, 2020. The employer contribution to be paid is depending on the date and the amount of the exercise in the future.

Our calculation of share-based compensation and related expected employer contribution cost contain uncertainties as management is required to make estimates and apply judgment with regards to contractual terms of share-based payment arrangements (including exercise prices, attrition rates, and vesting periods and conditions), the analysis of number and type of grants, as well as market prices underlying shares at grant date.

For additional details regarding the financial impact, see Note 5.23.1 to our consolidated financial statements, “Stock option plans”, included in this Annual Report.

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	58	Chairman of the Management Board, President, Chief Executive Officer
Franck Grimaud	55	*Directeur Général*, Chief Business Officer
Peter Bühler	52	Chief Financial Officer
Juan Carlos Jaramillo	51	Chief Medical Officer
Frédéric Jacotot	58	General Counsel, Corporate Secretary
Supervisory Board Members		
Frédéric Grimaud	57	Chairman of the Supervisory Board
James Sulat	71	Vice Chairman of the Supervisory Board
Anne-Marie Graffin	60	Member of the Supervisory Board
Sharon Tetlow	62	Member of the Supervisory Board
Johanna Willemina Pattenier	62	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.

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 limit for the exercise of functions of the members of the Supervisory Board is 80 years of age. The limitations on holding such an appointment concurrently with an appointment in another company are subject to the applicable legal 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 Exicure, Inc. since January 2021 and on the Board of GS Holdings, Inc. since October 2021. He previously served 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.

Anne-Marie Graffin has served on our Supervisory Board since 2013. She served as Chief Executive Officer of the BigBooster 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 a Vice President, 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 M2Care SAS since October 2019. 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. Ms. Tetlow has served as a member of the Board of Directors of Catalyst Biosciences, Inc. since January 2020 and as Chair of its Audit Committee since June 2020. Ms. Tetlow has been a member of the Board of Directors of DICE Therapeutics, Inc. (NASDAQ:DICE) since November 2020 and serves as Chair of the Audit Committee and a member of the Nominating and Corporate Governance Committee. Ms. Tetlow also served on the Board of Altamont Pharma Acquisition Corp. from February 2021 to January 2022. 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, 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, 2021:

Member Role	Maximum Allowable **Attendance Fee**
Supervisory Board Chairman	€75,000
Supervisory Board Vice-Chairman	€55,000
Supervisory Board Committee Chairman	€55,000
Supervisory Board Committee Member	€45,000
Supervisory Board Member	€40,000

The following table sets forth information regarding the attendance fees earned by members of the Supervisory Board during the year ended December 31, 2021:

Member	Attendance Fee Earned in 2021
Frédéric Grimaud	€ 72,917
James Sulat	€ 54,167
Anne-Marie Graffin	€ 53,333
Thomas Casdagli[(1)]	—
Sharon Tetlow	€ 50,625
Johanna Willemina Pattenier	€ 43,750

(1) Mr. Casdagli was a member of the Supervisory Board until March 2021.

Compensation of Members of the Management Board—2021

Our Management Board is currently comprised of five members:

- Thomas Lingelbach, Chair of the Board, President & CEO, with a current term ending at the 2022 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021;

- Franck Grimaud, *Directeur Général* & Chief Business Officer, with a current term ending at the 2022 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021;

- Peter Bühler, Chief Financial Officer effective January 1, 2022, with a current term ending at the 2022 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021. However, Valneva Austria GmbH has undertaken, in the absence of a cause for termination (in the meaning of Section 27 of the Austrian White Collar Employment Act), to renew Mr. Bühler's Management Agreement related to his Managing Director position at Valneva Austria, for an additional 3 years;

- Frédéric Jacotot, General Counsel & Corporate Secretary, with a current term ending at the 2022 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021; and

- Juan Carlos Jaramillo, CMO, with a current term ending at the 2022 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021.

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, 2021. As Mr. Bühler joined the Company on January 1, 2022, his compensation is not included below.

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, effective at the end of our Combined General Meeting of June 27, 2019, and (b) our Supervisory Board decisions, as applicable.

Type of Compensation	Amount of compensation earned	Description
Fixed compensation	€420,000	As per Supervisory Board decision of February 9, 2021.
Annual variable compensation	€252,000	60% of 2021 gross annual salary set by the Supervisory Board of February 9, 2021. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2021, on February 4, 2022.
Exceptional compensation	€60,000	As per the Supervisory Board decision of February 4, 2022. Exceptional compensation in recognition of Mr. Lingelbach's contributions to the growth of the Company's share capital and market presence over the course of 2021.
Fringe benefits :		
– Car rental	Lease fee: €10,705.73 Insurance: €3,506.64 Other car related expenses (except fuel) : €4,554.91	Maximum €1,210 per month for the lease fee as per Mr. Lingelbach's Management Agreement (or €14,520 per year).
– Death and endowment insurance policy	€12,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement of home workplace journeys made by flights, and associated costs	€2,556.18	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	**€765,323.46**	

Mr. Franck Grimaud – Management Board member, President & CBO

Mr. Grimaud's compensation is set in accordance with (a) the provisions of the Management Agreement executed between Mr. Grimaud and Valneva SE, effective at the end of our Combined General Meeting of June 27, 2019, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€265,383	As per Supervisory Board decision of February 9, 2021.
Annual variable compensation	€132,691.50	50% of 2021 gross annual salary set by the Supervisory Board of February 9, 2021. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2021, on February 4, 2022.
Exceptional compensation	€60,000	As per Supervisory Board decision of February 4, 2022. Exceptional compensation in recognition of Mr. Grimaud's contributions to the growth of the Company's share capital and market presence over the course of 2021.
Fringe benefits :		
– Car rental	Lease fee: €10,234.11 Insurance: €1,750.02	Maximum €1,210 per month for the lease fee as per Mr. Grimaud's Management Agreement (or €14,520 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	**€478,062.63**	

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, effective at the end of our Combined General Meeting of June 27, 2019, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€206,619	As per Supervisory Board decision of February 9, 2021.
Annual variable compensation	€103,309.50	50% of 2021 gross annual salary set by the Supervisory Board of February 9, 2021. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2021, on February 4, 2022.
Exceptional compensation	€60,000	As per Supervisory Board decision of February 4, 2022. Exceptional compensation in recognition of Mr. Jacotot's contributions to the growth of the Company's share capital and market presence over the course of 2021.
Fringe benefits :		
– *Garantie Sociale des Chefs et Dirigeants d'Entreprises*	€8,657.36	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	**€378,585.86**	

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, effective on October 1, 2020, and (b) our Supervisory Board decisions, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed compensation	€288,420	As per Supervisory Board decision of February 9, 2021.
Annual variable compensation	€144,210	50% of 2021 gross annual salary set by the Supervisory Board of February 9, 2021. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2021, on February 4, 2022.
Exceptional compensation	€60,000	As per Supervisory Board decision of February 4, 2022. Exceptional compensation in recognition of Dr. Jaramillo's contributions to the growth of the Company's share capital and market presence over the course of 2021.
Fringe benefits:		
– Car allowance	€13,200	€1,100 per month as per Dr. Jaramillo's Management Agreement.
– Death and endowment insurance policy	€12,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement of home workplace journeys made by flights, and associated costs	€9,345.40	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	**€527,175.40**	

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 ending December 31, 2022:

Management Board Member	2022 Base Salary
Thomas Lingelbach	€525,000
Franck Grimaud	€275,000
Peter Bühler	€350,000 from January 1, 2022 until the end of the General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2021 – then annual base salary increased to €380,000
Frédéric Jacotot	€215,000
Juan Carlos Jaramillo	€317,000

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, 2021:

Plan name	**BSA 27**
General Meeting date	June 30, 2016
Grant decision date	December 7, 2017
BSAs issued by the Management Board	87,500
Subscription price per share	€ 2.574
BSAs lapsed as of December 31, 2021	15,625
BSAs exercised as of December 31, 2021	50,000
Outstanding BSAs as of December 31, 2021	21,875
Valneva SE ordinary shares potentially resulting from exercise of the warrants remaining as of December 31, 2021	21,875

Stock Options

Since 2013, we have granted stock options to employees and management pursuant to five 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, 2021:

Plan name	ESOP 2013	ESOP 2015	ESOP 2016	ESOP 2017	ESOP 2019
General Meeting date	June 28, 2013	June 26, 2014	June 30, 2016	June 30, 2016	June 28, 2018
Grant date	October 2, 2013	July 28, 2015	October 7, 2016	December 7, 2017	September 30, 2019
Subscription price	€2.919	€3.92	€2.71	€2.85	€3.05
Option/share conversion ratio	1: 1.099617653 (then rounded-up for each beneficiary)	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
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)
Stock options exercised as of December 31, 2021	0	0	363,050	427,025	0
Shares resulting from exercise of stock options	0	0	363,050	427,025	0
Outstanding stock options as of December 31, 2021	633,700	522,500	36,200	552,725	2,188,260
Of which outstanding stock options held by corporate officers	*210,000*	*100,000*	*0*	*0*	*0*
Shares potentially resulting from stock option exercise after December 31, 2021	696,903	522,500	36,200	552,725	2,188,260
Stock options having lapsed as of December 31, 2021	419,250	189,500	185,000	289,750	481,750

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.

In December 2019, the Company granted free ordinary shares to the members of the Management Board (331,667 shares for the Chairman and 262,570 for each of the other members of the Management Board) and to the members of the Management Committee.

The following table shows the free ordinary shares outstanding as of December 31, 2021:

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 shall vest and be delivered (*seront définitivement acquises*) to the participants two (2) years as from December 19, 2019, the second tranche, three (3) years as from December 19, 2019 and the third tranche, 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, 2021	0
Free ordinary shares being vested as of December 31, 2021	1,782,404 (including 856,807 by corporate officers)
Free ordinary shares lapsed as of December 31, 2021	409,543 (following former Management Board members and one employee leaving the Company)
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 objectives 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. If a Management Board member's term of office is not renewed upon expiration in June 2022, the shares already vested will be kept, but the unvested shares will be lost.

Plan name	Free ordinary share plan 2019-2023
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, 2023, 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.

Free Convertible Preferred Shares

In December 2017, we granted FCPS to the members of the Management Board or Executive Committee (now the Management Committee) and to Manufacturing Site Heads, with conversion rules based on our stock price four years after the initial grant. This plan is based on the following general principles: (a) the participants were required to make a personal investment, through the purchase of ordinary shares on the open market, (b) the conversion ratio gradually increases, depending on our stock price after four years, with a target price (giving the highest conversion ratio) at €8, and (c) the maximum gross gain is limited by decreasing the conversion ratio if the stock price exceeds the target.

The following table shows the FCPS outstanding as of December 31, 2021::

Plan name	Free Convertible Preferred Share program 2017-2021
General Meeting date	June 29, 2017
Management Board decision	December 7, 2017
FCPS granted by the Management Board	34,017 by Management Board decision on December 15, 2017 (5,596 to the Chair of the Management Board, 4,651 to the other Management Board members serving at that time, and 1,157 for each of the other Executive Committee members also serving at that time (now "Management Committee") and the Manufacturing Site Heads (exception: 1,718 FCPS for the Senior Vice-President for whom pre-requisite investment was greater)

Plan name	Free Convertible Preferred Share program 2017-2021
FCPS fully vested as of December 31, 2021	32,463 (Including 14,898 by corporate officers), by Management Board decision of December 15, 2021 – i.e. at the expiry of a four-year period as from December 15, 2017 and taking into account, when applicable, fulfillment of employment conditions.
FCPS being vested as of December 31, 2021	0
FCPS lapsed as of December 31, 2021	1,554 (following former Management Board members leaving the Company)
Conversion of FCPS into ordinary shares of the Company	In accordance with article 5 of the Terms & Conditions applicable to the 2017-2021 Free Convertible Preferred Share Program (as set by the Management Board on December 15, 2017, the ***T&Cs***), the 32,463 FCPS became potentially convertible into Valneva SE ordinary shares on the day of their vesting – i.e. on December 15, 2021 (the ***Conversion Date***), on the basis of a conversion ratio to be determined according to (a) the Final Share Price (as defined below), and (b) the conversion table as appended to the T&Cs; it being specified that no conversion could occur if the Final Share Price was lower than €4.50 (the ***Floor Price***). The ***Final Share Price*** will be the volume-weighted average stock market price of the Company's ordinary shares on Euronext Paris over a period of 6 months immediately preceding the Conversion Date, as rounded to the second decimal place. On the Conversion Date, the Management Board noted that the Final Share Price (calculated between June 15, 2021 and December 14, 2021 inclusive) was €18.21, therefore higher than the Floor Price. Consequently, all the conditions required for a conversion of the FCPS were met. In order to be able to set the conversion ratio corresponding to the Final Share Price, the Management Board updated the conversion table attached as Annex A to the T&Cs, according to the principle set forth in Article 5, paragraph 4 of the T&Cs, as follows: If the Final Share Price is higher than €8, the conversion ratio will be such that the participants' gross gain will not exceed the gross gain they would have realized if the Final Share Price was €8. The Management Board, after having considered the updated conversion table, decided to set the conversion ratio applicable to the FCPS as follows: 27.23567 ordinary shares to 1 FCPS. In this respect, and in accordance with the T&Cs, where the total number of ordinary shares to be received by a holder of convertible preferred shares by applying the conversion ratio to the number of convertible preferred shares held is not a whole number, that holder shall receive the next lower whole number of ordinary shares. The fraction of ordinary shares forming a fractional lot shall be paid in cash. In such an event, the holder of convertible preferred shares shall receive an amount equal to the product of (i) the fraction of an ordinary share forming a fractional lot and (ii) an amount equal to the first recorded market price of the ordinary share for the stock exchange trading session immediately preceding that of the *ipso jure* conversion of the preferred shares into ordinary shares. Pursuant to Article 5 of the T&Cs, the holders of FCPS could in principle convert their FCPS into ordinary shares within a period of 3 months after the Conversion Date. According to decisions of the Supervisory Board and Management Board dated October 20, 2021, some foreign beneficiaries have been individually authorized to postpone the deadline for conversion of their FCPS up to a maximum of 12 months after full vesting of their FCPS, for reasons relating to the tax rules applicable to their country of residence. In any case, if the beneficiaries would not require conversion of the FCPS within the applicable period of time (the Conversion Period), these FCPS would automatically convert into ordinary shares at the expiry of such Conversion Period. * On December 16, 2021, the Company received a request for conversion of an aggregate of 4,115 FCPS, resulting in the issuance of 112,074 new ordinary shares. On January 3 and January 4, 2022, the Company received new requests for conversion of an aggregate of 28,348 outstanding FCPS, and resulting in the issuance of 772,070 new ordinary shares. Management Board members who are beneficiaries of the plan shall keep and retain under registered form at least 10% of the ordinary shares resulting from the conversion of their FCPS.

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, 2021, the Phantom Stock Option Programs consisted of an aggregate of 851,450 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 Mr. Grimaud, Mr. Sulat, and Ms. Graffin will expire at the end of the Annual General Meeting of shareholders in June 2022, and the terms of Ms. Tetlow and Dr. Pattenier will expire at the end of the Annual General Meeting of shareholders in June 2023. 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 exercise of functions of the members of the Supervisory Board is 80 years of age. 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 Frédéric Grimaud, James Sulat and Sharon Tetlow. Ms. Tetlow is the chair of the committee.

Our Supervisory Board has determined that 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. Prior to the first anniversary of our May 2021 listing on Nasdaq, Mr. Grimaud will resign from the audit and governance committee and will be replaced by an independent director; at that point, all members of the audit and governance committee will be independent. Our Supervisory Board has further determined that Mr. Sulat is an "audit committee financial expert" as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

The principal responsibility of our audit 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, 2021, we had a total of 762 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	256
Valneva Canada Inc.	5
Valneva France SAS	4
Valneva Scotland Ltd	251
Valneva SE	50
Valneva Sweden AB	175
Valneva UK Ltd	5
Valneva USA, Inc.	16
Total	**762**

Of these employees, approximately 50% were primarily engaged in manufacturing, 25% in research and development, 20% in general and administrative functions and 5% 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, 2021, 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 FCPS that vest within 60 days of December 31, 2021 and options and equity warrants (BSAs) that are currently exercisable or exercisable within 60 days of December 31, 2021. Ordinary shares subject to free ordinary shares and FCPS that vest within 60 days of December 31, 2021, and options and BSAs currently exercisable or exercisable within 60 days of December 31, 2021 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	13.03
Bpifrance Participations SA(2)	9,501,441	9.03
Management Board and Supervisory Board Members:		
Thomas Lingelbach(3)	612,910	*
Franck Grimaud(4)	810,047	*
Juan Carlos Jaramillo	—	—
Frédéric Jacotot(5)	235,995	*
Frédéric Grimaud(6)	13,981,577	13.29
James Sulat(7)	30,367	*
Anne-Marie Graffin(8)	14,250	*
Sharon Tetlow	—	—
Johanna Willemina Pattenier	—	—
All members of our Management Board and Supervisory Board as a group (9 individuals)(9)	**15,685,146**	**14.91**

* 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) 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. Based on a Schedule 13G filed with the Securities and Exchange Commission on February 10, 2022, Bpifrance, EPIC, Bpifrance S.A. hold beneficial ownership over 8,619,478 ordinary shares and CDC holds beneficial ownership over 9,501,441 shares (inclusive of the 8,619,478 shares beneficially held by Bpifrance, EPIC, Bpifrance S.A.). 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 current members of the board of directors of Bpifrance are Nicolas Dufourcq, Carole Abbey Duval, Antoine Saintoyant, Frederic Saint-Geours, Constance Valigny, Chloe Mayenobe, Victoire Aubry, Sophie Stabile, Romain Bonenfant and the French State, represented by Charles Sarrazin. 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) Consists of (i) 139,983 ordinary shares, (ii) 152,410 ordinary shares issuable upon vesting and conversion of 5,596 convertible preferred shares within 60 days of December 31, 2021, (iii) 110,555 ordinary shares issuable upon vesting of first tranche of the 2019 Free ordinary share plan within 60 days of December 31, 2021, and (iv) 209,962 ordinary shares issuable upon exercise of stock options within 60 days of December 31, 2021.

(4) Consists of (i) 485,889 ordinary shares, (ii) 126,673 ordinary shares issuable upon vesting and conversion of 4,651 convertible preferred shares within 60 days of December 31, 2021, (iii) 87,523 ordinary shares issuable upon vesting of first tranche of the 2019 Free ordinary share plan within 60 days of December 31, 2021, and (iv) 109,962 ordinary shares issuable upon exercise of stock options within 60 days of December 31, 2021.

(5) Consists of (i) 10,802 ordinary shares, (ii) 126,673 ordinary shares issuable upon vesting and conversion of 4,651 convertible preferred shares within 60 days of December 31, 2021, (iii) 87,523 ordinary shares issuable upon vesting of first tranche of the 2019 Free ordinary share plan within 60 days of December 31, 2021, and (iv) 10,997 ordinary shares issuable upon exercise of stock options within 60 days of December 31, 2021.
(6) Consists of (i) 270,496 ordinary shares, (ii) 6,250 ordinary shares issuable upon exercise of BSAs within 60 days of December 31, 2021, and (iii) the securities held by Groupe Grimaud described in footnote (1) above. Mr. Grimaud is the President & Chief Executive Officer of Groupe Grimaud.
(7) Consists of (i) 27,242 ordinary shares and (ii) 3,125 ordinary shares issuable upon exercise of BSAs within 60 days of December 31, 2021.
(8) Consists of (i) 11,125 ordinary shares and (ii) 3,125 ordinary shares issuable upon exercise of BSAs within 60 days of December 31, 2021.
(9) Consists of (i) 14,647,316 ordinary shares, (ii) 405,756 ordinary shares issuable upon conversion of 14,898 convertible preferred shares, (iii) 12,500 ordinary shares issuable upon exercise of BSA vested within 60 days of December 31, 2021, (iv) 285,601 ordinary shares issuable upon vesting of first tranche of the 2019 Free ordinary share plan, and (v) 330,921 ordinary shares issuable upon exercise of stock options vested within 60 days of December 31, 2021.

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2019 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.

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, 2021, approximately 15,728,996 shares, or 15% of our ordinary shares outstanding at that date, were held of record by 13 residents of the United States.

B. Related Party Transactions

Since January 1, 2021, 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 May 2021, Bpifrance Participations SA purchased 1,514,576 of our ordinary shares at the public offering price of €11.00 per share, for an aggregate purchase price of €16.7 million. In November 2021, Bpifrance Participations SA purchased 294,117 of our ordinary shares at the public offering price of €17.00 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 with Groupe Grimaud La Corbière SA (now Groupe Grimaud La Corbière SAS), or Groupe Grimaud, which was subsequently assigned to Vital Meat SAS, 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 March 31, 2022, we granted Groupe Grimaud a two-year 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. Under this agreement, Groupe Grimaud and affiliates made payments to us totaling €233.2 thousand excluding tax in 2021.

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.

E. 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

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 contemplate 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 has exercised, has a minimum value of approximately $28.8 million for 200,000 doses. The second option year, if exercised, has a minimum value of approximately $36 million for 250,000 doses. Like most governmental contracts, these contracts can be terminated by DLA for convenience at any time.

We will also 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 $5.4 million recognized as of December 31, 2021.

Since 2009, we have also had a Federal supply schedule contract with the Department of Veterans Affairs listing IXIARO.

Pfizer License Agreement

In April 2020, we entered into a research collaboration and license agreement, or the Pfizer License, with Pfizer. In connection with the Pfizer License, 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 VLA-15 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. 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 19% on net sales of licensed products, subject to specified offsets and reductions. 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.

The Pfizer Agreement 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.

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. The EC APA includes an order for approximately 24.3 million doses of the Product for delivery to Participating Member States in 2022 and provides an option for Participating Member States to purchase up to approximately 35.7 million doses of the Product for delivery in 2023. Participating Member States will contribute up-front payments equal to a certain percentage of the total purchase price for their respective quantities of the Product, and such up-front payments would apply to the Product purchased following exercise of the 2023 option.

We are obligated to manufacture the Product within the European Union and European Economic Area and to deliver the Product according to a specified delivery timeline. The EC APA provides that, if delivery of the Product is delayed by a certain period of time, any Participating Member State may cancel its purchase of the delayed doses of the Product, which would require us to reimburse certain amounts of the up-front payment associated with such delayed and cancelled doses to such Participating Member State and, in certain circumstances, make us subject to claims for liquidated damages. Delivery of the Product is subject to first obtaining a marketing authorization for the Product from the EMA, and we are required to use best reasonable efforts to obtain this marketing authorization as soon as reasonably possible. The EC may terminate the EC APA in the event that we do not receive a marketing authorization by April 30, 2022. In such case, the EC and Participating Member States must notify us within 15 days whether they intend to terminate the agreement on this basis, and we shall have 30 days to obtain a marketing authorization or otherwise propose an acceptable remediation plan. Further, the EC APA provides that, if we do not obtain a marketing authorization covering the entire adult population (adults aged 18 and older) by June 30, 2022, any Participating Member State shall have the right to cancel its purchase of a certain percentage of doses, which would require us to reimburse to such Participating Member State the equivalent percentage of its up-front payment.

The EC APA will remain in place until all quantities of the Product ordered thereunder have been delivered. In addition to the termination provisions mentioned above, the EC may terminate the EC APA if delivery of all doses ordered for 2022 has not taken place by December 31, 2022 or any later date as may be agreed. In the event of such a termination, we would be required to repay any unspent and uncommitted amounts of up-front payments received from the Participating Member States. The EC may also terminate the EC APA in case of our material uncured breach of its provisions or in the event of certain insolvency situations, breaches of tax or social security contribution obligations, conflicts of interest, fraud, or force majeure. We may terminate the EC APA in the event of an uncured material breach of the EC or force majeure, and we may terminate the order of any Participating Member State in the event of an uncured material breach or such Participating Member State or force majeure.

IDT Commercial Manufacturing Services Agreement

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 will manufacture VLA2001 and provide other contract manufacturing services under separate product schedules. A separate product schedule pertaining to Valneva's proprietary vaccine candidate VLA2001, or the IDT Product Schedule, provides that IDT will manufacture a certain number of batches of VLA2001 during the year ending December 31, 2022. The IDT Agreement provides an option for IDT to manufacture additional batches during 2023. The maximum value of the IDT Product Schedule, including the exercise of the maximum amount under the option, is approximately €280.6 million. Valneva and IDT may enter into further product schedules, each of which would set the pricing terms applicable to the manufacturing and services to be provided thereunder.

The IDT Product Schedule for VLA2001 will be in effect until December 31, 2023 unless otherwise extended or terminated. The IDT Agreement will expire in November 2026 unless previously terminated. Valneva may terminate the IDT Agreement or the IDT Product Schedule for convenience. Either party may terminate the IDT Agreement or the IDT Product Schedule, in whole or in part, in case of material breach, insolvency, or certain compliance failures.

UK Supply Agreement

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 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. Valneva received notice in September 2021 of the UK Authority's decision to terminate the UK Supply Agreement, and the termination became effective in October 2021, as described 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. Pursuant to the terms of the UK Supply Agreement, the UK Authority placed an initial order for 60 million doses to be delivered in 2021 and was granted an option for a further 40 million doses to be delivered in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. In January 2021, the UK Authority exercised its option to order 40 million doses for delivery in 2022. The UK Supply Agreement required the UK Authority to pay us advance payments to fund certain manufacturing-related expenses over the life of the project, subject to our continued supply of product in accordance with the terms of the UK Supply Agreement. As of December 31, 2021, we had received advance payments totaling £359.2 million (€408.3 million). We are obligated to pay the UK Authority a low single-digit royalty on net sales, to non-UK customers, of product manufactured using any facilities used under the UK Supply Agreement, subject to a maximum royalty payment of €100 million, and this requirement survived termination of the UK Supply Agreement.

Following the close of business on September 10, 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. We had not received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, if the UK Authority were to successfully bring proceedings for damages against Valneva in respect of the alleged anticipatory breach, it could be argued that the applicable contractual cap on our liability under the UK Supply Agreement could be as high as an amount equivalent to the sums paid to us by the UK Authority prior to termination. However, we believe that it is very unlikely that any such claim by the UK Authority will be successful. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination for alleged anticipatory breach nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, 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. We remain obligated to pay the UK Authority a low single-digit royalty on net sales, as noted above.

The impact of the termination of the UK Supply Agreement was assessed at the end of 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 is more than remote, a refund liability of €166.9 million was recognized for the royalty on sales and other certain obligations which survive the termination of the UK Supply Agreement. Moreover, provisions for the present obligation under the onerous purchase agreements and write-downs for materials of COVID-19 vaccine were recognized.

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.

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. 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.

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 below.

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.

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

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, 2021. 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. 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 corresponding to the standard corporate income tax rate set forth in Article 219-I of the FTC for legal persons. Special rules apply to U.S. holders who are residents of more than one country. 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, 2021, our market capitalization exceeds 1 billion euros, pursuant to BOI-ANNX-000467-29/12/2021.

However, given that Nasdaq Global Select Market, on which ADSs are listed, is not currently acknowledged by the AMF, the acquisition of ADSs is currently out of the scope of the tax on financial transactions, but this may change in the future if the Nasdaq Global Select Market becomes acknowledged by the French AMF.

In the case where Article 235 *ter* ZD of the FTC is not applicable, the French tax code provides that transfers of shares—issued by a French company which are listed on a regulated or organized market within the meaning of Articles L421-1 and L424-1 of French monetary code (*Code monétaire et financier*) or, pursuant to French tax administrative doctrine (BOI-ENR-DMTOM-40-10-10-12/09/2012 # 50), listed on another similar regulated or organized market operating under similar conditions—are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written deed (*acte*) executed either in France or outside France.

However neither the French tax code, nor case law or official guidelines published by the French tax authorities indicate if the transfer of ADSs should be in the scope of the 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.

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, 2021**
EUR/USD +10%	6,818
EUR/USD -10%	(8,334)
EUR/GBP +10%	(11,986)
EUR/GBP -10%	14,650
EUR/SEK +10%	(2,884)
EUR/SEK -10%	3,525
EUR/CAD +10%	(557)
EUR/CAD -10%	681

As of December 31, 2021, the changes in impact from an increase or a decrease in USD were mainly caused by a decrease in cash and cash equivalents and intercompany (IC) receivables denominated in USD in Valneva Austria GmbH.

As of December 31, 2021, the increase in the Foreign Currency Exchange Risk in GBP was caused by higher refund liabilities denominated in GBP in Valneva Austria GmbH and by increased IC liabilities denominated in Euro in Valneva Scotland Ltd, both relating to the COVID-19 vaccine program. For more information see Note 5.1 of to our consolidated financial statements as of and for the years ended December 31, 2021 and 2020 included elsewhere in this Annual Report.

As of December 31, 2021, the increase in the Foreign Currency Exchange Risk in SEK was caused by increased 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 USD. 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. For more information see Note 5.29 of to our consolidated financial statements as of and for the years ended December 31, 2021 and 2020 included elsewhere in this Annual Report.

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 rate. During 2020 and 2019, our investments at variable rates, as well as the borrowings at variable rates, were denominated in EUR, SEK, USD, CAD and in GBP. We analyze our interest rate exposure on a dynamic basis. Based on this analysis, we calculated the impact on profit and loss of a defined interest rate change. The same interest rate change was used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As of December 31, 2021 and December 31, 2020, no material interest risk was identified. In case of increasing interest rates, the positive effect from cash in banks will be higher than the negative effect from variable interest-bearing liabilities; in case of decreasing interest rates, there will be no material negative impact.

Credit Risk

We are exposed to credit risk. We hold bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of our counterparts, we rely on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. We have policies that limit the amount of credit exposure to any single financial institution. We are also exposed to credit risks from our trade debtors, as our income from product sales, collaborations, licensing and services arises from a small number of transactions. We have policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits as set by the Management Board.

C. Interim Periods

Not applicable.

D. Safe Harbor

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See "Special Note Regarding Forward-Looking Statements."

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Citibank 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 and is also incorporated by reference as an exhibit to this Annual Report. 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 share**s** 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.

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.

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and our chief financial officer (principal financial officer), has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13(a)-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended), as of December 31, 2021. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2021 as a result of the material weaknesses described below. We are undertaking the remedial steps to address the material weakness in our disclosure controls and procedures as discussed below.

Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities & Exchange Commission for newly public companies.

In connection with the preparation of our financial results for the year ended December 31, 2020, management previously identified three material weaknesses in our internal control over financial reporting:

(i) a lack of formal, documented and implemented processes, controls and review procedures,
(ii) insufficient controls on manual journal entries due to insufficient segregation of duties in the finance and accounting function and
(iii) insufficient controls over the accuracy and completeness of information that is being processed and reported by third parties, used to recognize revenue and record inventory.

In response to the identified material weaknesses, we took a number of actions to improve our internal control over financial reporting during the year ended December 31, 2021, including the following:

- We identified and formalized the majority of our key business processes controls and general IT controls;
- We designed and began implementing an approval flow for manual journal entries in our ERP system addressing segregation of duties at one of our sites; and
- We designed and implemented controls over our third parties to ensure that information provided regarding revenue and inventory is complete and accurate.

As a result of the remediation activities described, as of December 31, 2021, management has concluded that one of the three previously disclosed material weaknesses has been remediated. The remediated material weakness previously identified in our internal control over financial reporting related to:

>

- (iii) Insufficient controls over the accuracy and completeness of information that is being processed and reported by third parties, used to recognize revenue and record inventory.

As noted above, we began to implement the manual journal entries approval flow in our ERP system at one of our sites in the year ended December 31, 2021. As the implementation occurred in December 2021, it was deemed that the transactions and coverage period of less than one month was not sufficient to fully remediate, for the year ended December 31, 2021, material weakness (ii) relating to insufficient controls on manual journal entries due to insufficient segregation of duties in the finance and accounting function. Assuming the effective operation of the new approval flow across all of our sites, management expects that material weakness (ii) will be remediated in the first half of 2022.

With the oversight of senior management and our audit committee, we continue to evaluate our internal control over financial reporting and are taking several remedial actions to address the material weakness that has been identified in connection with (i) a lack of formal, documented and implemented processes, controls and review procedures. These actions include, but are not limited to, the following:

- We performed a control gap analysis and identified the remaining controls that require implementation and formalization;
- We identified the controls that are complex in nature or performance, and we are working towards enhancing the level of documentation supporting their activity; and
- We are implementing measures to enhance the documentation of the accuracy and completeness of source data.

B. Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

D. Changes in Internal Control Over Financial Reporting

Other than as noted above in "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..

Item 16. [Reserved]

A. Audit Committee Financial Expert

Our Supervisory Board has determined that 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 Mr. Sulat is an "audit committee financial expert" as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

B. Code of Ethics

We have adopted a Code of Conduct applicable to all of our employees and members of our Management Board and Supervisory Board. Our Code of Conduct is available on our website. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

C. Principal Accountant Fees and Services

PricewaterhouseCoopers Audit and Deloitte & Associés served as our independent auditors for the year ended December 31, 2021 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, 2021 and 2020.

Principal Accountant Fees and Services:

€ in thousand	**Year ended December 31,**							
	PricewaterhouseCoopers				**Deloitte & Associés**			
	2021	%	**2020**	**%**	**2021**	**%**	**2020**	**%**
Audit fees	**1,122**	**91%**	**607**	**78%**	**1,114**	**93%**	**589**	**77%**
provided by the statutory auditor	*937*		*517*	-	*939*		*492*	-
provided by the statutory auditor's network	*185*		*90*	-	*174*		*97*	-
Audit-related Fees	**90**	**7%**	**170**	**22%**	**85**	**7%**	**173**	**23%**
provided by the statutory auditor	*85*		*145*	-	*85*		*155*	-
provided by the statutory auditor's network	*5*		*25*	-	*0*		*18*	-
Tax Services	**25**	**2%**	**0**	-	**0**	**0**	**0**	-
provided by the statutory auditor's network	**25**	-	**0**	-	**0**	-	**0**	-
All Other Fees	**0**	-	**0**	-	**0**	-	**0**	-
Total	**1,238**	**100%**	**777**	**100%**	**1,199**	**100%**	**762**	**100%**

"**Audit fees**" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that PricewaterhouseCoopers and Deloitte & Associés provides, such as consents and assistance with and review of documents filed with the SEC.

"**Audit-related Fees**" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

"**Tax fees**" are the aggregate tax fees billed for services related to the production of certification in the context of the declaration of expenses for the obtention of grants and the preparation of special reports relating to certain operations on the Company's capital.

Auditor Name	**Auditor Location**	**Auditor Firm ID**
PricewaterhouseCoopers Audit	Neuilly-sur-Seine, France	1347
Deloitte & Associés	Paris, France	1756

Audit and Non-Audit Services Pre-Approval Policy

French law requires that audit committees pre-approve any non-audit services to be performed by a company's statutory auditors. Additionally, French law requires audit committees to ensure that such non-audit services will not affect the independence of the statutory auditors in performing their audit services, and the fees received for non-audit services cannot exceed 70% of the total fees for audit services.

Accordingly, our Audit and Governance Committee, or the Committee, has authority to propose the retention and compensation of the Company's registered public accounting firms and oversees the independence and performance of such firms with respect to both audit-related and non-audit-related services. The Committee may approve the provision of services other than the certification of financial statements by the auditors following an analysis of the potential impact of providing such services on the auditors' independence and the approval of any safeguards that may be required to mitigate such impact.

Prior to engagement of any prospective auditors, the Committee reviews a written disclosure by the prospective auditors of all relationships between the prospective auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and discusses with the prospective auditors the potential effects of such relationships on the independence of the prospective auditors, consistent with Ethics and Independence Rule 3526, Communication with Audit Committees Concerning Independence ("Rule 3526"), of the Public Company Accounting Oversight Board (United States). Consistent with Rule 3526, at least annually, the Committee receives and reviews written disclosures from the auditors delineating all relationships between the auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and a letter from the auditors affirming their independence, and considers and discusses with the auditors any potential effects of any such relationships on the independence of the auditors as well as any compensation or services that could affect the auditors' objectivity and independence.

The Committee has considered the non-audit services provided by PricewaterhouseCoopers and Deloitte & Associés as described above and believes that they are compatible with maintaining PricewaterhouseCoopers and Deloitte & Associés's independence as our independent registered public accounting firms.

D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

F. Changes to Certifying Accountant

Not applicable.

G. Corporate Governance

As a French *société européenne*, we are subject to various corporate governance requirements under French law. We are a "foreign private issuer" under the U.S. federal securities laws and the Nasdaq listing rules. The foreign private issuer exemption will permit us to follow home country corporate governance practices instead of certain Nasdaq listing requirements. A foreign private issuer that elects to follow a home country practice instead of Nasdaq listing requirements must submit to Nasdaq a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws.

We apply the 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
3.1*	Bylaws (*statuts*) of the Registrant (English translation)				
4.1	Form of Deposit Agreement	F-1/A	333-255155	4.1	April 29, 2021
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-255155	4.2	April 29, 2021
4.3*	Description of Securities				
10.1†	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
10.2†	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
10.3 †*	Advance Purchase Agreement, dated January 12, 2021, by and between the European Commission and Valneva Austria GmbH.				
10.4†	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
10.5 †*	Amendment to Supply Agreement, dated October 28, 2021, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.				
10.6 †*	Master Supply and Commercial Manufacturing Services Agreement, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH.				
10.7 †*	Product Schedule, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH.				
10.8†	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
10.9†	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
10.10†	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
10.11†	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
10.12†	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
10.13†	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
10.14#	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

10.15†	Distribution Agreement (IXIARO), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Austria GmbH.	F-1	333-255155	10.10	April 9, 2021
10.16†	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	10.11	April 9, 2021
10.17+	Employee Stock Option Plan 2013	F-1	333-255155	10.12	April 9, 2021
10.18+	Employee Stock Option Plan 2015	F-1	333-255155	10.13	April 9, 2021
10.19+	Employee Stock Option Plan 2016	F-1	333-255155	10.14	April 9, 2021
10.20+	Employee Stock Option Plan 2017	F-1	333-255155	10.15	April 9, 2021
10.21+	Employee Stock Option Plan 2019	F-1	333-255155	10.16	April 9, 2021
10.22+	Free Convertible Preferred Share Plan 2017-2021	F-1	333-255155	10.17	April 9, 2021
10.23+	Free Share Plan 2019-2023	F-1	333-255155	10.18	April 9, 2021
10.24+	Phantom Stock Option Plan 2017 and Form of Exercise Notice	F-1	333-255155	10.19	April 9, 2021
10.25+	Phantom Stock Option Plan 2019	F-1	333-255155	10.20	April 9, 2021
10.26+	Phantom Stock Plan 2020	F-1	333-255155	10.21	April 9, 2021
10.27+	Terms and Conditions Applicable to BSA 27 Equity Warrants and Form of Exercise Notice	F-1	333-255155	10.22	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				
21.1	Subsidiaries of the Registrant	F-1	333-255155	21.1	April 9, 2021

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 S.E.

By: */s/ Thomas Lingelbach*
Thomas Lingelbach
Chief Executive Officer

Date: March 24, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

VALNEVA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Management Board and Shareholders 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, 2021 and 2020, and the related consolidated statements of income (loss) and 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”).

Change in Accounting Principle

As discussed in Note 5.13 to the consolidated financial statements, the Company changed the manner in which it accounts for leases effective January 1, 2019, due to the adoption of IFRS 16 – “Leases”.

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 Public Company Accounting Oversight Board (United States) (“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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Deloitte & Associés

/s/ PricewaterhouseCoopers Audit

/s/ Cédric Mazille

Bordeaux and Neuilly-sur-Seine, France

March 23, 2022

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

CONSOLIDATED FINANCIAL STATEMENTS 2021

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, 2021

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,**		
		2021	**2020**	**2019**
Product sales	5.4/5.5	62,984	65,938	129,511
Other revenues	5.4/5.5	285,101	44,383	(3,315)
Revenues		**348,086**	**110,321**	**126,196**
Cost of goods and services	5.4/5.6	(187,920)	(54,302)	(52,781)
Research and development expenses	5.4	(173,283)	(84,454)	(38,022)
Marketing and distribution expenses	5.4	(23,643)	(18,264)	(24,145)
General and administrative expenses	5.4	(47,606)	(27,539)	(18,398)
Other income and expenses, net	5.8	22,976	19,117	6,338
OPERATING LOSS		**(61,390)**	**(55,120)**	**(811)**
Finance income	5.9	8,379	689	1,449
Finance expenses	5.9	(16,964)	(10,738)	(3,082)
Result from investments in associates	5.15	(5)	(133)	1,574
LOSS BEFORE INCOME TAX		**(69,979)**	**(65,302)**	**(870)**
Income tax income/(expense)	5.10	(3,446)	909	(874)
LOSS FOR THE PERIOD		**(73,425)**	**(64,393)**	**(1,744)**
Losses per share for loss for the period attributable to the equity holders of the Company, expressed in € per share	5.11			
- **basic**		**(0.75)**	**(0.71)**	**(0.02)**
- **diluted**		**(0.75)**	**(0.71)**	**(0.02)**

The accompanying notes form an integral part of these financial statements

1.2 Comprehensive Income (Loss)

€ in thousand	Note	Year ended December 31,		
		2021	2020	2019
Loss for the period		**(73,425)**	**(64,393)**	**(1,744)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit or loss				
Currency translation differences	5.22.1	(2,877)	2,438	656
Items that will not be reclassified to profit or loss				
Defined benefit plan actuarial gains/(losses)	5.30.1	205	(78)	(13)
Other comprehensive income/(loss) for the year, net of tax		**(2,672)**	**2,360**	**644**
TOTAL COMPREHENSIVE LOSS FOR THE YEAR ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(76,097)**	**(62,033)**	**(1,100)**

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

2 CONSOLIDATED BALANCE SHEETS

€ in thousand	Note	As at December 31,	
		2021	2020
ASSETS			
Non-current assets		**231,520**	**140,737**
Intangible assets	5.12	32,700	35,409
Right of use assets	5.13	48,285	43,374
Property, plant and equipment	5.14	125,545	34,779
Investments in associates	5.15	2,124	2,130
Deferred tax assets	5.10.2	3,582	5,570
Other non-current assets	5.20	19,282	19,476
Current assets		**585,832**	**308,427**
Inventories	5.18	124,098	26,933
Trade receivables	5.19	44,013	19,232
Other current assets	5.20	71,036	57,828
Cash and cash equivalents	5.21	346,686	204,435
TOTAL ASSETS		**817,352**	**449,164**
EQUITY			
Capital and reserves attributable to the Company's equity holders		**170,581**	**77,422**
Share capital	5.22	15,786	13,646
Share premium	5.22	409,258	244,984
Other reserves	5.22	52,512	52,342
Retained earnings/(Accumulated deficit)	5.22	(233,549)	(169,156)
Loss for the period		(73,425)	(64,393)
LIABILITIES			
Non-current liabilities		**277,791**	**195,872**
Borrowings	5.24	50,726	46,375
Lease liabilities	5.13/5.27	53,687	49,392
Contract liabilities	5.28	4,741	58
Refund liabilities	5.29	158,970	97,205
Provisions	5.30	8,308	2,358
Deferred tax liabilities	5.10.2	1,290	412
Other liabilities	5.31	69	72
Current liabilities		**368,979**	**175,870**
Borrowings	5.24	7,107	6,988
Trade payables and accruals	5.25	68,119	36,212
Income tax liability	5.10	83	—
Tax and Employee-related liabilities	5.26	17,249	13,165
Lease liabilities	5.13/5.27	3,135	2,696
Contract liabilities	5.28	124,017	89,578
Refund liabilities	5.29	95,611	14,222
Provisions	5.30	48,708	10,169
Other liabilities	5.31	4,950	2,841
TOTAL LIABILITIES		**646,771**	**371,742**
TOTAL EQUITY AND LIABILITIES		**817,352**	**449,164**

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

3 CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	**Note**	**Year ended December 31,**		
		2021	**2020**	**2019**
Cash flows from operating activities				
Loss for the year		(73,425)	(64,393)	(1,744)
Adjustments for non-cash transactions	5.32	56,476	37,941	12,704
Changes in non-current operating assets and liabilities	5.32	59,353	88,472	3,597
Changes in working capital	5.32	36,127	77,740	(6,682)
Cash generated from operations	5.32	**78,532**	**139,759**	**7,875**
Income tax paid		(1,631)	(2,021)	(2,346)
Net cash generated from operating activities		**76,901**	**137,738**	**5,529**
Cash flows from investing activities				
Purchases of property, plant and equipment	5.14	(92,229)	(18,936)	(10,502)
Purchases of intangible assets	5.12	(942)	(535)	(382)
Proceeds from sale of intangible assets		—	24	—
Interest received		54	107	199
Net cash used in investing activities		**(93,116)**	**(19,340)**	**(10,685)**
Cash flows from financing activities				
Proceeds from issuance of common stock, net of costs of equity transactions	5.23	166,614	75	(2,484)
Disposal of treasury shares	5.23	209	215	21
Proceeds from borrowings, net of transaction costs	5.32.2	859	50,266	11,781
Repayment of borrowings	5.32.2	(1,956)	(21,995)	(11,684)
Payment of lease liabilities	5.13/5.27	(2,805)	(2,111)	(2,709)
Interest paid		(8,417)	(4,711)	(2,621)
Net cash generated from/(used in) financing activities		**154,504**	**21,740**	**(7,696)**
Net change in cash and cash equivalents		**138,288**	**140,138**	**(12,852)**
Cash and cash equivalents at beginning of the year		204,394	64,439	77,084
Exchange gains/(losses) on cash		3,960	(183)	207
Restricted cash	5.21	44	41	—
Cash and cash equivalents at end of the year		**346,686**	**204,435**	**64,439**

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, 2019 before IFRS 16 adoption		***90,917,837***	**13,638**	**244,900**	**52,060**	**(170,676)**	**3,264**	**143,186**
Changes in Accounting Policy – Initial Application of IFRS 16		—	—	—	(9,474)	—	—	(9,474)
Balance as at January 1, 2019		***90,917,837***	**13,638**	**244,900**	**42,587**	**(170,676)**	**3,264**	**133,712**
Total comprehensive loss		—	—	—	644	—	(1,744)	(1,100)
Income appropriation		—	—	—	—	3,264	(3,264)	—
Share-based compensation expense:								
- value of services		—	—	—	2,504	—	—	2,504
- exercises		*25,975*	4	12	—	—	—	16
Treasury shares		—	—	—	21	—	—	21
Balance as at December 31, 2019		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Balance as at January 1, 2020		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Total comprehensive loss		—	—	—	2,360	—	(64,393)	(62,033)
Income appropriation		—	—	—	—	(1,744)	1,744	—
Share-based compensation expense:	5.22							
- value of services		—	—	—	4,012	—	—	4,012
- exercises		*26,750*	4	71	—	—	—	75
Treasury shares	5.22	—	—	—	215	—	—	215
Balance as at December 31, 2020		***90,970,562***	**13,646**	**244,984**	**52,342**	**(169,156)**	**(64,393)**	**77,422**

€ 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, 2021		***90,970,562***	**13,646**	**244,984**	**52,342**	**(169,156)**	**(64,393)**	**77,422**
Total comprehensive loss		—	—	—	(2,672)	—	(73,425)	(76,097)
Income appropriation		—	—	—	—	(64,393)	64,393	—
Share-based compensation expense:	5.22							
- 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**

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 two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

The Group's portfolio includes two commercial vaccines for travelers: IXIARO (also marketed as JESPECT) indicated for the prevention of Japanese encephalitis and DUKORAL indicated for the prevention of cholera, and, in some countries, prevention of diarrhea caused by enterotoxigenic Escherichia coli. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the United States and over 750 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,	
			2021	2020
BliNK Biomedical SAS[1]	FR	Equity method	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%

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 and third-party products such as Flucelvax, Fluad, Moskito Guard, Rabipur and Encepur.

[1] see Note 5.15

Valneva Canada Inc. (Montreal, Quebec) commercializes IXIARO, DUKORAL and third-party products as KamRAB in 2020 and Vivotif in 2019.

Valneva France SAS (Lyon, France) was founded in February 2019 and commercializes IXIARO and DUKORAL since 2020.

Valneva Scotland Ltd. (Livingston, United Kingdom) is primarily involved in the production of Valneva's Japanese encephalitis vaccine, IXIARO, as well as in the production of chikungunya and COVID-19 vaccines, which are currently in the development phase.

Valneva Sweden AB (Solna, Sweden) manufactures the DUKORAL vaccine and commercializes DUKORAL, IXIARO and third-party products such as Moskito Guard and Vivotif in the Nordic countries. In addition, Valneva Sweden AB provides R&D services.

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

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

SIGNIFICANT EVENTS OF THE PERIOD

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 has 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 have decreased significantly, adversely impacting the Group's financial results. The Group has been and expects to continue to be impacted by the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its November 2021 report, the United Nations World Tourism Organization, or UNWTO, noted that despite the improvement in the third quarter of the year, the pace of recovery remains slow and uneven across world regions due to varying degrees of mobility restrictions, vaccination rates and traveler confidence. Rising concerns over the Delta and Omicron variants of the virus have led several countries to re-impose restrictive measures. In addition, the volatility and lack of clear information on entry requirements could continue to affect the resumption of international travel during the Northern Hemisphere's summer season. However, vaccination programs worldwide, together with fewer restrictions for vaccinated travelers and the use of digital tools such as the EU Digital COVID Certificate, have contributed to the gradual normalization of travel. The recovery of international travel is forecast by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to recover to 2019 demand levels between mid-2023 to end of 2024. If international travel does not resume as quickly or as much as expected, the Group's product sales will continue to be severely affected, and Valneva may not be able to complete the development of its vaccine candidates without additional financing. 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 €346.7 million as at December 31, 2021. 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, 2021 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 is described in the following notes as at December 31, 2021 and for the year ended December 31, 2021:

Impact from COVID-19	**Note**	
COVID segment	5.1/5.28/5.29	The Company has developed a COVID-19 vaccine candidate VLA2001 and reported positive topline results from its pivotal Phase 3 trial in 2021. Regulatory submissions are ongoing and Valneva expects potential regulatory approvals in the first quarter of 2022. Valneva signed an Advance Purchase Agreement with the European Commission to supply up to 60 million doses of VLA2001, for a period of over two years. Valneva and the Kingdom of Bahrain signed an Advance Purchase Agreement to supply 1 million doses of VLA2001. The agreement with the UK Authority to provide up to 190 million doses of VLA2001 was terminated in September, 2021 and became effective in October, 2021. For further information on the termination refer to Note 5.2.2. In order to prepare for the commercialization of the COVID-19 vaccine, capital expenditure and inventory have been built up in 2021.
Revenues from contracts with customers	5.5	In 2021, commercialized products revenues from DUKORAL and IXIARO continued to be adversely impacted by the worldwide reduction in travelling due to the COVID-19 pandemic, with DUKORAL experiencing the greatest impact. In 2021, IXIARO product sales were €45.1 million (a decrease of €3.4 million compared to €48.5 million in 2020), and DUKORAL product sales were €2.4 million (a decrease of €10.9 million, compared to €13.3 million in 2020).
Impairment testing	5.16	Impairment tests for commercialized products IXIARO and DUKORAL were performed and resulted in no impairment charges for 2021.
Inventories	5.18	The income statement included a €5.7 million of write-down due to lower sales expectations and limited shelf life of the finished goods
Trade receivables	5.19	An assessment of expected credit loss resulted in only 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 2021.

Public offering in May 2021

In May 2021, Valneva 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 (refer to Note 5.22). The net proceeds from the global offering amounted to €82.8 million.

Public offering in November 2021

In November 2021, Valneva 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 (refer to Note 5.22). The net proceeds from the global offering amounted to €81.3 million.

Significant agreements signed in the periods presented

In January 2019, Valneva and the U.S. Government Department of Defense (DoD) signed a new contract for the supply of its Japanese encephalitis vaccine IXIARO through 2019 and the beginning of 2020 with a value of $59 million guaranteed and potentially worth up to $70 million.

In June 2019, Valneva and GSK (Glaxo Smith Kline) announced a mutual agreement to terminate the Strategic Alliance Agreement ("SAA"), originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively). Valneva paid €9.0 million to GSK immediately and would pay up to a further €7.0 million when milestones of marketing approvals of its Lyme vaccine are fulfilled. As a result, Valneva regained control of its main research and development assets, including its Lyme vaccine candidate (VLA15). In 2019, the effect was €10.7 million negative other revenues reflecting both the current and future payment obligations.

In July 2019, Valneva and Coalition for Epidemic Preparedness Innovations ("CEPI") announced a new partnering agreement. CEPI will provide Valneva up to $23.4 million for vaccine manufacturing and late-stage clinical development of a single-dose, live-attenuated vaccine (VLA1553) against chikungunya, see Note 5.8.

In February 2020, the Group signed a debt financing agreement with US healthcare funds Deerfield and OrbiMed. The loan agreement has a borrowing capacity of up to $85 million. Repayments of principal will start in 2023, while the loan will mature in 2026. For more details see Note 5.24.1.

In April 2020, Valneva and Dynavax announced a collaboration to advance vaccine development for COVID-19. Dynavax is providing CpG 1018, a component of the US FDA- and EMA-approved HEPLISAV-B vaccine, to support the development of Valneva's COVID-19 vaccine candidate VLA2001, while Valneva is leveraging its technical and platform capabilities to develop an inactivated, whole virus vaccine candidate against COVID-19. In September 2020, Valneva and Dynavax announced a commercial partnership for the supply of Dynavax's CpG 1018 adjuvant for use in VLA2001. This commercial agreement includes a purchase order commitment amount of up to $136.8 million. No deliveries for commercial use took place between Dynavax and Valneva in 2020. As at December 31, 2020, Valneva recorded €31.1 million in advance payments from this agreement (see Note 5.20). During 2021, deliveries took place between Dynavax and Valneva. As at December 31, 2021, Valneva paid €47.9 million of advance payments, of which €40.7 million have been written off as Valneva does not need those deliveries in the future and those payments were non-refundable. As at December 31, 2021, Valneva recorded €7.2 million of advance payments in other current assets and €41.9 million in inventories from this agreement. In the consolidated statement of cash flows for the year ended December 31, 2021, the cash outflows of advance payments and payments for deliveries are reflected in the loss for the year and changes in working capital relating to inventories and trade and other receivables.

In April 2020, a new collaboration to co-develop and commercialize the Group's Lyme disease vaccine candidate (VLA15) was signed with Pfizer Inc. (NYSE: PFE). This agreement was entered into with a customer as defined by IFRS 15 guidance on revenue contracts with customers, it included a $ 130 million (€116.9 million) upfront payment, which was received in June 2020. Valneva will refund 30% of development costs incurred by Pfizer up to an agreed amount, through completion of the development program, which is planned for 2025. In addition, Pfizer will be obligated to pay Valneva low double-digit tiered royalties starting at 19% on net sales of licensed products, subject to specified offsets and reductions. Therefore, as at December 31, 2020, €81.9 million was recognized as discounted refund liabilities. The transaction price was determined taking into account the refund obligation of Valneva. The agreement includes R&D 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 the further involvement of Valneva. The transaction has been allocated to the various performance obligations in proportion to their standalone selling price. In 2020, €31.6 million were recognized as other revenues. €2.8 million of costs to obtain a contract were included in other assets as at December 31, 2020. In 2021, €14.3 million was recognized as other revenues. €3.0 million costs to obtain a contract were included in other non-current assets as at December 31, 2021, and €79.6 million has been recognized as discounted refund liabilities. For more details see Notes 5.5 and 5.29.

In June 2020, Valneva and Bavarian Nordic A/S (OMX: BAVA) announced a marketing and distribution partnership for their commercial products. Pursuant to the agreement, Valneva commercializes Bavarian Nordic's marketed vaccines, leveraging its commercial infrastructure in Canada, the UK, France and Austria. Valneva also markets and distributes these products in Belgium and the Netherlands. The partnership includes vaccines that protect against rabies, Japanese encephalitis, tick-borne encephalitis and cholera. This agreement had no material financial impact on the Group's consolidated financial statements as at and for the year ended December 31, 2020. Revenues are recognized at a point in time when products are delivered to the customer. In 2021, those product sales (mainly Rabipur, Encepur) amounted to €8.2 million.

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, contemplate 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 the DoD has exercised, has a minimum value of approximately $28.8 million for 200,000 doses. The second option year, if exercised, has a minimum value of approximately $36 million for 250,000 doses. These changes bring the total minimum value of the contract to approximately $ 118 million, assuming the exercise of the second-year option which remains unchanged, compared to a minimum value of $135 million in the initial contract. In order to support its customer through this pandemic period, 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 in a contract liability amounted to $5.4 million recognized as at December 31, 2021 (as at December 31, 2020: nil).

In September 2020, Valneva announced an agreement with the UK Authority for the supply Valneva's inactivated COVID-19 vaccine, VLA2001 (the UK Supply Agreement). Under the agreement, Valneva was to provide the UK Authority with 60 million doses of VLA2001 in the second half of 2021. The UK Authority had options over 40 million additional doses in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. The UK Authority also invested up-front in the scale up and development of the vaccine. In January 2021, the UK Authority exercised its option to order 40 million doses. In September 2021, the UK Authority gave notice of termination of this Supply Agreement. The termination of this UK Supply Agreement became effective in October 2021. For further information about the termination of the UK Supply Agreement, refer to Note 5.5.2.

In January 2021, Valneva and Instituto Butantan, a producer of immunobiologic 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 (see Note 5.8.1). Under the collaboration, Valneva will transfer 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, 2021, €2.1 million was recognized as other revenues and €0.8 million was included in contract liabilities (as at December 31, 2020: €1.0 million).

In November 2021, Valneva 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 shall deliver 24.3 million doses in 2022 (starting in April 2022), subject to approval of VLA2001 by the European Medicines Agency (EMA). The EC has an option to purchase a further 35.7 million doses for delivery in 2023. During 2021, no revenue was recognized, as the deliveries will start in the second quarter of 2022. Advanced payments of €116.9 million were included in contract liabilities as at December 31, 2021.

In November 2021, Valneva and the Kingdom of Bahrain, signed an APA for the supply of one million doses of VLA2001. As at December 31, 2021, accounts receivable and contract liabilities related to this agreement comprised €3.8 million.

In November 2021, Valneva and IDT Biologika announced their collaboration for the production of VLA2001. Under the collaboration, IDT Biologika will 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. As at December 31, 2021, advance payments related to the agreement with IDT Biologika to produce the COVID-19 vaccine in amount of €16.4 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 2021 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 23, 2022 and authorized for issuance by the Supervisory Board on March 23, 2022.

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 4	Insurance Contracts – deferral of IFRS 9	January 1, 2021	None
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2	January 1, 2021	None
Amendments to IFRS 16	(I) COVID-19-Related Rent Concessions (II) COVID-19-Related Rent Concessions beyond June 30, 2021	January 1, 2021	None

The amendments listed above did not have any impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

Interpretations Committees agenda decisions		Effective Date	Effects
IAS 38	Configuration or Customisation Costs in a Cloud Computing Arrangement (IAS 38 Intangible Assets)	January 1, 2021	None
IAS 19	Attributing Benefit to Periods of Service (IAS 19 Employee Benefits)	January 1, 2021	No material effects

The interpretations listed above did not have any material impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

(b) ***New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2021, 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, 2021:

- IFRS 17 – Insurance contracts
- Amendments to IAS 1 – Classification of Liabilities as Current or Non-current
- Amendments to IFRS 3 – Reference to the Conceptual Framework
- Amendments to IAS 16 – Property, Plant and Equipment—Proceeds before Intended Use
- Amendments to IAS 37 – Onerous Contracts - Cost of Fulfilling a Contract
- Amendments to IAS 12 – Deferred Tax related to Assets and Liabilities arising from a Single Transaction
- Annual Improvements to IFRS Standards 2018-2020 Cycle – Amendments to IFRS 1 First-time Adoption of IFRS, IFRS 9 Financial Instruments, IFRS 16 Leases, and IAS 41 Agriculture.

These standards 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 and 2019, 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	**2021**	**2020**
EUR/$ +10%	6,818	3,229
EUR/$ -10%	(8,334)	(3,947)
EUR/GBP +10%	(11,986)	(10,022)
EUR/GBP -10%	14,650	12,249
EUR/SEK +10%	(2,884)	(400)
EUR/SEK -10%	3,525	489
EUR/CAD +10%	(557)	(228)
EUR/CAD -10%	681	279

As at December 31, 2021, the changes in impact from an increase or a decrease in $ were mainly caused by a decrease in cash and cash equivalents and in intercompany (IC) receivables denominated in $ in Valneva Austria GmbH.

As at December 31, 2021, the increase in the Foreign Currency Exchange Risk in GBP was caused by higher refund liabilities denominated in GBP in Valneva Austria GmbH and by increased IC liabilities denominated in Euro in Valneva Scotland Ltd, both relating to the COVID-19 vaccine program (see Note 5.1).

As at December 31, 2021, the increase in the Foreign Currency Exchange Risk in SEK was caused by increased 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 2021, as well as 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, 2021 and December 31, 2020, 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, 2021 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 December 31, 2020 € 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	7,004	25,569	37,900	5,148	—	—	75,621
Lease liabilities	3,442	28,078	3,677	9,446	9,963	3,850	58,456
Refund liabilities	20,025	82,670	48,566	—	—	—	151,260
Trade payables and accruals	36,212	—	—	—	—	—	36,212
Tax and employee-related liabilities[2]	8,300	—	—	—	—	—	8,300
Other liabilities	27	25	—	—	—	—	52
	75,010	**136,342**	**90,142**	**14,594**	**9,963**	**3,850**	**329,901**

As at December 31, 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[2]	10,101	—	—	—	—	—	10,101
Other liabilities	27	25	—	—	—	—	52
	190,499	**209,952**	**81,295**	**27,282**	**9,928**	**1,905**	**520,861**

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.

2 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.

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*, the 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 the directors have 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 5.2.2 and note 5.29: Revenue recognition of other revenues: 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 whether revenue from collaborations, licensing and service agreements is recognized over time or at a point in time. In particular, Note 5.5.2. underlines the judgements made in applying accounting policies in the context of the terminations, particularly regarding probability of repayment obligations in the context of revenue recognition, of

  - Valneva's COVID-19 vaccine UK Supply Agreement in 2021

  - Valneva's strategic alliance agreements (SAA) with GlaxoSmithKline (GSK) in 2019

- Notes 5.8 and 5.31: Other income: The Group receives funding from CEPI, which include 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 has global partnership between public, private, philanthropic, and civil society organizations. Because CEPI is an NGO 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 required Management's judgement.
- Note 5.13: Lease term: When determining lease terms, the Group makes judgements whether it is reasonably certain to 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: Revenue recognition of product sales: estimate of expected returns and replacements, and supply of products free of charge;
- Note 5.5: Other revenues: likelihoods for refund liabilities; for revenues recognition in accordance to the actual costs compared to the budget;
- Notes 5.8 and 5.31: Other income: 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 where Valneva can benefit from this intangible. 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 5.16 Impairment test of intangible, tangible assets, and investments in associates: 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 VLA2001 and receive regulatory approval, or if Valneva fails to successfully manufacture or commercialize VLA2001 if approved, an impairment may be required. For the main estimates and sensitivities related to the impairment test regarding the CGU refer to note 5.16.
- 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 taken. For the assessment of write-downs of work in progress, finished goods and purchased goods, the forecasted sales plans for 2022 and a minimum shelf life at the time of selling has been taken into account. In addition, those inventory have been assessed on the likelihood of the release of those products.
- 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 liability related to the UK Supply agreement: As at December 31, 2021 the royalty obligation was assessed at the maximum amount (maximum royalty payment of €100 million), as all COVID sales are expected to occur outside the UK. As of December 31, 2020 the royalty obligation was assessed at a lower level, as the main production capacity was planned for sales within the UK. As at December 2021, a sensitive estimate were the revenue forecast and the timing of the expected cash payments. The major part of the royalty obligation is expected to be non-current, and therefore thoese amounts have been discounted. The related estimated cash-outs are expected to happen from 2022 to 2026.
- 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, the management made assumption 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 5.16: 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.

As at January 1, 2021, the following changes were implemented into the Group's segment reporting structure.

- Given the materiality of the Group's COVID-19 business, a separate segment was introduced covering all activities related to the development, manufacturing, and distribution of the SARS-CoV-2 vaccine candidate.

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 Valneva's SARS-CoV-2 vaccine candidate)

- "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 COVID-19 vaccine candidates, which is presented separately). 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.
- "Technologies and services" (services and inventions at the commercialization stage, i.e. revenue generating 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.

As at January 1, 2021, the Group changed its internal reporting process and amended the following allocation rule: general and administrative (G&A) costs were allocated to the four operational segments based on three key criteria (each equally weighted): 1) Revenues, 2) R&D spend and 3) full-time equivalent personnel (FTEs). The allocation of local G&A spend is based on the above criteria measured on local level, whereas the allocation of global functional G&A spend is based on global key criteria. The Group also monitors G&A spend dedicated to corporate projects and any project which is 1) material in spend, 2) one-time in nature, and 3) supports the entire business remains reported under "Corporate Overhead". In 2021 the major items included in "Corporate Overhead" were costs related to the placement of new shares on Nasdaq in May and November 2021.

Segment reporting information for earlier periods has been restated to conform to these changes.

5.4.1 Income statement by segment

Income statement by segment for the year ended December 31, 2019

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	129,511	—	—	—	—	129,511
Other Revenues	163	—	(10,516)	7,038	—	(3,315)
Revenues	**129,674**	**—**	**(10,516)**	**7,038**	**—**	**126,196**
Cost of goods and services	(47,789)	—	(1)	(4,991)	—	(52,781)
Research and development expenses	(3,928)	—	(32,864)	(1,229)	—	(38,022)
Marketing and distribution expenses	(22,930)	—	(895)	(261)	—	(24,145)
General and administrative expenses	(10,161)	—	(7,124)	(795)	(318)	(18,398)
Other income and expenses, net	7	—	7,709	484	(1,861)	6,338
Operating profit/(loss)	**44,873**	**—**	**(43,691)**	**(245)**	**(2,238)**	**(811)**

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

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies 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	**Commercialized products**	**COVID**	**Vaccine candidates**	**Technologies 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)	—	(23,642)
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)**

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,		
	2021	**2020**	2019
United States	40,339	36,414	63,700
Canada	4,226	8,965	24,396
Austria	9,341	3,333	2,668
United Kingdom	2,707	1,847	8,594
Nordics	2,436	2,866	11,027
Germany	726	7,060	10,345
Other Europe	3,075	2,068	4,961
Rest of World	134	3,384	3,819
Product sales	**62,984**	**65,938**	**129,511**

Non-current operating assets per geographical segment

€ in thousand	As at December 31,	
	2021	**2020**
United States	66	93
Canada	239	98
Austria	61,237	58,896
Nordics	53,020	27,540
United Kingdom	87,387	21,977
Other Europe	4,582	4,958
Non-current assets	**206,531**	**113,562**

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 on sites where production and research and development activities are performed. Sales activities by distribution sites do not require major non-current operating assets. Revenues are structured where the final customer is. In some countries there are customers, but no assets.

5.4.3 Information about major customers

Product sales to the largest customer amounted to €41.8 million (2020: €33.8 million, 2019: €46.7 million). Other revenues from the largest customer amounted to €253.3 million (2020: two largest customers with revenues €31.6 million and €7.5 million, 2019: two largest customers with revenues €4.1 million and €0.8 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, normally concluded with retailers and, in the United States, with the DoD ("direct product sales") as well as with distributors ("indirect sales – sales through distributors"), generally include one 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.

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 expected rebates, discounts and considerations for product returns are recognized on an accrual basis and reported as refund liabilities in the consolidated balance sheet.

In most cases, Valneva sells the products through retailers. When more than one party is involved in providing/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 to fulfill 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 other of Valneva's 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. Payables to customers are deducted from revenue for principals, 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 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, 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, therefore the revenue is recognized at the point in time at which the licensee is able to direct the use 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 constraint is removed.

Revenue for research and development services within the Group's contracts currently in place is recognized over time. For those contracts including constraints, once the constraint is removed the transaction price is updated and revenue is recognized in line with the revenue recognition of the corresponding performance obligation. The progress is measured on an input basis (costs incurred related to total costs expected). It is considered that this input method is 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 the transaction price changes.

Vaccine Supply Agreement with the UK Authority

In September 2020, Valneva 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 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, or the UK, including an obligation for Valneva to upgrade its manufacturing facilities in Scotland. Valneva received notice in September 2021 of the UK Authority's decision to terminate the UK Supply Agreement, and the termination became effective in October 2021, as described below. 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 GBP359.2 million (€408.3 million) under the UK Supply Agreement.

Under the UK Supply Agreement, Valneva was obligated to use commercially reasonable efforts to develop the vaccine candidate, to secure marketing authorization (and to proceed with 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. Pursuant to the terms of the UK Supply Agreement, the UK Authority placed an initial order for 60 million doses to be delivered in 2021 and was granted an option for a further 40 million doses to be delivered in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. In January 2021, the UK Authority exercised its option to order 40 million doses for delivery in 2022. With respect to sales to non-UK customers of product manufactured using any facilities used under the UK Supply Agreement, Valneva is obligated to pay the UK Authority a low single-digit royalty on such net sales, subject to a maximum royalty payment.

In September 2021, Valneva received notice of the UK Authority's decision to terminate the UK Supply Agreement. Valneva had not received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases detailed thereafter, each with different potential or actual consequences.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that Valneva would allegedly, at some time in the future, breach its obligations regarding the delivery schedule under the UK Supply Agreement. Valneva strongly disputes the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and did not consider such termination to be valid. However, if the UK Authority were to successfully bring proceedings for damages against Valneva in respect of the alleged anticipatory breach, it could be argued that the applicable contractual cap on the liability under the UK Supply Agreement could be as high as an amount equivalent to the sums paid by the UK Authority prior to termination. However, Management believed that it was very unlikely that any such claim by the UK Authority would be successful. In any event, the UK Authority did not notify Valneva of any specific claim for damages in connection with the purported termination for alleged anticipatory breach nor did it indicate the amount of any possible claim as of the date these financial statements are authorized for issue. Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. Valneva acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective in October 2021. The UK Supply Agreement provided that, in the case of termination for convenience by the UK Authority, Valneva shall not be obliged to refund or repay any amount paid by the UK Authority. The above-mentioned royalty on sales and other certain obligations survived termination of the UK Supply Agreement.. The other obligations are related to investments in manufacturing, such as the Alemida manufacturing facility, which were acquired with funds advanced by the UK, Valneva may have certain obligation to the UK Authority, such as a partial return of funding received, in respect of those assets if they are sold, disposed or repurposed.

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 is more than remote, a refund liability of €166.9 million was recognized for the royalty on sales and other certain obligations which survive the termination of the UK Supply Agreement. Moreover, provisions for the present obligation under the onerous purchase agreements and write-downs for materials of COVID-19 vaccine were recognized. For more detailed information see Notes 5.30.2 and 5.18.

Valneva will update this estimate of the refund liability in accordance with IFRS 15.55 in 2022 when these uncertainties are resolved and would recognize revenue in the future, to the extent that it becomes highly probable that no future significant reversal in the amount of cumulative revenue recognized will occur.

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, 2019 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	129,674	—	(10,516)	5,768	124,926
Other revenues	—	—	—	1,270	1,270
Revenues	**129,674**	**—**	**(10,516)**	**7,038**	**126,196**

Year ended December 31, 2020 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	65,939	—	31,604	11,814	109,357
Other revenues	—	—	—	965	965
Revenues	**65,939**	**—**	**31,604**	**12,779**	**110,321**

Year ended December 31, 2021 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	63,002	253,314	3,257	27,613	347,186
Other revenues	—	—	—	899	899
Revenues	**63,002**	**253,314**	**3,257**	**28,512**	**348,086**

Valneva's total revenues for 2019 include a negative revenue of €10.7 million related to the June 2019 mutual agreement to terminate its SAA, with its customer GlaxoSmithKline Biologicals SA, or GSK (see Note 5.3.1), which included recognition of negative revenues related to both current and future payment obligation, which consist of:

€ in thousand	2019
Settlement fee (fixed)	(9,000)
Settlement fee (variable; excluding financing component)	(5,987)
Release of SAA related contract liabilities	4,274
Net effect of SAA termination	**(10,714)**

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

Type of goods or service

Year ended December 31, 2019 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO	94,307	—	—	—	94,307
DUKORAL	31,471	—	—	—	31,471
Third party products	3,896	—	—	—	3,896
Others	—	—	(10,516)	5,768	(4,748)
Revenues from contracts with customers	**129,674**	**—**	**(10,516)**	**5,768**	**124,926**

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**

In 2020, commercialized products revenues from DUKORAL and IXIARO were adversely impacted by the worldwide reduction in travel due to the COVID-19 pandemic:

- in 2020, IXIARO product sales were €48.5 million - a decrease of €45.8 million compared to €94.3 million in 2019
- in 2020, DUKORAL product sales were €13.3 million - a decrease of €18.2 million compared to €31.5 million in 2019.
- In 2020 commercialized products revenues from third party products were €4.2 million - an increase of €0.3 million compared to €3.9 million in 2019.

In 2021, commercialized products revenues from DUKORAL and IXIARO continued to be adversely impacted by the worldwide reduction in travel due to the COVID-19 pandemic:

- in 2021, IXIARO product sales were €45.1 million - a decrease of €3.4 million compared to €48.5 million in 2020;
- in 2021, DUKORAL product sales were €2.4 million - a decrease of €10.9 million compared to €13.3 million in 2020;
- in 2021 commercialized products revenues from third party products were €15.4 million, - an increase of €11.3 million compared to €4.2 million in 2020, primarily due to the marketing and distribution partnership with Bavarian Nordic where first sales of Rabipur and Encepur started in 2021. In addition, the influenza vaccine product sales increased as well. In 2021, revenues within the COVID segment totaled €253.3 million resulting from the termination of the UK Supply Agreement as described above.

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 by the end of 2020, revenue from this vaccine candidate is included in the Technologies and Services segment from 2021 onward.

In 2021 revenues from technologies and services amounted to €27.6 million, compared to €11.8 million in 2020 and €5.8 million in 2019. In 2021 this revenue included €14.3 million from the collaboration with Pfizer related to the Lyme vaccine candidate.

Geographical markets

Year ended December 31, 2019 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	63,700	—	162	130	63,992
Canada	24,396	—	—	—	24,396
Austria	2,668	—	—	4,136	6,803
United Kingdom	8,596	—	—	15	8,610
Nordics	11,027	—	—	5	11,032
Germany	10,345	—	—	150	10,495
Other Europe	4,961	—	(10,678)	440	(5,277)
Other markets	3,980	—	—	893	4,873
Revenues from contracts with customers	**129,674**	**—**	**(10,516)**	**5,768**	**124,926**

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
Other Europe	2,068	—	—	2,373	4,441
Other markets	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
Other Europe	3,075	—	—	3,210	6,286
Other markets	134	—	3,257	1,294	4,684
Revenues from contracts with customers	**63,002**	**253,314**	**3,257**	**27,613**	**347,186**

Sales channels

Commercialized products are sold via the following sales channels:

	Year ended December 31,		
€ in thousand	**2021**	**2020**	**2019**
Direct product sales	60,325	54,160	110,386
Indirect product sales (Sales through distributors)	2,678	11,778	19,125
Total product sales	**63,002**	**65,939**	**129,511**

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:

		Year ended December 31,		
€ in thousand	**Notes**	**2021**	**2020**	**2019**
Consulting and other purchased services		169,158	65,212	29,840
Cost of services and change in inventory		105,648	10,778	5,320
Employee benefit expense other than share-based compensation	5.7	85,334	58,264	46,219
Share-based compensation expense	5.7	14,678	6,328	2,552
Raw materials and consumables used		14,676	12,434	9,844
Depreciation and amortization and impairment	5.12/5.13/ 5.14	14,281	9,939	8,607
Building and energy costs		10,960	8,140	6,995
Supply, office and IT costs		7,409	3,333	3,281
License fees and royalties		4,865	4,384	7,553
Advertising costs		2,176	2,496	6,801
Warehousing and distribution costs		1,419	1,898	3,013
Travel and transportation costs		538	529	1,921
Other expenses		1,309	822	1,399
Operating expenses		**432,452**	**184,558**	**133,345**

The increase in operating expenses of €244.0 million in 2021, compared to 2020, primarily resulted from the increased research and development expenses due to the Company's advanced clinical trial programs, the inventory write-down - due to the COVID-19 pandemic for commercialized product as well as write-down on COVID-19 vaccine related inventory related to the termination of the UK Supply Agreement (refer to Note 5.5.2).

Principal Accountant Fees and Services:

€ in thousand	**Year ended December 31,**							
	PricewaterhouseCoopers				**Deloitte & Associés**			
	2021	**%**	**2020**	**%**	**2021**	**%**	**2020**	**%**
Audit fees	**1,122**	**91%**	**607**	**78%**	**1,114**	**93%**	**589**	**77%**
provided by the statutory auditor	*937*	*—*	*517*	*—*	*939*	*—*	*492*	*—*
provided by the statutory auditor's network	*185*	*—*	*90*	*—*	*174*	*—*	*97*	*—*
Audit-related Fees	**90**	**7%**	**170**	**22%**	**85**	**7%**	**173**	**23%**
provided by the statutory auditor	85	*—*	*145*	*—*	*85*	*—*	*155*	*—*
provided by the statutory auditor's network	*5*	*—*	*25*	*—*	*0*	*—*	*18*	*—*
Tax Fees	**25**	**2%**	**0**	**—**	**0**	**—**	**0**	**—**
provided by the statutory auditor's network	25	**—**	**0**	**—**	**0**	**—**	**0**	**—**
All other Fees	**0**	**—**	**0**	**—**	**0**	**—**	**0**	**—**
Total	**1,238**	**100%**	**777**	**100%**	**1,199**	**100%**	**762**	**100%**

In 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,		
	2021	2020	2019
Salaries	47,717	38,515	34,128
Social security contributions	35,923	18,555	10,621
Share-based compensation expense	14,678	6,328	2,552
Training and education	603	351	672
Other employee benefits	1,091	842	798
Total Employee benefit expense	**100,012**	**64,592**	**48,771**

The social security contributions included a provision of €26.5 million (2020: €7.4 million, 2019: nil) of employer contribution charges on share-based payment programs which are due at exercise of the programs.

During 2021, the Group had an average of 722 employees (2020: 532 employees, 2019: 508 employees).

5.8 Other income/(expenses), net

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 $23.4 million for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine (VLA1553) against chikungunya. In line with CEPI's commitment to equitable access, the funding will underwrite a partnership effort to accelerate regulatory approval of Valneva's single-dose chikungunya vaccine for use in regions where outbreaks occur and support WHO 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 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 which Instituto Butantan benefits from the CEPI grant, is recognized as revenue (refer to Note 5.1). In 2021, due to a change in estimate of the likelihood of repayment milestones, minus €0.9 million of grant income related to CEPI (2020: €5.8 million).

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 under "Grants" 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.

Other income and expenses, net include the following:

€ in thousand	Year ended December 31,		
	2021	2020	2019
Research and development tax credit	21,949	9,937	6,314
Grant income	1,684	7,680	1,886
Profit/(loss) on disposal of fixed assets and intangible assets, net	(42)	(10)	(92)
Profit/(loss) from revaluation of lease agreements	—	1,584	—
Taxes, duties, fees, charges, other than income tax	(212)	(168)	(146)
Miscellaneous income/(expenses), net	(403)	95	(1,623)
Other income and expenses, net	**22,976**	**19,117**	**6,338**

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,		
	2021	2020	2019
Finance income			
Interest income from other parties	249	119	199
Fair value gains on derivative financial instruments	—	397	—
Foreign exchange gains, net	8,130	173	1,250
Total finance income	**8,379**	**689**	**1,449**
Finance expenses			
Interest expense on loans	(7,273)	(6,162)	(1,588)
Interest expense on refund liabilities	(8,478)	(3,640)	(89)
Interest expenses on lease liabilities	(903)	(907)	(926)
Other interest expense	(309)	(30)	(30)
Fair value losses on derivative financial instruments	—	—	(449)
Total finance expenses	**(16,964)**	**(10,738)**	**(3,082)**
Finance income/(expenses), net	**(8,584)**	**(10,049)**	**(1,633)**

In 2021, the net finance result amounted to minus €8.6 million compared to minus €10.0 million in the year 2020 and compared to minus €1.5 million in 2019. 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 income/(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,**		
	2021	**2020**	**2019**
Current tax			
Current income tax charge	(32)	(69)	(2,849)
Adjustments in respect of current income tax of previous year	(19)	109	(258)
Deferred tax			
Relating to origination and reversal of temporary differences	(3,395)	869	2,233
Income tax income/(expense)	**(3,446)**	**909**	**(874)**

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,**		
	2021	**2020**	**2019**
Loss before tax	(69,979)	(65,302)	(870)
Tax calculated at domestic tax rates applicable to profits in the respective countries	18,824	16,675	1,431
Income not subject to tax (mainly R&D tax credit)	10,739	2,612	1,727
Expenses not deductible for tax purposes	(2,509)	(1,789)	(169)
Deferred tax asset not recognized	(26,902)	(15,852)	(7,405)
Utilization of previously unrecognized tax losses	—	—	5,480
Income tax credit	(459)	109	105
Effect of change in applicable tax rate	(3,291)	(771)	(1,708)
Exchange differences	296	(105)	62
Income tax of prior years	(64)	170	(256)
Minimum income tax	(80)	(141)	(142)
Income tax income/(expense)	**(3,446)**	**909**	**(874)**
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, 2021, the deferred tax assets of €153.8 million (December 31, 2020: €126.3 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, 2021, the Group had tax losses carried forward of €628.3 million (December 31, 2020: €529.5 million), of which €234.9 million were related to Valneva SE (December 31, 2020: €192.0 million), €380.0 million were related to Valneva Austria GmbH (December 31, 2020: €321.1 million), €0 million were related to Valneva USA, Inc. (December 31, 2020: €0.4 million), €0.8 million were related to Valneva Scotland, Ltd. (December 31, 2020: €3.1 million) and €12.6 million were related to Valneva Sweden AB (December 31, 2020: €12.9 million).

Tax losses carried forward in France, Austria, United Kingdom and Sweden have no expiry date, whereas the tax loss from US entities will begin to expire in the year 2033 if unused.

The gross movement on the deferred income tax account was as follows:

€ in thousand	**2021**	**2020**	**2019**
Beginning of year	5,158	4,988	2,689
Exchange differences	(529)	(699)	66
Income statement charge / (credit)	(3,395)	869	2,233
End of year	**2,292**	**5,158**	**4,988**

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

€ in thousand	**As at December 31,**	
	2021	**2020**
Deferred tax asset from		
Tax losses carried forward	156,470	131,633
Fixed assets	2,007	2,033
Inventory	1,837	4,108
Borrowings and accrued interest	1,284	1,161
Provision	1,611	1,564
Other items	2,891	2,019
Non-recognition of deferred tax assets	(153,836)	(126,283)
Total deferred tax assets	**12,264**	**16,235**
Deferred tax liability from		
Fixed assets	(2,359)	(1,187)
Intangible assets	(6,855)	(7,480)
Other items	(758)	(2,410)
Total deferred tax liability	**(9,972)**	**(11,077)**
Deferred tax, net	**2,292**	**5,158**

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 will be gradually reduced over the next years to 25%. The rate was 26.5% in 2021 and will be reduced to 25% from 2022 onward on the full amount of taxable profits.

The deferred tax assets and liabilities presented above as at December 31, 2021 and December 31, 2020 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,		
	2021	**2020**	**2019**
Net profit (loss) from continuing operations attributable to equity holders of the Company (€ in thousand)	(73,425)	(64,393)	(1,744)
Weighted average number of outstanding shares	97,619,320	90,757,173	91,744,268
Basic earnings (losses) from continuing operations per share (€ per share)	**(0.75)**	**(0.71)**	**(0.02)**

(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,		
	2021	2020	2019
Profit used to determine diluted earnings per share (€ in thousand)	(73,425)	(64,393)	(1,744)
Weighted average number of outstanding shares for diluted earnings (losses) per share[3]	97,619,320	90,757,173	91,744,268
Diluted earnings/(losses) from continuing operations per share (€ per share)	**(0.75)**	**(0.71)**	**(0.02)**

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;

[3] Potentially dilutive securities (2021: 5,846,267 share options; 2020: 5,481,763 share options) have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact due to the losses reported.

- 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 2021 and 2020, 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 - 15 years

The useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods of 24 years, 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 December 31, 2020					
Opening net book value	1,629	38,183	1,953	48	41,813
Additions	48	401	—	86	535
Amortization charge	(569)	(2,723)	(194)	—	(3,486)
Disposals	—	(3,329)	(5)	—	(3,333)
Exchange rate differences	3	(108)	(16)	3	(119)
Closing net book value	**1,112**	**32,423**	**1,737**	**137**	**35,409**
As at December 31, 2020					
Cost	5,589	80,183	9,851	137	95,759
Accumulated amortization and impairment	(4,477)	(47,759)	(8,113)	—	(60,350)
Closing net book value	**1,112**	**32,423**	**1,737**	**137**	**35,409**

€ in thousand	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
Year ended December 31, 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**

The disposal of acquired R&D technology and projects in 2020 included €3.3 million from de-recognition of the Lyme disease vaccine candidate (VLA15) (see Note 5.1). In April 2020, a Research Collaboration and License agreement for Lyme VLA15 was signed between Pfizer and Valneva. Under the agreement, Valneva continues performing R&D services for the VLA15-221 study and grants Pfizer an exclusive license enabling Pfizer to develop the vaccine candidate to licensure. Upon completion of the transfer of the license in December 2020, the intangible asset with a value amounting to €3.3 million was de-recognized and expensed as cost of services sold (COSS) on the Income Statement.

As at December 31, 2021 and December 31, 2020, there were no acquired research and development technology projects 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 the development costs) with definite useful life are comprised primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €79.0 million and a net book value amounting to €30.6 million (December 31, 2020: €33.2 million).

For impairment test refer to Note 5.16.

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. The Group changed the manner in which it accounts for leases effective January 1, 2019 due to the adoption of IFRS 16 – Leases.

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 3.186%, 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.

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, 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.

RoU 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 without an option for the lessee to prolong the contract to more than 12 months or it is not reasonably certain to exercise such an option. 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

	Right-of-use assets				Lease liabilities
€ in thousand	**Land, buildings and leasehold improvements**	**Manufacturing and laboratory equipment**	**Furniture, fittings and other**	**Total assets**	**Total Lease liabilities**
Year ended December 31, 2020					
Opening net book value	49,039	58	236	49,334	58,901
Additions	117	—	151	267	267
Amortization	(2,309)	(22)	(141)	(2,471)	—
Revaluation due to variable payments	(4,507)	—	2	(4,505)	(6,096)
Termination of contracts	—	—	(33)	(33)	(26)
Lease payments	—	—	—	—	(2,910)
Interest expenses	—	—	—	—	800
Exchange rate differences	782	—	1	782	1,152
Closing net book value	**43,121**	**37**	**216**	**43,374**	**52,088**

	Right-of-use assets				Lease liabilities
€ in thousand	**Land, buildings and leasehold improvements**	**Manufacturing and laboratory equipment**	**Furniture, fittings and other**	**Total assets**	**Total Lease liabilities**
Year ended December 31, 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	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**

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 refer to Note 5.16.

As at December 31, 2021, RoU assets increased to €48.3 million from €43.4 million as at December 31, 2020, mainly due to a new lease contract for land and building in Sweden (addition of €6.4 million, partly offset by amortization expenses of €0.5 million), as well as a new lease contract for land and building in Scotland (December 31, 2021: €1.2 million). Major lease agreements were for the premises in Austria (Decem ber 31, 2021: €24.0 million, December 31, 2020: €24.8 million) and Sweden (December 31, 2021: €22.1 million, December 31, 2020: €17.6 million).

For more details on lease liabilities see Note 5.27.

5.13.2 Other amounts recognized in the consolidated income statement

€ in thousand	**Year ended December 31,**		
	2021	**2020**	**2019**
Expense relating to short-term leases (included in other income and expenses)	340	96	146
Expense relating to leases of low-value assets that are not shown above as short-term leases (included in other income and expenses)	21	—	3
Income relating to revaluation of lease liabilities (included in other income and expenses)	42	1,591	—
Expenses relating to termination of lease contracts (included in other income and expenses)	(38)	(7)	—

Income relating to revaluation of lease liabilities in 2020 referred to the partial early termination of the rental contract in Sweden.

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, 2020						
Opening net book value	9,248	5,944	707	313	3,791	20,003
Additions	2,578	8,553	241	30	7,535	18,936
Depreciation charge	(1,087)	(2,471)	(211)	(73)	—	(3,842)
Impairment charge	—	—	—	—	(140)	(140)
Disposals	—	(2)	(1)	(3)	—	(6)
Exchange rate differences	(87)	16	(10)	(9)	(82)	(172)
Closing net book value	**10,651**	**12,041**	**726**	**257**	**11,105**	**34,779**
December 31, 2020						
Cost	24,062	28,743	2,573	1,453	11,105	67,935
Accumulated depreciation and impairment	(13,411)	(16,702)	(1,847)	(1,196)	—	(33,156)
Closing net book value	**10,651**	**12,041**	**726**	**257**	**11,105**	**34,779**

€ 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**
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**

Additions in 2020 and 2021 mainly referred to investments in Scotland and Sweden and related to the production of the COVID-19 vaccine VLA2001.

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

5.15 Investments in associates

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.

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,	
			2021	2020
BliNK Biomedical SAS	FR	Equity method	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.

While the Company retains a substantial ownership interest in the entity, BliNK is run as an independent business by its own management team. The Company does not have control over BliNK in the regards of IFRS 10, but rather holds a significant influence in BliNK in accordance with IAS 28.3, and therefore the investment in associates is accounted for by using the equity method in accordance with IAS 28.

In 2021, the Company recorded a loss of €0.0 million related to its share of equity in BliNK (2020: loss of €0.3 million). The total equity of BliNK amounted to €4.3 million as at December 31, 2021 (December 31, 2020: €4.4 million). Refer to Note 5.16 impairment testing.

5.15.1 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,	
	2021	2020
BliNK Biomedical SAS		
Non-current assets	2	3
Current assets	4,782	4,759
Non-current liabilities	209	209
Current liabilities	93	38
Revenue	810	836
Loss from continuing operations	(16)	(272)
Total comprehensive income	(16)	(272)

5.15.2 Reconciliation to the carrying amount

€ in thousand	As at December 31,	
	2021	2020
Net assets of associate	4,344	4,355
Proportion of the Company's ownership interest in BliNK Biomedical SAS	48.9%	48.9%
Balance	**2,121**	**2,130**

5.16 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, 2021, impairment tests were performed on the IXIARO, the DUKORAL and the COVID cash-generating units (CGUs).

IXIARO annual product sales in 2021 declined moderately due to the COVID-19 crisis and travel restrictions. No triggering event was identified in 2021. However, an impairment test has been performed for the IXIARO CGU as at December 31, 2021 on a voluntary basis.

For the DUKORAL CGU a more significant year-over-year reduction in product sales was experienced and a triggering event was identified during H1 2021. In addition to the impairment test performed in June 2021 another voluntary impairment test was performed in December 2021.

€ in thousand	Year ended December 31, 2021	2020	% 2021 vs 2020
Product Sales			
IXIARO	45,118	48,480	(6.9%)
DUKORAL	2,440	13,300	(81.7%)

For the first time an impairment test has been performed for the COVID CGU, where the termination of the UK Supply Agreement represented a triggering event ('loss of a major customer').

As a basis, the long-range business model including product specific financial plans covering a period of five years was used consistently across all CGUs tested. The Group's long range business model includes assumptions on market size / market share, product sales and resulting profitability. The value in use calculations are based on the plans for the next five years and a terminal value applied for the periods beyond 2026. A terminal value has been applied on the IXIARO and DUKORAL CGUs while no terminal value has been applied on the COVID CGU.

Business plan assumptions have been revised to reflect reductions in expected sales and assuming a recovery of IXIARO sales to pre-COVID levels by 2025 to 2026. The calculation used post tax risk-adjusted cash flow projections and a discount rate of 7.49%. The discount rate of 7.49% was based on a negative risk-free rate of 0.20%, 6.68% market risk premium, a negative country risk premium of 0.37%, 1.03% currency risk, a levered beta of 1.12, and a peer group related equity-capital ratio. The net carrying value of IXIARO related assets amounted to €48.2 million as at December 31, 2021 (December 31, 2020: €46.7 million).

During 2021, due to the impact of the COVID-19 pandemic situation affecting future profitability and cash generation of the DUKORAL CGU, the Group tested the related product line for impairment. While there were no material intangible assets held for DUKORAL the carrying amount of property, plant and equipment and RoU assets as well as working capital were tested. For DUKORAL sales recovery to pre-COVID levels is not expected, driven by the expected entry of a competing product in some European markets within the coming years. The calculations used post tax risk-adjusted cash flow projections based on the Group's long-range business plan and a discount rate of 7.23% per annum. The discount rate of 7.23% per annum was based on negative risk-free rate of 0.20%, 6.68% market risk premium, negative country risk premium of 0.36%, 0.74% currency risk, a levered beta of 1.13 and a peer group related equity-capital ratio. The net carrying value of DUKORAL related assets amounted to €13.7 million as at December 31, 2021 (December 31, 2020: €15.1 million).

During 2021, the Group invested significant funds into building up COVID manufacturing capacities across both the Livingston and Solna production sites. In addition to property, plant and equipment, RoU assets as well as intangible assets the Group holds significant working capital (mainly inventories) related to the COVID CGU. Business plan assumptions have been revised after termination of the UK Supply Agreement and after signing of supply agreements with the European Commission and Bahrain and foresee a continuation of COVID-19 vaccine sales during the planning horizon of 5 years. The calculations used post tax risk-adjusted cash flow projections based on the Group's long-range business plan and a discount rate of 7.77% per annum. The discount rate of 7.77% per annum was based on negative risk-free rate of 0.20%, 6.68% market risk premium, country risk premium of 0.49%, 0.46% currency risk, a levered beta of 1.12 and a peer group related equity-capital ratio. The net carrying value of COVID related assets amounted to €214.5 million as at December 31, 2021.

The impairment tests resulted in no impairment charges.

No triggering event was identified for the CGUs.

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 7.23% for DUKORAL, 7.49% for IXIARO (2020: 7.30% for DUKORAL, 7.55% for IXIARO) and 7.77% for COVID. 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 7.49% to 53.11% would trigger an impairment loss for IXIARO (2020: 4,689 basis points from 7.55% to 54.44%), increase from 7.23% to 13.10% would trigger an impairment loss for Dukoral (2020: increase of 328 basis points from 7.30% to 10.58%) and an increase in the discount rate from 7.77% to 75.34% would trigger an impairment loss for COVID.

Sensitivity analysis	2021			2020	
	IXIARO	DUKORAL	COVID	IXARO	DUKORAL
WACC	7.49%	7.23%	7.77%	7.55%	7.30%
Break-even WACC	53.11%	13.10%	75.34%	54.44%	10.58%
Impairment if WACC increases by 1%	NO	NO	NO	NO	NO
Impairment if sales reduce by 10%	NO	NO	NO	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 and DUKORAL revenues of 10% (which reflects the sensitivity to slower than currently expected recovery of the travel vaccine market assumption taken) would result in no impairment loss in 2021 and 2020. A potential reduction in COVID revenues of 10% (as a result of e.g. later than expected licensure or manufacturing capacity constraints) would result in no impairment loss in 2021.

As at December 31, 2021 an impairment test was performed on the investment held in BliNK Biomedical SAS. A triggering event was identified given the net income of BliNK showed a loss giving situation for the year ended December 31, 2021. As a basis the BliNK business plan for the next 5 years has been used. No terminal value has been applied for the period beyond the planning horizon of 5 years. The calculation used post tax risk-adjusted cash flow projections and a discount rate of 6.84%. The discount rate of 6.84% was based on a negative risk-free rate of 0.20%, 6.49% market risk premium, a levered beta of 1.12, and a peer group related equity-capital ratio. The impairment test resulted in no impairment charges.

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

As at December 31, 2019, impairment charges amounting to €0.1 million were recognized following the decision of Emergent BioSolutions Inc. to not make use of their opt-in right post successful finalization of a Phase 1 clinical study. The impairment charge of €0.1 million was recognized for acquired R&D technology and projects.

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, 2020 € in thousand	Assets at fair value through profit and loss	Assets at amortized cost	Total
Assets as per balance sheet			
Trade receivables	—	19,232	19,232
Other assets[4]	—	11,918	11,918
Cash and cash equivalents	—	204,435	204,435
Assets	**—**	**235,584**	**235,584**

	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
Liabilities as per balance sheet			
Borrowings	—	53,363	53,363
Trade payables and accruals	—	36,212	36,212
Tax and employee-related liabilities[5]	—	8,300	8,300
Lease liabilities	—	52,088	52,088
Refund liabilities	—	111,426	111,426
Other liabilities[6]	—	51	51
Liabilities	—	**261,439**	**261,439**

As at December 31, 2021 **€ in thousand**	**Assets at fair value through profit and loss**	**Assets at amortized cost**	**Total**
Assets as per balance sheet			
Trade receivables	—	44,013	44,013
Other assets[4]	—	11,522	11,522
Cash and cash equivalents	—	346,686	346,686
Assets	**—**	**402,221**	**402,221**

	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[5]	—	10,101	10,101
Lease liabilities	—	56,822	56,822
Refund liabilities	—	254,582	254,582
Other liabilities[6]	—	44	44
Liabilities	—	**447,502**	**447,502**

4 Prepayments and tax receivables and other non-financial assets are excluded from the other assets balance, as this analysis is required only for financial instruments.

5 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.

6 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, 2021 and December 31, 2020, 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, 2021 and December 31, 2020, 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,**	
	2021	**2020**
Trade receivables		
Receivables from governmental institutions (AAA-country)	289	36
Receivables from governmental institutions (AA-country)	23,086	15,595
Receivables from governmental institutions (A-country)	606	—
AA	2	188
A	3,442	787
Counterparties without external credit rating or rating below A	16,589	2,631
Trade receivables	**44,013**	**19,237**
Other assets		
A	11,296	11,644
Assets from governmental institutions (AA-country)	199	—
Counterparties without external credit rating or rating below A	27	336
Other assets	**11,522**	**11,979**
Cash and cash equivalents		
AA	3,457	3,984
A	332,361	149,477
Counterparties without external credit rating or rating below A	10,868	50,973
Cash and cash equivalents	**346,686**	**204,435**

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, 2021 and December 31, 2020 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, 2021 and December 31, 2020.

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, 2021 and December 31, 2020, 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,**	
	2021	**2020**
Raw materials	102,082	4,790
Work in progress	55,681	14,914
Finished goods	8,135	13,625
Purchased goods (third party products)	7,362	1,303
Gross amount of inventories before write-down	**173,260**	**34,631**
Less: write-down provision	(49,162)	(7,698)
Inventories	**124,098**	**26,933**

The increase in raw materials and work in progress is primarily related to the production of the COVID-19 vaccine.

In 2021, the cost of inventories, which is recognized as an expense and is included in the position "Cost of goods and services", amounted to €145.3 million (2020: €27.0 million), of which €127.1 million (2020: €9.6 million) related to raw materials which cannot be used and failed batches, which were written down. In 2021, €121.4 million (2020: nil) of these expenses related to the COVID-19 vaccine and stem from write-downs for materials which cannot be used, failed batches and batches at risk of failure (see termination of UK supply agreement in Note 5.5.2). €5.7 million (2020: €9.6 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.

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

€ in thousand	**As at December 31,**	
	2021	**2020**
Raw materials	29,751	470
Work in progress	15,096	2,730
Finished goods	3,974	4,435
Purchased goods (third party products)	342	63
Total Write-down provision	**49,162**	**7,698**

Given the expected reductions in product sales related to Valneva's commercialized vaccines IXIARO and DUKORAL due to the current COVID-19 pandemic, the Company has performed a review of both commercial and raw material inventories and has included write-downs in the COGS as at December 31, 2021 and December 31, 2020. 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 €7.6 million as at December 31, 2021 (December 31, 2020: €7.4 million), €4.0 million (December 31, 2020: €4.4 million) thereof related to finished goods, €3.3 million (December 31, 2020: €2.4 million) related to work in progress and €0.3 million related to purchased goods (December 31, 2020: €0.5 million related to raw materials and €0.1 million related to purchased goods). As at December 31, 2021, the remaining write-down provisions concerning raw materials amounting to €29.8 million and work in progress amounting to €11.8 million mainly related to the COVID-19 vaccine. As at December 31, 2020, write-down provisions concerning work in progress amounting to €0.3 million related to failed batches.

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,**	
	2021	**2020**
Trade receivables	44,030	19,237
Less: loss allowance of receivables	(17)	(6)
Trade receivables, net	**44,013**	**19,232**

In 2021 and 2020, no material impairment losses were recognized. As at December 31, 2021, the amount of trade receivables past due amounted to €21.2 million (2020: €0.4 million) and mainly related to accounts receivable due from highly rated governmental authorities. In the months of January 2022 and February 2022 this amount of trade receivables past due of €21.2 million was lowered by €18.7 million due to payments received in the months of January 2022 and February 2022.

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, 2021, trade receivables included €40.9 million (December 31, 2020: €18.7 million) receivables from contracts with customers.

5.20 Other assets

Other assets include the following:

€ in thousand	As at December 31,	
	2021	2020
R&D tax credit receivables	35,390	19,637
Advance payments	27,375	33,671
Tax receivables	6,145	5,468
Prepaid expenses	5,131	2,544
Contract costs	3,010	2,846
Consumables and supplies on stock	1,722	1,061
Miscellaneous current assets	23	158
Other non-financial assets	78,796	65,385
Deposits	11,339	11,358
Miscellaneous financial assets	183	560
Other financial assets	11,522	11,918
Other assets	**90,318**	**77,303**
Less non-current portion	(19,282)	(19,476)
Current portion	**71,036**	**57,828**

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 to the COVID-19 and chikungunya vaccine candidates.

As at December 31, 2021 and December 31, 2020, the deposits mainly related to a deposit associated with a lease agreement.

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 (see Note 5.1).

As at December 31, 2020, advance payments amounting to €31.1 million related to the collaboration agreement with Dynavax.

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 3 months.

€ in thousand	As at December 31,	
	2021	2020
Cash in hand	3	2
Cash at bank	346,639	173,107
Short-term bank deposits (maximum maturity of 3 months)	—	31,285
Restricted cash	44	41
Cash and cash equivalents	**346,686**	**204,435**

As at December 31, 2021 and December 31, 2020, the restricted cash was a Certificate of Deposit with restricted limited access to secure the credit limit for the Company's commercial card. As at December 31, 2020, the minimum liquidity requirement for the Group according to the debt financing agreement with US healthcare funds Deerfield and OrbiMed (see Note 5.24.1) was €75.0 million, which was amended in January 2021 to be €50.0 million in 2021 and 2022 and €35.0 million from 2023 onward.

5.22 Equity

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

Number of shares	As at December 31,	
	2021	2020
Ordinary shares issued (€0.15 par value per share)	105,190,223	90,950,048
Convertible preferred shares registered	48,862	20,514
Total shares issued	**105,239,085**	**90,970,562**
Less Treasury shares	(124,322)	(146,322)
Outstanding shares	**105,114,763**	**90,824,240**

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.

In January 2021, 790,075 stock options (of which 363,050 were granted from ESOP 2016 and 427,025 from ESOP 2017) were exercised, which resulted in an increase in ordinary shares.

In May 2021, the Company announced the closing of its 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 "Option"), consisting of a public offering of 2,850,088 American Depositary Shares ("ADSs"), each representing two ordinary shares, in the United States at an offering price of $26.41 per ADS (the "U.S. Offering"), 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 (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, after full exercise of the Option, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately $107.6 million (€89.6 million). The cost of equity transactions in the amount of €6.8 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.

In November 2021, the Company announced the closing of its 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 "Option"), consisting of a public offering of 354,060 American Depositary Shares ("ADSs"), each representing two ordinary shares, in the United States at an offering price of $39.42 per ADS (the "U.S. Offering"), and a concurrent private placement of 4,466,880 ordinary shares in Europe (including France) and other countries outside of the United States at the corresponding offering price of €17.00 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, after full exercise of the Option and before deducting underwriting commissions and estimated expenses payable by the Company, were approximately $102.0 million (€88.0 million). The cost of equity transactions in the amount of €6.7 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, 2021, the Company had 6,572,937 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. 21 of the Combined General Meeting held on June 23, 2021, the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future, under resolutions 13 to 20 of said Meeting, may not exceed €5,175 million, it being specified that to this maximum aggregate amount will be added the additional nominal amount of shares or securities to be issued in accordance with applicable legal or regulatory provisions and, if applicable, with contractual provisions providing for other forms of adjustment, in order to preserve the rights of the holders of securities or other rights giving immediate and/or future access to the capital of the Company.

5.22.1 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, 2020	**52,820**	**(4,836)**	**(1,112)**	**8,357**	**(9,474)**	**45,756**
Currency translation differences	—	2,438	—	—	—	2,438
Defined benefit plan actuarial losses	—	(78)	—	—	—	(78)
Share-based compensation expense:						
- value of services	—	—	—	4,012	—	4,012
Purchase/sale of treasury shares	—	—	215	—	—	215
Balance as at December 31, 2020	**52,820**	**(2,474)**	**(898)**	**12,368**	**(9,474)**	**52,342**

€ 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 gains	—	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**

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 2021 and 2020.

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,		
	2021	2020	2019
Stock option plans	646	1,182	1,177
Free convertible preferred share plans	652	1,266	1,198
Free ordinary shares program	1,334	1,563	130
Equity warrants	—	—	—
Phantom shares	11,877	2,317	74
Share-based compensation expense	**14,509**	**6,328**	**2,578**

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.

Since 2013, the Company granted stock options to employees and management pursuant to five successive plans.

Since 2015, the employee stock option plans have primarily been for the benefit of non-executive employees, while members of the Management Board and the Management Committee, as well as the Manufacturing site Heads (since 2017), would have the opportunity to participate in four-year free share programs (convertible preferred shares or ordinary).

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:

	2021			2020		
	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	4,911,410	4,975,831	3.06	5,247,110	5,313,098	3.06
Granted	—	—	—	—	—	—
Forfeited	(187,950)	(189,168)	3.07	(335,700)	(337,267)	3.06
Exercised	(790,075)	(790,075)	2.79	—	—	—
Outstanding at year end	**3,933,385**	**3,996,588**	**3.11**	**4,911,410**	**4,975,831**	**3.06**
Exercisable at year end	3,203,817	3,267,020		2,855,570	2,919,991	

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. No stock options were exercised in 2020.

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,**	
Expiry date	**in € per share**	**2021**	**2020**
2023	2.919	696,903	645,900
2025	3.92	522,500	533,000
2026	2.71	36,200	399,250
2027	2.85	552,725	998,000
2029	3.05	2,188,260	2,335,260
Outstanding at year end		**3,996,588**	**4,911,410**

In 2021 and 2020, no stock options were granted. The fair value of the granted options was determined using the Black Scholes valuation model.

5.23.2 Free ordinary shares

In 2019, 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 2019-2023 is to provide a long-term incentive program for the Company's senior management. No further free ordinary shares were granted in 2021 and 2020.

In 2019, the number of free ordinary shares granted was as follows:

	Number of free ordinary shares granted
Management Board	1,381,947
Other Management Committee members	810,000
Free ordinary shares granted	**2,191,947**

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

	Number of free shares	
	2021	**2020**
Outstanding as at January 1	1,842,404	2,191,947
Forfeited	—	349,543
Outstanding at year end	**—**	**1,842,404**

Subject to vesting conditions (including performance and presence 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 tranche vested on December 19, 2021, the second tranche will vest on December 19, 2022, and the third tranche will vest on December 19, 2023. Vesting is subject to performance conditions.

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 December 19, 2023. As this was considered remote at the grant date (judgement by Management), 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 December 19, 2021, 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, subject again to meeting the performance conditions 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 FCPS will be convertible into the Company's ordinary shares four years after their initial granting if the conversion conditions set out below are met.

Upon expiration in December 2021 (the **Conversion Date**), the Management Board determined the conversion ratio, on the basis of (a) the Final Share Price (as hereinafter defined) and (b) the conversion table below.

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.

As the Final Share Price was higher than €8.00, the conversion ratio was determined that the beneficiaries' gross gain will not exceed the gross gain they would have realized if the Final Share Price was €8.00.

Following the full payment of the amount of personal investment required, the Management Board conditionally granted the program beneficiaries a number of FCPS:

	Number of FCPS 2017 granted to the beneficiaries
Management Board	24,200
Other Executive Managers	9,817
Free convertible preferred shares granted	**34,017**

Changes in the FCPS are as follows:

	Number of shares		Number of FCPS
	2021	2021	2020
Outstanding as at January 1		32,463	34,017
Granted		—	—
Expired		—	(1,554)
Outstanding at year end		**32,463**	**32,463**
Exercisable at year end (number of shares)	**884,144**		

The fair value of FCPS 2017 was determined using the Monte Carlo valuation model.

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 2020, 690,000 phantom shares were granted. In 2021, no new phantom shares were granted.

The carrying amount of the liability relating to the phantom shares as at December 31, 2021 was €14.3 million (December 31, 2020: €2.3 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**	**2021**	**2020**
2023	2.919	4,950	10,450
2025	3.92	6,000	14,000
2026	2.71	—	9,000
2027	2.85	6,250	32,000
2029	3.05	134,250	176,750
2030	—	690,000	690,000
Outstanding at year end		**841,450**	**932,200**

The significant inputs into the models were:

	As at December 31,	
	2021	**2020**
Expected volatility (%)	72.97	43.81
Expected vesting period (term in years)	0.25 – 4.39	0.25 – 5.40
Risk-free interest rate (%)	(0.78) – (0.64)	(0.82) – (0.71)

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) are 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) amounts to €2.574.

Changes in the equity warrants outstanding are as follows:

	Number of equity warrants	
	2021	**2020**
Outstanding as at January 1	43,750	103,875
Granted	—	—
Exercised	(21,875)	(26,750)
Forfeited	—	(33,375)
Outstanding at year end	**21,875**	**43,750**

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,	
	2021	**2020**
Non-current		
Other loans	50,726	46,375
Non-current borrowings	**50,726**	**46,375**
Current		
Other loans	7,107	6,988
Current borrowings	**7,107**	**6,988**
Total borrowings	**57,834**	**53,363**

The maturity of non-current borrowings is as follows:

€ in thousand	**As at December 31,**	
	2021	**2020**
Between 1 and 2 years	21,102	5,925
Between 2 and 3 years	15,502	14,270
Between 3 and 4 years	12,306	12,559
Between 4 and 5 years	674	10,524
Over 5 years	1,143	3,097
Non-current borrowings	**50,726**	**46,375**
Current borrowings	7,107	6,988
Total borrowings	**57,834**	**53,363**

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

€ in thousand	**As at December 31,**	
	2021	**2020**
Borrowings denominated in EUR	4,708	5,855
Borrowings denominated in USD	53,126	47,508
Total borrowings	**57,834**	**53,363**

5.24.1 Other loans

In February 2020, Valneva Austria GmbH signed a loan agreement (the Loan Agreement) with US healthcare funds Deerfield Management Company and OrbiMed (the Lenders).

Principal payments will start in 2023, while the loan will mature in 2026. The intended use of proceeds was to repay existing borrowings from the European Investment Bank and allow the Group to continue to advance its leading Lyme and chikungunya development programs in the short term. As at December 31, 2021, $60.0 million (€54.1 million) was drawn down in two tranches under the Loan Agreement. As at December 31, 2021 the carrying amount was €49.7 million. The interest rate is 9.95% (equivalent to 10.09% on an annual basis). The loan is secured by all of Valneva's assets, including the intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries.

Noting the COVID-19 pandemic 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 with quarterly minimum revenues representing an annual total of €64 million in 2021 and an annual total of €103.75 million in 2022. The parties also agreed to modify the minimum cash requirement to €50 million for 2021 and 2022 and to €35 million for the following years.

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 8% and of an indemnity representing the interests expected until March 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	2021	2020
Balance as at January 1	**46,190**	—
Proceeds of issue	—	52,935
Transaction costs	—	(4,162)
Accrued interest	6,167	4,538
Payment of interest	(6,459)	(2,698)
Exchange rate difference	3,774	(4,423)
Balance as at December 31	**49,671**	**46,190**
Less: non-current portion	(44,360)	(41,261)
Current portion	**5,311**	**4,929**

As at December 31, 2021, Other loans also included borrowings related to financing of Research and Development expenses and CIR (R&D tax credit in France) of €4.7 million (December 31, 2020: €5.9 million) as well as the amount related to CEPI of €3.5 million (December 31, 2020: €1.3 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, 2021, €54.4 million (December 31, 2020: €52.0 million) of the outstanding borrowings and other loans were guaranteed, secured or pledged. These borrowings and other loans are 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, 2021, material differences were identified only for guaranteed other loans. Based on an estimated arms' length interest rate of 9.55%, the fair value is €4.2 million (carrying amounts is €4.7 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,	
	2021	2020
Trade payables	16,035	24,898
Accrued expenses	52,084	11,314
Balance as at December 31	**68,119**	**36,212**
Less non-current portion	—	—
Current portion	**68,119**	**36,212**

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,**	
	2021	**2020**
Employee-related liabilities	10,101	8,300
Social security and other taxes	7,148	4,866
Balance as at December 31	**17,249**	**13,165**
Less non-current portion	—	—
Current portion	**17,249**	**13,165**

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,**	
	2021	**2020**
Between 1 and 2 years	25,301	2,296
Between 2 and 3 years	2,150	24,434
Between 3 and 4 years	2,214	1,280
Between 4 and 5 years	2,289	1,331
Between 5 and 10 years	10,733	7,384
Between 10 and 15 years	9,114	8,907
Over 15 years	1,886	3,759
Non-current lease liabilities	**53,687**	**49,392**
Current lease liabilities	3,135	2,696
Total Lease liabilities	**56,822**	**52,088**

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

€ in thousand	**As at December 31,**	
	2021	**2020**
EUR	24,650	25,633
SEK	30,657	26,166
Other	1,515	289
Total lease liabilities	**56,822**	**52,088**

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	2021	2020
Balance as at January 1	89,636	1,426
Revenue recognition	(89,364)	(594)
Exchange rate differences	7	101
Addition	128,479	88,703
Balance as at December 31	**128,758**	**89,636**
Less non-current portion	(4,741)	(58)
Current portion	**124,017**	**89,578**

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. With regards to changes to the position because of revenue recognized in 2021, €87.0 million related to the UK Supply Agreement (refer to Note 5.1).

As at December 31, 2020, €87.0 million related to the UK Supply Agreement (see Note 5.1), €1.6 million related to CTM services provided to different customers and €1.0 million related to the agreement for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine, VLA1553, in LMICs with Instituto Butantan.

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	2021	2020
Balance as at January 1	111,426	6,553
Additions	159,179	109,296
Payments	(18,022)	(477)
Other releases	(15,198)	—
Interest expense capitalized	8,478	3,640
Exchange rate difference	8,718	(7,586)
Balance as at December 31	**254,581**	**111,426**
Less non-current portion	(158,970)	(97,205)
Current portion	**95,611**	**14,222**

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

As at December 31, 2020, €81.9 million (thereof €70.0 million non-current) related to the collaboration with Pfizer Inc. (see Note 5.1), €20.9 million (all non-current) related to the UK Supply Agreement (see Note 5.5.2), €6.3 million (all non-current) related to the expected payment to GSK related to the termination of the SAA in 2019 (see Note 5.1) and €2.3 million related to refund liabilities to customers related to rebate programs and right to return products.

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,	
	2021	2020
Employer contribution costs on share-based compensation plans	26,520	7,351
Phantom shares	14,267	2,390
Retirement termination benefits	422	550
Leaving indemnities	—	112
Balance as at December 31	**41,210**	**10,403**
Less non-current portion	8,308	2,358
Current portion	**32,901**	**8,045**

(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, 2021: €24.5 (December 31, 2020: €7.75).

(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 using the projected unit credit method. This method sees each period of service as giving rise to an additional unit of benefit entitlement and measures each unit separately to determine the final obligation. 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,	
	2021	2020
Discount rate	1.00%	0.50%
Salary increase rate	2.00%	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)	22	22

Changes in defined benefit obligation

Present value of obligation development:

€ in thousand	2021	2020
Balance as at January 1	**550**	**404**
Current service cost	77	68
Actuarial losses/(gains)	(205)	78
Balance as at December 31	**422**	**550**

5.30.2 Other provisions

€ in thousand	As at December 31,	
	2021	2020
Non-current	-	-
Current	15,806	2,124
Provisions	**15,806**	**2,124**

As at December 31, 2021, the significantly increased provision related mainly to onerous purchase agreements related to the termination of the UK Supply Agreement (€13.5 million). Secondly, the position comprised €2.1 million from a provision for expected legal and settlement costs under a court proceeding related to the Intercell AG/Vivalis SA merger (December 31, 2020: €1.9 million).

5.31 Other liabilities

€ in thousand	As at December 31,	
	2021	2020
Deferred income	4,966	2,861
Other financial liabilities	44	51
Miscellaneous liabilities	8	2
Other liabilities	**5,019**	**2,913**
Less non-current portion	(69)	(72)
Current portion	**4,950**	**2,841**

Deferred income mainly includes conditional advances from a grant 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,**		
		2021	**2020**	**2019**
Loss for the year		(73,425)	(64,393)	(1,744)
Adjustments for				
• Depreciation and amortization	5.12/5.13/5.14	14,281	9,799	8,532
• Write-off / impairment fixed assets/intangibles	5.12/5.13/5.14	—	140	75
• Share-based compensation expense	5.23	14,509	6,328	2,552
• Income tax expense/(income)	5.10	3,446	(909)	874
• Dividends received from associated companies	5.15	—	—	433
• (Profit)/loss from disposal of property, plant, equipment and intangible assets	5.8	46	10	92
• Share of (profit)/loss from associates	5.15	5	133	(1,574)
• Fair value losses on derivative financial instruments		—	—	178
• Provision for employer contribution costs on share-based compensation plans	5.30.1	19,079	7,351	—
• Other non-cash (income)/expense		(11,604)	4,470	(892)
• Interest income	5.9	(249)	(119)	(199)
• Interest expense	5.9	16,964	10,738	2,633
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):				
• Other non-current assets		194	(2,303)	79
• Long term contract liabilities	5.28	4,662	(674)	(2,321)
• Long term refund liabilities	5.29	54,501	90,653	6,016
• Other non-current liabilities and provisions		(3)	795	(178)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):				
• Inventory		(92,373)	(4,196)	(2,415)
• Trade and other receivables		(21,349)	(24,023)	(17,278)
• Contract liabilities	5.28	34,453	88,801	(989)
• Refund liabilities	5.29	80,160	10,614	448
• Trade and other payables and provisions		35,236	6,544	13,552
Cash generated from operations		**78,532**	**139,759**	**7,875**

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 expenses from disposal of Lyme VLA15 (see Notes 5.1 and 5.12), €1.6 million income from a revaluation of lease liabilities and right of use assets and €2.6 million 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,**		
	2021	**2020**	**2019**
Net book value	46	34	92
Loss on disposal of fixed assets	(46)	(10)	(92)
Proceeds from disposal of property, plant, equipment and intangible assets	**—**	**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, 2020	**19,759**	**6,557**	**26,316**
Repayments	(20,000)	(1,995)	(21,995)
Additions, net of transaction costs	—	50,266	50,266
Foreign exchange movements	—	(4,556)	(4,556)
Other changes[8]	241	3,090	3,331
Balance as at December 31, 2020	**—**	**53,363**	**53,363**
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**

8 Other changes include interest accruals and payments.

5.33 Commitments and contingencies

As at December 31, 2021, there were €23.6 million of capital expenditure contracted, mainly related to manufacturing sites for the COVID-19 vaccine candidate (December 31, 2020: €48.0 million).

5.33.1 Other commitments, pledges and guarantees

The other commitments relate to minimum payments consist of:

€ in thousand	As at December 31,	
	2021	2020
Loans and grants	143	1,454
Royalties	8,941	9,393
Other commitments	**9,084**	**10,846**

The pledges consist of:

€ in thousand	As at December 31,	
	2021	2020
Pledges on consolidated investments	19,901	19,474
Pledges on bank accounts	292,257	150,642
Pledges on receivable	344,519	160,511
Guarantees and pledges	**656,677**	**330,626**

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. The Company therefore held a provision of €2.1 million to cover this increase and potential settlement costs (December 31, 2020: €1.9 million). €0.3 million of additional expenses related to this litigation was included in “other expenses” in the year ended December 31, 2021.

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 first half of 2022. 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

Services provided by Valneva to Groupe Grimaud La Corbière SAS, being 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.

€ in thousand	Year ended December 31,		
	2021	2020	2019
Provision of services:			
Operating activities	231	187	236
Provision of services	**231**	**187**	**236**

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,		
	2021	2020	2019
Salaries and other short-term employee benefits[9]	1,930	2,950	2,449
Other long-term benefits	24	18	15
Share-based payments (expense of the year)	856	1,786	1,174
Key management compensation	**2,809**	**4,755**	**3,638**

5.34.3 Supervisory Board compensation

In 2021, the aggregate compensation of the members of the Company's Supervisory Board amounted to €0.3 million (2020: €0.2 million, 2019: €0.3 million). In the year 2017, the Company granted equity warrants to members of the Supervisory Board. For more information, see Note 5.23.

5.35 Events after the reporting period

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 Valneva's COVID-19 vaccine candidate and Valneva's other vaccine candidates. The funds under these grants will be received over three years, beginning in March 2022.

At year end, the Company assessed the inventory valuation taking into consideration the residual shelf life and production plan for 2022. This analysis resulted in a write-down of raw material for an amount of €23 million as at December 31, 2021. In 2022, one of the suppliers performed additional analysis and concluded in March 2022 on an extension of the shelf life. As a consequence, Valneva expects to use some of the material in the manufacturing process and will reverse a portion of the write-down. Since the extension of the shelf life was determined in 2022, the Company considers the developments after the reporting date as a non-adjusting subsequent event.

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

Exhibit 3.1

This document is a free translation. In case of discrepancy between the French and the English version, the French version shall prevail.

VALNEVA SE

European company with an Management Board and Supervisory Board
with a share capital of 16,074,817.20 Euros
Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain
Identification N° 422 497 560 RCS[1] Nantes

ARTICLES OF ASSOCIATION

As amended by the *Directeur General* decisions of February 25, 2022

[1] RCS – Trade and Companies Register

This document is a free translation. In case of discrepancy between the French and the English version, the French version shall prevail.

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 16,074,817.20 Euros. It is divided into:

- 107,144,934 ordinary shares with nominal value of 0.15 Euro each, fully subscribed and paid up (the ***Ordinary Shares***); and
- 20,514 preferred shares convertible into Ordinary Shares with nominal value of 0.15 Euro each, fully subscribed and paid up, granting the holder the special rights defined in these Articles of Association (the ***Convertible Preferred Shares***).

The Ordinary Shares and the Convertible Preferred Shares are collectively designated as ***the Shares***.

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 Ordinary 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 Ordinary 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.

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

Article 10.1 - Form of the Ordinary Shares

1. The fully paid up Ordinary Shares may take nominative or bearer form, at the choice of the shareholder, subject to the legal and regulatory provisions in effect.

   The Ordinary 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 Ordinary 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 10.2 - Form of preferred shares convertible into Ordinary Shares (**Convertible Preferred Shares**)*

1. The Convertible Preferred Shares are registered shares.

2. The provisions of Article 10.1 " Form of Ordinary Shares ", § 2., also apply to the Convertible Preferred Shares, subject to the following characteristics of the latter.

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

Article 13.1 - Rights and obligations common 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.

Article 13.2 - Stipulations specific to Ordinary Shares

1. Each Ordinary 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.

2. 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 Ordinary Shares fully paid up for all of the due payments. For the same nominal value, each capital or participating Ordinary Share shall confer one vote.

3. A double voting right, considering the proportion of the share capital which they represent, shall be attributed to all fully paid up Ordinary 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 Ordinary Shares attributed as a bonus to a shareholder by virtue of former Ordinary Shares for which it has already benefited from this right.

Article 13.3 - Stipulations specific to Convertible Preferred Shares

■ *Rights attaching to the Convertible Preferred Shares*

The Convertible Preferred Shares will not be entitled to the distribution of dividends.

The Convertible Preferred Share does not carry voting rights in General Meeting. In accordance with the provisions set by statute and Article 32 of these Articles of Association, it confers a right to participate and vote in special shareholders meetings for holders of Convertible Preferred.

The Convertible Preferred Shares do not carry preferential subscription rights to capital increases or any other corporate action with preferential subscription rights to Ordinary Shares and will not benefit from capital increases by free grants of new shares or by increasing the nominal amount of existing ordinary shares or through the capitalization of reserves, earnings or other items that may be capitalized, or through free grants of securities giving access to shares for the benefit of holders of ordinary shares.

The Convertible Preferred Shares are non-transferable.

■ *Right to convert Convertible Preferred Shares into Ordinary Shares subject to conditions*

(i) Conditions for converting Convertible Preferred Shares into Ordinary Shares

The Convertible Preferred Shares may be converted into Ordinary Shares at the end of four (4) years from their issuance date or their allocation date (the **Conversion Date**), according to a conversion ratio determined in the conditions described hereunder (the **Conditions of Convertible Preferred Shares**):

The number of Ordinary Shares that may result from the conversion will be calculated according to a conversion ratio determined by the Management Board based on the volume weighted average price of the Company's share for a period defined by the Management Board (**Volume Weighted Average Price**) on the Conversion Date (the **Conversion Ratio**). It being stipulated that the Management Board will determine for this purpose on the date the Convertible Preferred Shares are issued or awarded:

- the Volume Weighted Average Price from which the Convertible Preferred Shares may confer a right of conversion (the **Floor Price**) that may not, in any case be less than EUR 4;

- the target price on the Conversion Date above which the Ordinary Shares issued from the conversion will not increase (the **Ceiling Price**).

The Convertible Preferred Shares may not represent more than 6% of the share capital.

(ii) Procedures for conversion of Convertible Preferred Shares into Ordinary Shares

Subject to fulfillment of the Conditions of the Convertible Preferred Shares, the Convertible Preferred Shares will, on the Date of Conversion, be converted by the Company into Ordinary Shares at the request of the holder as from the Conversion Date and up to the cut-off date determined by the Management Board after which the Convertible Preferred Shares will automatically be converted if the holder has not requested conversion during this period.

The conversion of Convertible Preferred Shares into Ordinary Shares shall not require any payment by the holders of the Convertible Preferred Shares.

The nominal value of each of the Ordinary Shares shall be paid up by debiting the special blocked reserve account created for that purpose in the accounts (shareholders' equity) of the Company.

The conversion of Convertible Preferred Shares into Ordinary Shares will constitute de facto waiver by shareholders of their preferential subscription rights resulting from new ordinary shares that will be, as applicable, issued pursuant to this conversion.

The Ordinary Shares resulting from the conversion of Convertible Preferred Shares will be definitively fungible with existing ordinary shares of the company as from the conversion date.

When the total number of Ordinary Shares to be received by a holder of Convertible Preferred Shares by applying the Conversion Ratio to the number of Convertible Preferred Shares held is not a whole number, said holder will receive the next lowest number of Ordinary Shares.

The Management Board must note for the record, as applicable, the number of Ordinary Shares resulting from the conversion of Convertible Preferred Shares, and make the necessary modifications to the bylaws, in particular with respect to the allocation of Shares per class and record the capital increase as required by law.

On conversion of the Convertible Preferred Shares, every holder of Convertible Preferred Shares may obtain a number of Ordinary Shares calculated with regard to the number of Convertible Preferred Shares which it holds on the basis of the Conversion Ratio in effect.

When the number of Ordinary Shares so calculated is not a whole number, the fraction of Ordinary Shares forming a fractional lot shall be paid in cash.. In such an event, the holder of Convertible Preferred Shares shall receive an amount equal to the product (i) of the fraction of an Ordinary Share forming a fractional lot and (ii) an amount equal to the first recorded market price of the Ordinary Share for the stock exchange trading session preceding that of the ipso jure conversion of the Convertible Preferred Shares into Ordinary Shares.

Such amount shall be debited from the special blocked reserve account created for that purpose in the accounts (shareholders' equity) of the Company and, as the case may be, from any available reserve accounts.

(iii) Protection of the individual rights of holders of Convertible Preferred Shares

Amortisation of the share capital – Modification of profit-sharing – Issuance of preferred shares

The Company shall have the right to amortise its share capital, to modify the rules for sharing of its profits or the issuance of preferred shares, provided that, for as long as Convertible Preferred Shares are in circulation, it has taken the necessary measures to preserve the rights of the holders of the Convertible Preferred Shares, pursuant to the stipulations of the paragraph "*Financial Operations of the Company*" below.

Capital reduction due to losses

In the event of reduction of the share capital of the Company due to losses and carried out through a reduction in the nominal amount or number of shares comprising the share capital, the rights of the holders of the Convertible Preferred Shares shall consequently be reduced, as if the holders of the Convertible Preferred Shares had converted their Convertible Preferred Shares before the date on which the capital reduction had become final.

Financial operations of the company

On conclusion of one of the following operations:

1. financial operations with a listed preferential subscription right;

2. attribution of bonus ordinary shares of the Company to shareholders, division or consolidation of shares;

3. free attribution to shareholders of any financial instruments other than the ordinary shares of the Company;

4. absorption, merger, division;

5. amortisation of the share capital;

which the Company could realise starting from the date of issuance of the Convertible Preferred Shares, the maintenance of rights of holders of the Convertible Preferred Shares shall be ensured by carrying out an adjustment of the Conversion Ratio, pursuant to the following procedures (the ***Adjusted Conversion Ratio***).

This adjustment shall be carried out in such a way that it equalises the value of the Ordinary Shares, to the nearest thousandth of an Ordinary Share, which have been obtained in the event of conversion of the Convertible Preferred Shares immediately after the realisation of one of the above-mentioned operations, and the value of Ordinary Shares that would be obtained in case of conversion of Convertible Preferred Shares immediately after said operation.

In the event of adjustments carried out pursuant to paragraphs 1 to 5 below, the new Conversion Ratio shall be determined to the nearest thousandth (0.0005 being rounded up to the nearest thousandth, i.e. to 0.001). Any further adjustments shall be carried out on the basis of the preceding Conversion Ratio so calculated and rounded. At the same time, the Ordinary Shares shall only give rise to the delivery of a full number of Ordinary Shares, with the payment of partial Shares being specified in the paragraph "*Payment of partial shares*" above.

1. In the case of financial operations entailing a listed preferential subscription right, the Adjusted Conversion Ratio shall be equal to the product of the current Conversion Ratio before the start of the operation in question and the ratio below:

$$\frac{\text{Value of the Ordinary Share after detachment of the preferential subscription right + value of the preferential subscription right}}{\text{Value of the Ordinary Share after detachment of the preferential subscription right}}$$

To calculate this ratio, the value of the Ordinary Share after detachment of the preferential subscription right shall be determined as the arithmetic average of the first market prices on NYSE Euronext Paris exchange (or in the absence of a market price on NYSE Euronext Paris exchange, on another regulated or similar market on which the share and the subscription right are both listed) for all of the trading days included in the subscription period.

2. In the event of attribution of bonus Shares, as well as in the event of division or consolidation of Ordinary Shares, the Adjusted Conversion Ratio shall be equal to the product of the Conversion Ratio in effect before the start of the operation in question and the following ratio:

$$\frac{\text{Number of Ordinary Shares comprising the share capital after the operation}}{\text{Number of Ordinary Shares comprising the share capital before the operation}}$$

3. In the event of attribution free of charge of a financial instrument/financial instruments other than the ordinary shares of the Company, the Adjusted Conversion Ratio shall be determined as follows:

(a) if the right of free attribution of the financial instrument/financial instruments is subject to a listing on NYSE Euronext Paris exchange (or in the absence of a listing on NYSE Euronext Paris exchange, on another regulated or similar market), the new Conversion Ratio shall be equal to the product of the Conversion Ratio in effect before the start of the operation in question and the following ratio:

$$\frac{\text{Value of the ordinary share ex the free bonus right + value of the free bonus right}}{\text{Value of the ordinary share ex the free bonus right}}$$

To calculate this ratio:

- the value of the ordinary share ex the free bonus right shall be determined as the average weighted by the volumes of the first market prices quoted on NYSE Euronext Paris exchange (or in the absence of a price on NYSE Euronext Paris exchange, on another regulated or similar market on which the share and the subscription right are both listed) for the ordinary share ex the free bonus right for the first three stock exchange trading sessions, starting on the date on which the ordinary shares are listed ex the free bonus right;

- the value of the free bonus right shall be determined as in the above paragraph. If the free bonus right is not listed for at least each of these three stock exchange sessions, its value shall be determined by an independent expert of international reputation, chosen by the Company.

(b) if the bonus right for the financial instrument/financial instruments is not listed on the NYSE Euronext Paris exchange (or in the absence of a price on the NYSE Euronext Paris exchange, on another regulated or similar market), the Adjusted Conversion Ratio shall be equal to the product of the Conversion Ratio in effect before the start of the operation in question and the following ratio:

$$\frac{\text{Value of the ordinary share ex free bonus right + value of the financial instrument(s) attributed per ordinary share}}{\text{Value of the ordinary share ex free bonus right}}$$

To calculate this ratio:

- the value of the ordinary share ex the free bonus right shall be determined as in paragraph (a) above.

- if the attributed financial securities are listed or likely to be listed on the NYSE Euronext Paris exchange (or in the absence of a listing on the NYSE Euronext Paris exchange, on another regulated or similar market), for the 10-day trading period starting on the date on which the shares are listed ex-distribution, the value per share of the attributed financial security/securities shall be equal to the average weighted by the volumes of the prices of the said financial securities observed on the said market for the first three stock exchange trading sessions included in this period during which the said financial securities are listed. If the said attributed financial securities are not listed for at least each of these three stock exchange trading sessions, the per share value of the attributed financial security/securities shall be determined by an independent expert of international reputation, chosen by the Company.

4. In the event of absorption of the Company by another company or merger with one or several other companies to form a new company or a division, the Convertible Preferred Shares shall be exchanged for the preferred shares of the absorbing or new company or of the companies benefiting from the division and shall be converted into ordinary shares of the absorbing or new company or the companies benefiting from the division (the ***Replacement Shares***).

   The new Conversion Ratio shall be determined by multiplying the Conversion Ratio in effect before such an event by the exchange ratio for the Ordinary Shares into the Replacement Shares.

   The company or companies, which are beneficiaries of the contributions or the new company/companies shall replace the Company *ipso jure* in its obligations with regard to the holders of the Convertible Preferred Shares.

5. In the event of amortisation of the share capital, the Adjusted Conversion Ratio shall be equal to the product of the Conversion Ratio in effect before the amortisation and the following ratio:

$$\frac{\text{Value of the Ordinary Share before the amortisation}}{\text{Value of the Ordinary Share before the amortisation – amount of the amortisation per Ordinary Share}}$$

To calculate this ratio, the value of the Ordinary Share before the amortisation shall mean the average weighted by the volumes of the market prices quoted on the NYSE Euronext Paris exchange (or in the absence of a price on the NYSE Euronext Paris exchange, on another regulated or similar market) for the last three stock exchange trading sessions preceding the day on which the Ordinary Shares are listed ex-amortisation.

In the event that the Company executes operations for which an adjustment has not been stipulated by way of paragraphs 1 to 5 above and where a further provision of law or regulation provides for an adjustment, the Company shall make this adjustment pursuant to the applicable legal or regulatory provisions, taking account of practices in the field within the French market. In the event that the Ordinary Share of the Company is no longer admitted to trading on the NYSE Euronext Paris exchange (or in the absence of a price on the NYSE Euronext Paris exchange, on another regulated or similar market), the values referred to above shall be determined by an independent expert of international reputation, chosen by the Company.

(iv) Repurchase of Convertible Preferred Shares

If the functions of a holder of Convertible Preferred Shares within the Company or its subsidiaries is terminated for one of the following reasons:

- dismissal for gross or willful misconduct or the removal as corporate officer or employee of the Company or one of its subsidiaries in similar circumstances;
- voluntary early retirement with full pension benefits, in the absence of prior written approval from the Company;
- resignation in the absence of prior written approval from the Company,

the Company will buy back the Convertible Preferred Shares for the purpose of their cancellation.

The Convertible Preferred Shares will be repurchased at a price corresponding to their nominal value per share.

The Company will inform the holder of Convertible Preferred Shares concerned of the repurchase to be carried out by any means before the actual date of the repurchase.

All Convertible Preferred Shares repurchased on this basis will be definitively canceled as from that repurchase date and the capital of the company will be reduced by the corresponding amount, with the creditors possessing a right of objection.

The Management Board must note for the record, as applicable, the number of Convertible Preferred Shares repurchased and canceled by the company and make the necessary modifications to the Articles of Association with respect to the share capital and the number of shares making up the capital.

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 and the president shall not have a casting vote in the event of a tied 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 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.

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 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, 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.

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.

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 1 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 1.5 million;

(xi) implementation of any capital expenditure for an amount exceeding EUR 1 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 1.5 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 1 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 500,000, provided that any settlement or compromise relating to a litigation of an amount exceeding EUR 250,000 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, in accordance with the law. Copies and extracts of these minutes shall be certified under the conditions set by law.

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 13.2, the voting rights attached to Ordinary 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.

Each Preferred Share shall provide entitlement to the distribution of one fifteenth ($1/15^{th}$) of the amount of any distribution or, as the case may be, of the allocation of assets, decided in favour of the holders of each Ordinary Share.

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 Ordinary 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 4.3

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, 2021, 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, 2021, our issued share capital consisted of a total of 105,190,223 ordinary shares with a nominal value of €0.15 per share and 48,862 preferred shares convertible into ordinary shares, also with a nominal value of €0.15 per preferred share. Of these 105,190,223 issued ordinary shares, 105,065,901 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).

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.*

Exhibit 10.3

SENSITIVE

[***] = 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.

EN

ANNEX

to the

COMMISSION DECISION

approving an Advance Purchase Agreement on COVID-19 vaccines

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Sensitive*
RELEASABLE TO: Need to know basis

ADVANCE PURCHASE AGREEMENT ("**APA**")[1] for the development, production, purchasing and supply of a successful COVID-19 vaccine for EU Member States

NUMBER — **[***complete***]**

1. The European Commission (the '**Commission**'), acting on behalf and in the name of the Member States listed in Annex I (hereinafter referred to as "**Participating Member States**") being represented for the purposes of signature of this APA by Ms Stella Kyriakides, Commissioner for Health and Food Safety:

on the one part and

2. **Valneva Austria GmbH**, a limited liability company ("Gesellschaft mit beschränkter Haftung") incorporated under company number [***], whose registered office is at Campus Vienna Biocenter 3, 1030 Vienna, Austria

VAT registration number: [***]

(the '**contractor**'), represented for the purposes of the signature of this APA which has the form of a framework contract by [***]

on the other part,

The Commission, acting on behalf and in the name of the Participating Member States, and the contractor are together referred to as the "**Parties**" and each individually as a "**Party**"

HAVE AGREED

to the **special conditions and** the **general conditions of this APA** and the following annexes:

Annex I – List of Participating Member States and allocated volumes

[1] This APA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid- 19 vaccines on behalf of the Member States and related procedures.

Annex II – Model for Vaccine Order Form

Annex III – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

Annex IV – List of confirmed and planned manufacturing network partners including the location(s) of manufacturing

Annex V – Target Product profile

Annex VI – Contractor's insurance

Annex VII – Details of the utilisation of the Down Payment

which form an integral part of this APA.

RECITALS

A. The world is experiencing an emergency healthcare crisis due to the SARS-CoV-2 ("**COVID-19**") pandemic (the "**COVID-19 pandemic**") and the global demand for vaccines to prevent COVID-19 virus infection is expected to be in order of magnitude of billions of doses.

B. The contractor is currently working to develop and manufacture a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus, consisting in an inactivated whole virus of SARS-CoV-2 [***], to help protect against COVID-19 virus infection in humans.

C. The Commission intends to create the environment required to support a secure manufacturing network and optimisation for the production of vaccines against COVID-19. To this effect the Commission has concluded an Agreement with all Member States of the European Union to conclude, on behalf and in the name of the Member States, Advance Purchase Agreements with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID-19 pandemic at Union level.

D. The Commission wishes to secure the supply of the Product for human use for the Participating Member States during the COVID-19 pandemic as promptly as possible.

E. The intention of the Commission, on behalf of the Member States, is to ensure that the population in the European Union will be able to access a vaccine in sufficient quantities and at a fair price, but also in safe conditions. The vaccine should only be available to the population once its safety and efficacy will have been cleared by the competent regulatory bodies.

F. According to the Agreement between the Commission and the Member States[2] and in particular Article 4 thereof, the Commission can conclude an Advance Purchase Agreement that contains a right and an obligation for Participating Member States to acquire vaccine doses. Where the Commission intends to enter into such an agreement, it shall inform the Member States of such intention and the detailed terms. In case a Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission. All Participating Member States not having opted out in accordance with the Agreement between the Commission and the Member States are deemed to have authorised the Commission to negotiate and conclude an Advance Purchase Agreement with the vaccine manufacturer in their name and on their behalf.

G. This APA is such an agreement which the Commission enters into on behalf and in the name of the Participating Member States which have not opted out of the agreement. These Participating Member States will then have an obligation to acquire the Product and a right to be supplied with the respective Product doses. While the APA is legally binding upon those Participating Member States, it will be further implemented by means of the conclusion of contracts between the Participating Member States and the contractor. The present APA is complemented by a Vaccine Order Form ("**Vaccine Order Form**") between each of the Participating Member States and the contractor. A model Vaccine Order Form is attached in Annex II.

H. The development, production, advance sale and supply of the Product as per this APA require significant investments by the contractor to increase the speed of clinical development, and the preparation of the at-scale production capacity along the entire production value chain in the EU required for a rapid deployment of the millions of doses of the Product. The Participating Member States are willing to contribute to financing of those investments in the form of up-front payments.

I. Pursuant to these terms and conditions, access to Product doses will be allocated to Participating Member States as provided in Annex I. The up-front payments, paid by the Participating Member States, should be taken into account in equal terms per *dose* ordered by the Participating Member States.

J. The Parties recognise that the timelines to develop, produce, sell and supply the Product are accelerated and that the Participating Member States are willing to share risks arising from this accelerated timetable, [***]

[2] Such agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, OJ L 117, 15.4.2020, p. 3. The agreement was approved Decision C(2020) 4192 final of 18 June 2020 (see Annex III to this *APA*).

K. Against this background, the Commission wishes to enter into, on behalf and in the name of the Participating Member States, an Advance Purchase Agreement with the contractor to secure the availability of a total of 24.341.449 doses of the Product and 35.658.551 optional doses of the Product, to be allocated among the Participating Member States in accordance with the allocation principles set out in this APA.

This APA sets out:

1. the procedure and conditions by which the Participating Member States shall pay for the Product from the contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the contractor shall conclude under this APA; and
3. the obligations of the Parties during and after the duration of this APA.

All terms and conditions issued by the contractor (end-user agreements, general terms and conditions, etc.) are held inapplicable, unless explicitly mentioned in the special conditions of this APA. In all circumstances, in the event of contradiction between this APA and documents issued by the contractor, this APA prevails, regardless of any provision to the contrary in the contractor's documents.

TABLE OF CONTENT

I. SPECIAL CONDITIONS

I.1 Order of priority of provisions

If there is any conflict between different provisions in this APA, the following rules must be applied:

(a) The provisions set out in the special conditions take precedence over those in the other parts of the APA, including its annexes.
(b) The provisions set out in the general conditions take precedence over those in the Vaccine Order Forms signed by the Participating Members States.
(c) All terms and conditions issued by the contractor (such as end-user agreements, general terms and conditions, etc.) are held inapplicable, unless they are issued under or in accordance with this APA (such as the final specifications, (Formal) Notifications, etc.). In all circumstances, in the event of contradiction between this APA and documents issued by the contractor, this APA prevails, regardless of any provision to the contrary in the contractor's documents.

I.2 Subject matter

The subject of this APA is the advance purchase of (i) 24.341.449 doses of the Product, as described below in Article I.4.2, to be allocated among the Participating Member States by the Commission in accordance with the allocation principles set out below in Article I.4.3, and (ii) the optional and additional purchase of up to 35.658.551 Option Doses, according to the conditions laid down in Article I.4.4.

On the basis of this APA, the contractor (i) commits to use Best Reasonable Efforts to obtain a Marketing Authorisation for the Product; and, (ii) if a Marketing Authorisation for the Product is obtained, [***] supply the contractually agreed volumes of the Product to the Participating Member States in accordance with said Marketing Authorisation and the Delivery Schedule set out below in Article I.4.7.

Each Participating Member State shall issue a Vaccine Order Form as regards its allocation of the Doses, through which the contractor shall supply to the Participating Member States the Product doses in accordance with the terms of this APA.

The delivery of the Product to the individual Participating Member States shall be carried out in accordance with the terms and conditions of this APA and in particular in accordance with the allocation set out in Annex I, as well as the additional delivery details set out in the Vaccine Order Forms concluded between the contractor and each Participating Member State using the model Vaccine Order Form provided as Annex II to this APA.

I.3 Entry into force and duration of the APA

I.3.1 The APA enters into force on the date on which the contractor and the Commission have signed it.

I.3.2 Unless earlier terminated in accordance with Article II.16 or expired in accordance with Article I.3.5, the APA is concluded for a period of [***] with effect from the date of its entry into force.

I.3.3 Its duration may be extended upon mutual agreement if at the end of the term of [***] not all of the Doses, and, as the case may be, doses of Product purchased under the 2023 Option (as defined below) have been supplied. [***] The Participating Member States and the contractor may not sign any Vaccine Order Form after the APA expires.

I.3.4 The APA continues to apply to signed Vaccine Order Forms after its expiry.

I.3.5 The APA shall automatically expire on the date on which all the Doses and, as the case may be, all doses of Product purchased under the 2023 Option, have been delivered and paid in full.

I.3.6 Articles I.4.6, I.4.7.3(d), I.4.7.4(5), I.4.7.6, I,8, I.10, I.11.1, I.11.2, I.11.3, I.11.4, I.11.5, II.4, II.5, II.7, II.16.5, II.18, II.19, II.20 and any other clause which produces legal effects after the termination or expiry of this APA according to its wording, shall survive the termination or expiry of this APA.

I.4 IMPLEMENTATION OF THE APA

I.4.1 General principles and Variant Switch

I.4.1.1 General principles

The APA shall be implemented following signature between the Commission on behalf and in the name of the Participating Member States and the contractor as follows:

(1) Following entry into force of this APA, this APA is binding upon the contractor, the Commission and all Participating Member States on behalf and in the name of which the Commission has concluded this APA, as identified in Annex I.

(2) Within 10 days after the signature of the APA by the Commission, each Participating Member State shall place an order for its allocated portion of the Doses by sending the contractor the duly completed and signed Vaccine Order Form (the format for which is set out in Annex II) in PDF format and by email, to the contractor’s address specified in the Vaccine Order Form.

(3) Within 10 days of receipt of the Vaccine Order Form from a Participating Member State, the contractor must send back to the Participating Member State the Vaccine Order Form duly signed and dated in PDF format and by email, to the Participating Member State’s address specified in the Vaccine Order Form.

(4) The Parties acknowledge that any delivery is dependent on the date on which the Marketing Authorisation for the Product is obtained.

(5) Wherever this APA provides that:

a) certain rights enjoyed by the Participating Member States under the APA shall be exercised by the Commission, the Commission alone shall be entitled to (Formally) Notify the contractor of the exercise of such rights. Such (Formal) Notification shall be binding upon all Participating Member States, or, in situations where this APA provides that the Commission can exercise certain rights on behalf of some but not necessarily all Participating Member States, upon the Participating Member States concerned by such notification;

b) certain Notifications of the contractor shall be issued to the Commission, such Notification to the Commission shall bind all Participating Member States. The Commission is acting on behalf and in the name of the Participating Member States in such cases.

The foregoing sub-sections a) and b) shall not apply to the Vaccine Order Forms, unless provided otherwise in the APA or the relevant Vaccine Order Form. The Vaccine Order Forms shall only be implemented, performed and consummated by the contractor and the relevant Participating Member State (but not the Commission).

I.4.1.2 Variant Switch

The contractor will keep the Commission informed of the availability of any new strains which contractor may use as basis to manufacture COVID-19 vaccines and the impact on production of contractor's arrangements to address any new strains. The Participating Member States can then elect to request contractor to switch the strain used as basis for the Doses to such a new strain ("**Variant Switch**"). The following conditions shall apply to any such Variant Switch:

[***]

I.4.2 Doses

The contractor commits to supply 24.341.449 doses in the aggregate of the Product (the "**Doses**") to all Participating Member States in accordance with the terms of this APA and the applicable Vaccine Order Forms. Annex V provides the target Product profile, as at the date of signature of the APA, which contractor may vary as the Product is being developed. [***]

Each Participating Member State shall, in proportion to the Doses allocated to such Participating Member State in accordance with Article I.4.3, contribute to the relevant costs for the Doses in the form of an up-front payment of [***] of the total price of the Doses as laid down in Article I.7.1 (the "**Down Payment**"). This amount shall be invoiced upon signature of the APA and paid as provided in Article I.8.1.

[***] of the price of the Doses actually delivered to such Participating Member State is invoiced upon delivery and paid as provided in Article I.8.3.

I.4.3 Allocation between Participating Member States; Vaccine Order Forms

a) The volumes of Doses shall be allocated between Participating Member States in accordance with Annex I.

b) Each Participating Member State and the contractor will conclude a Vaccine Order Form, using the model Vaccine Order Form attached as Annex II to this APA, setting out the details of the delivery of the doses of the Product allocated to the respective Participating Member State. For the avoidance of doubt, each Participating Member State is obligated to conclude a Vaccine Order Form for the Doses contractually allocated to it in Annex I, unless such Member State has opted out of this APA pursuant to the Agreement between the Commission and the Member States.

I.4.4 Increase of Doses

I.4.4.1 General principle

If the Commission, acting on behalf of one or more of the Participating Member States, wishes to purchase doses of Product in addition to the Doses, it may elect to purchase such doses in accordance with the provisions of this APA.

I.4.4.2 Option for deliveries in 2023

The contractor will keep the Commission informed of its manufacturing capacity for 2023. The Participating Member States may then, to the extent permitted by such capacity and [***] from the contractor's informing the Commission of such capacity, elect to purchase doses of Product in addition to the Doses for delivery in 2023 up to 35.658.551 doses in the aggregate (the "**2023 Option**"). The following conditions shall apply to any 2023 Option:

- [***]

- the request for the 2023 Option shall be notified to the contractor by the Commission, acting in the name and on behalf of the relevant Participating Members States and shall specify the Participating Member States participating in such 2023 Option (the "**Exercising Member States**") and the allocation of doses of Product to be purchased by and delivered to each such Exercising Member State (the "**Option Doses**");

- the contractor shall confirm the available supplies of the Product for the order for Option Doses to the Commission [***];

- the order for the Option Doses shall be formalized through the conclusion of Vaccine Order Forms by the Exercising Member States;

- each Exercising Member State shall, in proportion to the Option Doses allocated to such Exercising Member State, contribute to the relevant costs for the Option Doses in the form of an up-front payment of [***] of the total price of the Option Doses (the "**Down Payment for Option Doses**"), payable [***] after the receipt of an invoice issued by contractor following the receipt of a Vaccine Order Form signed by the Exercising Member State. The balance of payments for the supply of Option Doses will be paid by each Participating Member State upon delivery as provided under the APA.

- subject to the above provisions, the other terms of this APA applicable to the Doses shall apply *mutatis mutandis* to the Option Doses.

I.4.5 Development timeline; Special Commitments

The contractor's current assumptions on development timelines in support of an EU Marketing Authorisation for a Vaccine based on the Wuhan Strain are:
-[***].

To produce the Doses, the contractor shall not manufacture or have manufactured the Product at manufacturing sites located outside the territory of the European Union or the European Economic Area without the prior consent of the Commission, which consent may not be unreasonably withheld, conditioned or delayed if the manufacturing at such sites is required to accelerate the production of the Doses for delivery to Participating Member States. However, consent may be refused if the sites located outside the territory of the European Union or the European Economic Area (EEA) [***].

I.4.6 Right of the Participating Member State to re-sell, export, donate and/or distribute

The Participating Member States shall be entitled to re-sell, export, distribute and/or donate for free any of the Products supplied to them pursuant to this APA to any other EU Member State, EEA Member State and/or Switzerland, [***].
[***]
[***] For the avoidance of doubt, any re-sale, export, distribution or donation activities shall be carried out under the sole cost and responsibility of the relevant Participating Member State, unless the Parties agree otherwise in writing.

I.4.7 Delivery

The contractor shall deliver the Product doses to the Participating Member States in accordance with the allocation provided in Annex I and the other terms and conditions of this APA. The Parties acknowledge and agree that the allocation provided in Annex I, as well as the numbers in the Delivery Schedule in accordance with Article I.4.7.2, can be amended by an exchange of letters between the Commission, represented for this purpose by the Deputy Director-General for Health of the European Commission's Directorate-General for Health and Food Safety, and the contractor.

I.4.7.1 Delivery Schedule

The contractor commits to deliver Product doses to the Participating Member [***] and [***] supply such doses on the schedule and in the quantities as set out in the initial delivery schedule provided below ("**Delivery Schedule**").

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The schedule and quantities set out in the Delivery Schedule are based on the contractor's current expectation that the Marketing Authorisation for the Product based on the Wuhan Strain will be granted [***] (the "**Expected Approval Date**"). [***]

The contractor shall use Best Reasonable Efforts to obtain Marketing Authorisation for the Product as soon as reasonably possible in order to meet the Expected Approval Date. [***] Under no circumstances will any delivery of Product doses be required under this APA prior to receipt of a Marketing Authorisation for the Product.

I.4.7.2 Performance under the Delivery Schedule

a) The Delivery Schedule may only be updated in the following circumstances:

- the Marketing Authorisation for the Product is received after the Expected Approval Date. In such situation, the delivery dates in the Delivery Schedule will be delayed with the same amount of time as the Marketing Authorisation is delayed beyond the Expected Approval Date;

- to account for a Variant Switch as foreseen in Article I.4.1.2; or

- if required due to occurrence of a Force majeure event affecting the Delivery Schedule.

The contractor shall henceforth comply with such updated Delivery Schedule.

In case any updated Delivery Schedule proposed by the contractor pursuant to this Article proposes the delivery of the Doses with a delay of more than [***] compared to the initial Delivery Schedule (the "**Delayed Doses**"), then any concerned Participating Member State may cancel its purchase [***]. Any cancellation shall be notified by the Commission to the contractor in writing and shall indicate the amount of cancelled Delayed Doses, as well as the Participating Member States involved. In case of cancellation of Delayed Doses, the contractor shall reimburse to the Participating Member States [***].

b) The schedule set out in the Delivery Schedule reflects the [***] delivery rate in which Product doses are expected to be delivered. The actual delivery dates within the applicable Delivery Schedule for the Product doses will be agreed between the contractor and the Participating Member States in line with the Delivery Schedule which may not be derogated from, [***]. Once the Marketing Authorisation for the Product is obtained, the contractor shall make the first delivery of Doses within the later of [***] after receipt of the Marketing Authorisation for the Product if the Marketing Authorisation is granted on or after the Expected Approval Date and subject to the labelling and packaging material being approved by the EMA [***] before the Expected Approval Date, or [***].

Save in exceptional circumstances and as mutually agreed between the contractor and the relevant Participating Member State(s), deliveries of Product doses shall be made in a [***] manner between Participating Member States with a minimum of one delivery per month per Participating Member State and pro rata to each Participating Member State based on the allocation provided in Annex I, subject to the contractor's [***]. To the extent a Participating Member State considers that deliveries of Products are carried out in [***], the Commission, on behalf of the Participating Member States, shall be exclusively in charge of resolving any disagreements in this respect with the contractor, and no payment of contractor's invoices shall be delayed on such grounds.

I.4.7.3 Late Deliveries

a) In the event that doses of Product are not delivered [***] for which their delivery is foreseen in the Delivery Schedule [***], such doses ("**Missing Doses**") shall be considered as being delivered late ("**Late Delivery**") and Participating Member States which have not been fully delivered their share of the Product Doses due [***] pursuant to the allocation provided in Annex I shall be entitled to apply the measures foreseen in Article II.14 to the contractor [***]. Any Participating Member State wishing to apply the measures foreseen in Article II.14 to the contractor shall notify the contractor of that intention [***].

b) In the event that the contractor [***], the concerned Participating Member States may cancel the purchase of such Missing Doses provided that such right to cancellation is exercised [***].

c) For the avoidance of doubt, the measures foreseen in Article II.14 and the cancellation rights referred to in Articles I.4.7.2(a) and I.4.7.3(b) shall not apply if the contractor is unable to respect the Delivery Schedule due to a situation of *Force majeure*, [***] or because the Marketing Authorisation is delayed for reasons not imputable to the contractor.

Following any cancellation under Articles I.4.7.2(a) or I.4.7.3(b), the contractor shall consequently reimburse to each relevant Participating Member States:

- [***].

d) [***].

e) For the avoidance of doubt, no Doses that had actually been delivered before the receipt by the contractor of notification of cancellation can be subject to a cancellation.

Nothing in this Article shall affect the Delivery Schedule of Doses not subject to a Late Delivery.

I.4.7.4 Marketing Authorisation for sub-groups of the population

In case the contractor receives a Marketing Authorisation which does not cover the entire adult population but is limited to sub-groups of that population, the following provisions shall apply:

1) [***];

2) [***];

3) in case the contractor does not manage to receive a Marketing Authorisation for the entire adult population by 30 June 2022 [***], the Participating Member States shall have the right to cancel the [***] Doses. [***];

   [***].

4) in case of cancellation of Doses under the above subparagraph I.4.7.4 3), the contractor shall be obliged to reimburse 100% of the Down Payment, prorated with respect to its number of cancelled Doses.

5) [***].

6) Table:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***].

I.4.7.5 Form of Delivery and transfer of title

The Product doses will be delivered by the contractor to the Participating Member States [***]. Title on the Product will transfer upon full payment of the corresponding invoice by the relevant Participating Member State, such retention of title not preventing, however, the administration of the Product to the patients as and when deemed necessary by the relevant treating healthcare professionals.

I.4.7.6 Distribution

Following delivery of the Product doses, each Participating Member State will solely control and assume all responsibility, at such Participating Member State's own cost and expense, for conducting all distribution and related activities relating to the Product doses in the Participating Member State's territory and to countries in the EU, EEA or Switzerland, or other countries/entities, to which the Participating Member State re-sells, exports, distributes and/or donates Product doses in accordance with Article I.4.6. If a Participating Member State re-sells, exports, distributes and/or donates Product doses in accordance with Article I.4.6, contractor may agree to deliver directly such doses to the recipient country provided the relevant parties agree reasonable terms for such delivery and contractor does not incur additional costs.

I.4.7.7 Traceability

During the term of this APA and for a period of ten (10) years thereafter (or longer if required by applicable laws), each Participating Member State will maintain an inventory control system for traceability of the Product supplied to or for the benefit of such Participating Member State, including any Product provided by such Participating Member State to a Donation Country or Resale Country. The inventory control system is without prejudice to other traceability requirements in accordance with the applicable laws.

I.5 ACCEPTANCE/REJECTION OF PRODUCT

I.5.1 Contractor warrants that the Product (1) shall comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product and (2) shall be manufactured in all material respects in accordance with the Good Manufacturing Practices in effect at the time of manufacture in the place of manufacture. Subject to the terms of this Article I.5 and Article I.6.2, a Participating Member State may claim a remedy (a "**Product Claim**") for any portion of Product delivered to such Participating Member State by the contractor which at the time of delivery (a) does not comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product or (b) has not been manufactured in accordance with the said Good Manufacturing Practices ("**Deficient Product**"). Such Participating Member State will visually inspect the Product, or review documentation provided by or on behalf of the contractor, upon delivery or receipt (as applicable) and will give the contractor written notice of the Product Claims:

- immediately in case of visible damages resulting from transportation; or
- [***] for other apparent damage after such delivery or receipt; or

- in the case of any deficiency at the time of delivery to such Participating Member State that was not reasonably susceptible to discovery upon such delivery or receipt, [***].

In the absence of notice, the Product is deemed to be accepted by the Participating Member State.

I.5.2 The contractor will have no obligation for any Product Claims to the extent the Deficient Product was caused exclusively by actions or omissions of such Participating Member State or Third Parties occurring after the time of delivery of the Product by the contractor or its designee.

I.5.3 Upon receipt of a Product Claim, the contractor will have [***] to advise the Participating Member State by notice in writing whether it disagrees with the content of the Product Claim. If, after joint testing or investigation has been performed, the Parties still cannot agree on whether such Product is a Deficient Product, the contractor or the Participating Member State may refer such dispute to a technical expert for resolution in accordance with Article I.5.4 (a "**Technical Dispute**").

I.5.4 If any Technical Dispute arises, the contractor and the Participating Member State will first try to resolve it amicably. The contractor or the Participating Member State may send a notice of a Technical Dispute to the other, and each Party will appoint, [***], an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the Technical Dispute. If the representatives fail to resolve the matter [***], or if a Party fails to appoint a representative as required above, the expert determination procedure below may be started by either Party. [***], the contractor and the Participating Member State will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. As a condition of the expert's appointment, the contractor and the Participating Member State will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The contractor and the Participating Member State do not intend that the expert acts as an arbitrator and therefore any matters requiring legal interpretation or adjudication including disputes relating to the conduct of the Technical Dispute are solely reserved for the dispute resolution procedure under Article I.10.2. For the avoidance of doubt, any technical determination by the expert under a Technical Dispute may be used as evidence under Article I.10.2. The contractor and the Participating Member State will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) [***]. The contractor and the Participating Member State will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly [***]. At all times the contractor and the Participating Member State will co-operate and seek to narrow and limit the issues to be determined. The technical determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the contractor and the Participating Member State with respect to the referred Technical Dispute. Each of the contractor and the Participating Member State will bear its own costs for any matter referred to an expert under this Article I.5.4 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the contractor and the Participating Member State.

I.5.5 If a Participating Member State makes a Product Claim pursuant to this Article I.5 and (a) the contractor and this Participating Member State agrees the Product that is the subject of such Product Claim is a Deficient Product (such agreement not to be unreasonably withheld, conditioned or delayed) or (b) any previously delivered Product is determined to be a Deficient Product, the contractor will replace such Deficient Product [***] after the time of such agreement or determination, any other remedy under this APA being excluded in case of Deficient Product unless the concerned Participating Member State and contractor agree otherwise.

I.5.6 In the cases referred to in Article I.5.5, the contractor may instruct the concerned Participating Member State to place the Product at the contractor's disposal. The contractor will bear the cost of [***] disposal of any Deficient Product.

I.6 WARRANTIES AND RELEASE

I.6.1. The contractor warrants to the Commission and the Participating Member States that:

(a) as of the date hereof, this APA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;

(b) as of the date hereof, it is not under any obligation, contractual or otherwise, to any third party in respect of the delivery of the Doses that conflicts with or is inconsistent with the terms of this APA or that would impede the complete fulfilment of its obligations under this APA;

(c) it will not undertake any contractual obligations, including any settlements, that would conflict with, hinder or impede the fulfilment of its obligations under this APA; and

(d) [***].

I.6.2. The Commission and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against the contractor arising out of or relating to:

(a) lack of safety or efficacy of the Vaccine, [***];
(b) use or administration of the Vaccine under pandemic conditions, except to the extent such claim arises from contractor's breach of this APA which classifies as Willful Misconduct or Gross Negligence; or
(c) delays in delivery of the Vaccine doses under this APA, the only remedies available in case of delays being, if applicable, [***].

I.7 PRICES

I.7.1 Price per Dose of Product

The price per single dose of Product purchased hereunder, [***], shall be [***].

For clarity, the price for the total Product volume shall be obtained by multiplying the price of a single Product dose by the total number of Product doses covered by this APA.

The total price of the Doses shall be [***] doses, equalling [***].

I.7.2 Down payment and payment schedule under the APA

The Down Payment for the Doses is [***] of the total price of the Doses as laid down in Article I.7.1, equalling [***].

The payment schedule for purchases of Doses by or on behalf of Participating Member States is addressed in Article I.4.2.

I.8 Payment Arrangements

I.8.1 Payment of the Down Payment

The invoices for the Down Payment shall be issued by contractor upon signature of the APA.

The contractor must send the invoice for the Down Payment to each Participating Member State in PDF format by email.

Each invoice for the Down Payment shall be paid in a single instalment.

The invoice for the Down Payment must contain the following information:
- Name of the addressee
- APA number
- Contractor name and bank account.

The invoice must indicate the place of taxation of the contractor for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT (where VAT is applicable).

Provided that the invoice includes the above information, each Participating Member State shall pay the invoice [***] after receipt of the invoice.

I.8.2 Utilisation of the Down Payment

The Parties acknowledge and agree that the Down Payment is intended to cover costs incurred by the contractor for [***].

The contractor intends to use the Down Payment as further specified in Annex VII.

I.8.3 Payment for the supply of Product

The contractor must send an invoice in PDF format by email to the Participating Member States for payment by the Participating Member States under Article I.4.2.

Invoices shall be established by the contractor for a given order of Product doses and for an identified delivery scheduled in accordance with the APA.

Each invoice shall be accompanied by the following documentation (as applicable):

- Proof of delivery of the Products referred to in Article I.4.2 of this APA, to the place of delivery indicated by the Participating Member State concerned in the Vaccine Order Form (or offer of such delivery if the Participating Member State illegitimately refuses acceptance of delivery).

Each invoice must contain the following information:

- Name of the concerned Participating Member State
- APA and Vaccine Order Form number/reference
- Order reference
- Date of receipt of the Marketing Authorisation for the Product
- Product name
- Quantity delivered (or offered to be delivered if the Participating Member State illegitimately refuses acceptance of delivery),
- Delivery reference and date
- Contractor name and bank account.

The Participating Member States must pay these invoices [***] from their respective date of issuance.

I.8.4 Currency

Any payments to be made by the Participating Member States under this APA, including under any Vaccine Order Form, shall be made, and any invoices issued pursuant to this APA shall be issued, in euros (EUR).

I.8.5 Refundability of Unspent Amounts

If this APA is terminated pursuant to Article II.16.1, then the Participating Member States will be entitled to a refund of Unspent Amounts in accordance with Article II.16.5.

I.8.6 Bank account

Payments must be made to the contractor’s bank account denominated in euro, identified as follows:

[***]

I.8.7 Communication Details

For the purpose of this APA, communications must be sent to the following addresses:

The Commission:

European Commission

Directorate-General for Health and Food Safety

E-mail: SANTE-PROCUREMENT@ec.europa.eu

Participating Member States will provide their respective communication details in the Vaccine Order Forms.

Contractor:

[***]

By derogation from this Article, different contact details for the Commission, the Participating Member States or the contractor may be provided in Vaccine Order Forms.

I.8.8 Suspension if no payment

Timely payment by all the Participating Member States of amounts under this APA is of essence. If any Participating Member State fails to pay any amounts when due, contractor shall have the right to suspend performance of the APA in relation to that Participating Member State until full payment. In particular, the Parties acknowledge and agree that (i) compliance by contractor with delivery schedules is conditional on timely payments, (ii) any such suspension of manufacturing and deliveries may cause subsequent delay in supply, and that (iii) related quantities of Products may be redirected by contractor to other entities.

I.9 EXPLOITATION OF THE RESULTS OF THE APA

The Commission and the Participating Member States acknowledge and agree that the contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the "**Vaccine IP Rights**"). The contractor shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this APA, the contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor.

I.10 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.10.1 This APA is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (ESI Regulation, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369.

This APA shall be governed by the laws of [***].

I.10.2 Dispute Resolution

(a) In the event of a dispute arising under this APA or a Vaccine Order Form between the contractor and the Commission or a Participating Member State, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, [***], the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

(b) The Commission, the Participating Member States and the contractor irrevocably submit to the exclusive jurisdiction of the courts located in [***] to settle any dispute which may arise under or in connection with this APA or the legal relationships established by this APA including under a Vaccine Order Form.

I.11 OTHER SPECIAL CONDITIONS

I.11.1 Each Participating Member State and the contractor will each maintain records necessary to permit a Recall of any Product delivered to such Participating Member State.

I.11.2 Each Participating Member State and the contractor will Notify the other Party [***] from notifying the European Medicines Agency of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in the Participating Member State's territory.

I.11.3 Upon receiving this notice or upon this discovery, and save where contractor challenges any decision regarding a Recall, such Participating Member State and the contractor will stop making any further shipments of any Product in their possession or control in such Participating Member State's territory until a decision has been made whether a Recall or some other corrective action is necessary.

I.11.4 The decision to initiate a Recall or to take some other corrective action, if any, with respect to the Product in such Participating Member State's territory will be made by the competent authority concerned, or by the contractor (after having consulted with the competent authority(ies) concerned).

I.11.5 If: (i) any regulatory authority issues a decision, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be recalled in such Participating Member State's territory; (ii) a court of competent jurisdiction orders a recall in such Participating Member State's territory; or (iii) the contractor (after having consulted the concerned competent authority(ies)) determines that any Product should be recalled in such Participating Member State's territory (each a '**Recall**'), then the contractor, the Participating Member State(s) and the competent authority(ies) shall assist each other in the Recall process, as appropriate, having regard to all 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.

In the event of any Recall, [***].

[***].

I.11.6 The contractor shall use Best Reasonable Efforts to obtain Marketing Authorisation for the Product. [***].

I.11.7 The contractor shall provide to the Commission and the Participating Member States, via the Commission, the following information as part of and until its submission for Marketing Authorisation and full production:

(a) summarised key updates on progress made in the clinical development of the Product; final reports of clinical studies and safety evaluations submitted to the European Medicines Agency, promptly after submission to the European Medicines Agency;

(b) key updates on [***].

(c) the use of the Down Payment, linked to points (a) to (b), in general terms [***]; and

(d) scientific publications and public announcements, after such publications and announcements have been published.

I.12 DEFINITIONS

For the purpose of this APA, the following definitions apply:

[***]**:** has the meaning set forth in Article I.4.4.2;

'Affiliate': with respect to a Party, any other individual, partnership, corporation, limited liability company, association, a joint stock company, trust, joint venture, unincorporated organization, or a governmental entity (or any department, agency, or political subdivision thereof) ("Person") that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise;

'APA': has the meaning set forth in the preamble;

'**Best Reasonable Efforts**' shall mean with respect to the diligence to be expected by the contractor, [***];

'Breach of obligations': failure by a Party to fulfil one or more of its contractual obligations under this APA;

'CMOs': has the meaning set forth in the Recitals;

'Commission': has the meaning set forth in the preamble;

'contractor': has the meaning set forth in the preamble;

'Confidential information or document': any information or document, in any format, disclosed in writing or orally, received by either Party from the other or accessed by either Party in the context of the Implementation of the APA, that any of the Parties has identified in writing as confidential or which, due to the context in which it is disclosed, should be considered as confidential. It may not include information that is publicly available;

‘Conflict of interest’: a situation where the impartial and objective Implementation of the APA by the contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the APA;

‘**COVID-19**’: has the meaning set forth in the Recitals;

‘**COVID-19 pandemic**’: has the meaning set forth in the Recitals;

‘**Deficient Product’**: has the meaning set forth in Article I.5.1;

‘**Delayed Doses**’: has the meaning set forth in Article I.4.7.2;

[***];

‘**Delivery Schedule**’: has the meaning set forth in Article I.4.7.1;

‘Donation Country’: means a country to which Product is donated in accordance with Article I.4.6;

‘Doses’: has the meaning set forth in Article I.4.2;

‘Down Payment’: has the meaning set forth in Article I.4.2;

‘**Down Payment for Option Doses**’: has the meaning set forth in Article I.4.4.2;

'**EMA**': means the European Medicines Agency;

[***];

‘European Institutions’: has the meaning set forth in Article II.7.6;

‘**Exercising Member State**’: has the meaning set forth in Article I.4.4.2;

‘Expected Approval Date’: has the meaning set forth in Article I.4.7.1;

‘Financial Statement’: has the meaning set forth in Article II.16.5;

‘Force majeure’: any unforeseeable, exceptional situation or event beyond the control of the Parties that prevents either of them from fulfilling any of their obligations under the APA; the situation or event must not be attributable to error or negligence on the part of the Parties or on the part of the subcontractors and must prove to be inevitable despite their exercising reasonable due diligence. The situation or event must not be attributable to a Breach of obligations of the APA on the part of the Parties or on the part of the subcontractors. [***];

‘Formal notification’ (or ‘**Formally notify**’): form of communication between the Parties made in writing by mail, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

‘Fraud’: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the European Union’s financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the European Union’s financial interests;

‘Good Manufacturing Practices’ or ‘GMP’: means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as last amended), Directive 2003/94/EC, Directive 2017/1572 and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled “EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use”;

[***];

‘Implementation of the APA’: the purchase of the Product envisaged in the APA through the signature and Performance of Vaccine Order Forms;

‘Indemnified Persons’: has the meaning set forth in Article II.5.1;

‘Irregularity’: any infringement of a provision of European Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the European Union’s budget;

[***];

‘Losses’: has the meaning set forth in Article II.5.4;

[***];

‘**Marketing Authorisation**’: the approval under the relevant provisions of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down European Union procedures for the authorisation and supervisions of medicinal products for human and veterinary use and establishing a European Medicines Agency, by the European Commission necessary for the placing on the market of the Vaccine in the territory of the European Union, including conditional marketing authorisation in accordance with Article 14-a of Regulation 726/2004;

[***];

‘Notification’ (or ‘**Notify**’): form of communication between the Parties made in writing including by electronic means (except for Formal notifications which must be sent by mail);

‘Option Doses’: has the meaning set forth in Article I.4.4.2;

‘**Participating Member State(s):** has the meaning set forth in the preamble;

‘Party’ and ‘**Parties**’: have the meaning set forth in the preamble;

‘Performance of a Vaccine Order Form’: the execution of tasks and delivery of the Product by the contractor to the Participating Member States;

‘**Potential Termination Event**’: has the meaning set forth in Article II.16.1;

‘Pre-existing material’: any material, document, technology or know-how which exists prior to the contractor using it for the production of a Result in the Implementation of the APA;

‘Pre-existing right’: any industrial and intellectual property right on Pre-existing material; it may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the *creator*, the Commission as well as to any other third parties;

‘Product’ or 'Vaccine': the finished and packaged form of the contractor’s vaccine against COVID-19 based on the Wuhan Strain or any other strain agreed by the Parties. The Product will be delivered in a 10-dose vial;

‘**Product Claim’**: has the meaning set forth in Article I.5.1;

‘Professional conflicting interest’: a situation in which the contractor’s previous or ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form to an appropriate quality standard;

‘Recall’: has the meaning set forth in Article I.11.5;

‘**Refundable Items’**: has the meaning set forth in Article II.16.5;

‘Related person’: any natural or legal person who is a member of the administrative, management or supervisory body of the contractor, or who has powers of representation, decision or control with regard to the contractor;

‘Resale Country’: means a country to which Product is re-sold, exported or distributed in accordance with Article I.4.6;

‘Result’: any intended outcome of the Implementation of the APA, whatever its form or nature. A Result may be further defined in this APA as a deliverable. A Result may, in addition to newly created materials produced specifically for the Participating Member States by the contractor or at its request, also include Pre-existing materials;

[***];

‘**Technical Dispute’**: has the meaning set forth in Article I.5.3;

‘**Termination Intent Notice**’: has the meaning set forth in Article II.16.1;

‘**Third Party’**: any Person other than (a) the Commission or any of the Participating Member States or (b) the contractor or its Affiliates;

‘**Third Party Claim**’: has the meaning set forth in Article II.5.9;

‘**Unspent Amounts**’: has the meaning set forth in Article II.16.5;

‘Vaccine IP Rights’: has the meaning set forth in Article I.9;

‘Vaccine Order Form’: has the meaning set forth in the Recitals;

‘**Variant Product**’: has the meaning set forth in Article I.4.1.2;

‘**Variant Switch**’: has the meaning set forth in Article I.4.1.2;

[***];

'Wuhan Strain' means the strain BetaCoV/Italy/SPL1/2020/EPI ISL 412974/2020-01-29 originating from Wuhan/NC 045512.2.

SIGNATURES

For the contractor,

[***]

Signature:_____

Done at [***]

AND

[***]

Signature:

Done at [***]

In duplicate in English.

For the Commission, on behalf and in the name of the Participating Member States,

[***]

Signature:_____

Done at [***]

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT

II.1 SEVERABILITY

Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the Parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in accordance with Article II.10. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.2 PROVISION OF PRODUCT

II.2.1 The contractor must supply the Product in accordance with the provisions of this APA.

II.2.2 The contractor must comply with the requirements provided for in this APA.

II.2.3 All periods specified in the APA are calculated in calendar days, unless otherwise specified.

II.2.4 The contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.3 COMMUNICATION BETWEEN THE PARTIES

II.3.1 Form and means of communication

Any communication of information, notices or documents under the APA must:

(a) be made in writing in paper or electronic format in the language of the contract;
(b) bear the APA number and, if applicable, the Vaccine Order Form number;
(c) be made using the relevant communication details set out in Article I.8.7; and
(d) be sent by mail or email (except for Formal notifications which must be sent by mail).

If a Party requests written confirmation of an e-mail within a reasonable time, the other Party must provide an original signed paper version of the communication as soon as possible.

The Parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings, except for Formal notifications which must be sent by mail.

II.3.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving Party receives it, unless this APA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving Party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.8.7. The sending Party must be able to prove the date of dispatch. In the event that the sending Party receives a non-delivery report, it must make every effort to ensure that the other Party actually receives the communication by email or mail. In such a case, the sending Party is not held in Breach of obligation to send such communication within a specified deadline.

Mail sent to the Commission or a Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.8.7 or in the relevant Vaccine Order form registers it.

Formal notifications are considered to have been received by the receiving Party on the date of receipt indicated in the proof received by the sending Party that the message was delivered to the specified recipient.

II.4 LIABILITY

II.4.1 Without prejudice to Article II.5, the Commission and the Participating Member States are not liable for any damage or loss caused by the contractor, including any damage or loss to Third Parties during or as a consequence of the Implementation of the APA.

II.4.2 Annex VI sets out a summary of contractor's insurance coverage. Contractor shall maintain such policy during the term of this APA. Upon request, the contractor must provide evidence of such insurance coverage to the Commission.

II.4.3 [***] The Commission and the Participating Member State shall, upon request, cooperate with the contractor and its legal representatives in connection with the investigation and defense against such action, including by providing or otherwise making available information in their possession with respect thereto. The Commission and the Participating Member State shall only be allowed to settle a Third Party Claim with the prior consent of the contractor, such consent not to be unreasonably withheld, conditioned or delayed.

II.4.4 [***] This liability cap shall not apply in case of liability for loss or damages caused by the contractor’s Breach of obligations classified as Willful Misconduct or Gross Negligence, in which case the contractor’s liability shall be uncapped.

[***]

II.4.5 The Parties acknowledge that they are not relying on any understanding, arrangement, statement, representation (including, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, condition, term, customary practice, course of dealing or provision except for the warranties set out in this APA. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statute or equivalent, case law or otherwise and any implied warranties and/or conditions as to merchantability, satisfactory quality, fitness for purpose and skill and care), other than fraudulent misrepresentations and the provisions set out in this APA, are hereby excluded to the maximum extent permissible by law.

II.5 INDEMNIFICATION

II.5.1 Due to the exceptional circumstances of the COVID-19 pandemic and the request to develop new vaccines at an unprecedented speed, the Commission, on behalf of the Participating Member States, declares that the use of the Vaccine supplied under this APA will happen under pandemic conditions requiring such use, in a context where it is impossible for the contractor to detect all possible defects of the Vaccine despite its observance of all Good Manufacturing Practices and obligations under the EMA pharmacovigilance regulations, and that the administration of doses of the Vaccine will therefore be conducted under the sole risk and responsibility of the Participating Member States.

Hence, each Participating Member State shall indemnify for and hold harmless the contractor and/or its Affiliates, as well as their respective sub-contractors and sub-licensees, officers, directors, employees, other agents and representatives (together, the "**Indemnified Persons**") against:

(a) liability incurred by an Indemnified Person in relation to Losses (defined in Article II.5.4) caused by doses of Vaccine administered in the jurisdiction of the Participating Member State in question;

(b) the consequences of any settlements to which the concerned Participating Member State(s) has/have consented to as per Article II.5.11; and

(c) reasonable and necessary direct external legal fees (including attorneys' and courts fees) and experts' fees, which an Indemnified Person incurs in relation to (i) claims connected to liability under sub-paragraph (a) above, and/or (ii) the circumstances referred to in sub-paragraph (b) above. Each Participating Member State agrees that any Indemnified Person has the right to select an attorney who is experienced and reputable in relation to the subject matter and in the Participating Member State concerned to defend itself in case of a Third Party Claim. For the avoidance of doubt, (1) the indemnification of legal and experts' fees subject to the conditions of this clause shall not be dependent on the success of a Third Party Claim; and (2) legal and experts' fees recovered from the claimant by an Indemnified Person following a court order, and legal and experts' fees covered by insurance, shall not be subject to indemnification under this clause.

Such indemnification shall be available regardless of whether the properties of the Vaccine causing the Losses originate from the testing, development, manufacture, delivery, export, import, distribution, sale, offer for sale, administration, use or deployment of the Vaccine.

II.5.2 [***].

II.5.3 [***].

II.5.4 [***].

II.5.5 Specifically and only for the purposes of this Article II.5:

"**Best Reasonable Efforts**" [***].

II.5.6. [***].

II.5.7. In case an Indemnified Person requests indemnification pursuant to Article II.5.1, the contractor shall give the Participating Member State(s) in question, or an independent expert as referred to in Article II.5.8, access to reasonable information necessary for the Participating Member State(s) to indemnify the Indemnified Persons and to verify whether the conditions pursuant to Articles II.5.1 to II.5.4 are fulfilled. [***]

II.5.8 A Participating Member State shall be allowed to access the information as referred to in Article II.5.7 through an independent expert in the field of the Losses, in particular in the field of public health. In that case, this Participating Member State shall Notify the contractor in advance of its intention to use an expert to conduct the verification pursuant to Article II.5.7 above, and shall specify the identity of such expert. The contractor shall be allowed to object to the use of and/or access to the information referred to in Article II.5.7 by such expert [***] counted from the date of receipt of such Notification. [***] In such case, the Participating Member State shall designate another independent expert and observe the same Notification process as the one described herein until the designated expert is approved by the contractor. The expert shall complete its assessment [***] of its appointment, and shall share its assessment report with the Parties. The expert's assessment shall not be binding on any Indemnified Person.

II.5.9 The contractor shall promptly inform the relevant Participating Member State(s) of any claim for a Loss which is brought against any of the Indemnified Persons and which an Indemnified Person considers asking for indemnification under this Article II.5 ("**Third Party Claim**"), stating the nature and basis of such claim and the maximum amount of damages, external legal fees, experts' fees and related disbursements estimated by the contractor, which could be payable by all Indemnified Persons as a result of such claim. The contractor shall keep the Participating Member State informed of any developments relating to such Third Party Claim, including updates in this estimated maximum amount of damages, fees and disbursements. The contractor's assessment of said maximum amount shall have no consequences on any indemnification unless the contractor has estimated such amount in bad faith.

II.5.10 [***].

[***]

II.5.11 [***] The Indemnified Persons shall only be allowed to settle a Third Party Claim with the prior consent of the relevant Participating Member State(s) in question, such consent not to be unreasonably withheld, conditioned or delayed. The relevant Participating Member States shall have the right to assume and control the defense of the Indemnified Persons against Third Party Claims, in which case the Indemnified Persons shall nevertheless have the right to retain and be advised by independent counsel and experts. [***]

II.6 Conflict of interest and Professional conflicting interests

II.6.1 The contractor must take all the necessary measures to prevent any situation of Conflict of interest or Professional conflicting interest.

II.6.2 The contractor must Notify the Commission as soon as possible of any situation that could constitute a Conflict of interest or a Professional conflicting interest during the Implementation of the APA. The contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

(a) verify that the contractor's action is appropriate;
(b) require the contractor to take further action within a specified deadline which shall be reasonable taking into account the context of the situation;
(c) decide, in the name and on behalf of a Participating Member State, not to award a Vaccine Order Form to the contractor.

The Commission cannot implement the action referred to in (c) above before having given to contractor the possibility to complete the rectification of the situation [***] or a shorter period if the urgency of the situation requires such shorter period.

II.6.3 The contractor must pass on all the relevant obligations in writing to:

(a) its personnel;
(b) any natural person with the power to represent it or take decisions on its behalf;
(c) third parties involved in the Implementation of the APA, including subcontractors.

The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.7 CONFIDENTIALITY

II.7.1 The Commission, the Participating Member State and the contractor must treat with confidentiality any Confidential Information. Contractor's Confidential Information includes, in particular, any and all know-how, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans, or other information whether oral, in writing, in electronic form, or in any other form; and any physical items, compounds, components, samples or other materials; disclosed by or on behalf of contractor to the Commission or to the Participating Member States or any of their Affiliates before, on or after the effective date of this APA.

II.7.2 The Commission, the Participating Member State and the contractor shall:

(a) not use Confidential information or documents of another Party for any purpose other than to perform its obligations under the APA or a Vaccine Order Form without the prior written agreement of such other Party;

(b) ensure the protection of such Confidential information or documents with the same level of protection as its own Confidential information or documents and in any case with due diligence;

(c) not disclose, directly or indirectly, Confidential information or documents to third parties unless such third parties agree to comply with this Article or are subject to substantially similar confidentiality obligations as provided in this Article.

II.7.3 The confidentiality obligations set out in this Article are binding on the Commission, the Participating Member States and the contractor during the Implementation of the APA and for as long as the information or documents remain confidential unless:

(a) the disclosing Party agrees to release the receiving Party from the confidentiality obligation earlier;

(b) the Confidential information or documents become public through other means than a breach of the confidentiality obligation;

(c) the applicable law requires the disclosure of the Confidential information or documents

II.7.4 The contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the APA a commitment that they will comply with this Article or ensure that such person is subject to substantially similar confidentiality obligations. At the request of the Commission, the contractor must provide a document providing evidence of this commitment.

II.7.5 Notwithstanding the other provisions of this Article, the Commission, the Participating Member States and the contractor may issue a press release and/or other public statement. The Parties shall consult together on the timing, contents and manner of any press release relating to this APA. A Party may subsequently publicly disclose any information previously contained in any public announcement made in accordance with this Article.

II.7.6 The contractor acknowledges that the Commission, along with other agencies and offices of the European Union (collectively, the "**European Institutions**"), are subject to requirements under Regulation (EC) 1049/2001[3], which may require the European Institutions to disclose information to Third Parties on request.

II.8 PROCESSING OF PERSONAL DATA

Both Parties agree each act as data controllers with regards to the processing of personal data they each undertake.

II.8.1 Processing of personal data by the Commission

Any personal data included in or relating to the APA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the APA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Deputy Director-General for Health of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection- public-procurement-procedures_en.

The contractor or any other person whose personal data is processed by the data controller in relation to this APA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this APA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.8.2 Processing of personal data by the contractor

The processing of personal data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

II.9 SUBCONTRACTING

II.9.1 [***]

II.9.2 [***]

II.9.3 [***].

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

II.9.4 [***][4].

II.10 AMENDMENTS

II.10.1 Any amendment to the APA (including a Vaccine Order Form) must be made in writing before all contractual obligations have been fulfilled.

II.10.2 No amendment can make changes to the APA (including a Vaccine Order Form) that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.11 ASSIGNMENT

II.11.1 The contractor cannot assign any of the rights and obligations arising from the APA without prior written authorisation from the Commission, which shall not be unreasonably withheld, conditioned or delayed. In such cases, the contractor must provide the Commission with the identity of the intended assignee.

II.11.2 Any right or obligation assigned by the contractor without authorisation is not enforceable against the Commission or the Participating Member States.

II.11.3 As an exception to Articles II.11.1 and II.11.2, contractor can assign, without the Commission's or the Participating Member States' authorization:

- any receivables under this APA to Third Parties, such as financial institutions, for the purposes of obtaining and maintaining funding, and/or providing such receivables as security to its creditors;
- this APA to:
    - a person that succeeds to all or substantially all of contractor's business or assets or all or substantially all of contractors' business or assets relating to this APA, whether by sale, merger, operation of law or otherwise;
    - a person that acquires all rights to the Product; or
    - an Affiliate of contractor;

and contractor shall provide notice of such assignment to the Commission and the Participating Member State.

II.12 INTELLECTUAL PROPERTY RIGHTS

II.12.1 Identification of Pre-existing rights

When delivering the Results, the contractor must warrant that, for any use that the Commission or the Participating Member States may envisage within the limits set in this APA, the newly created parts and the Pre-existing material incorporated in the Results are free of claims from creators or from any Third Parties and all the necessary Pre-existing rights have been obtained or licensed.

[4] [***]

[***]

II.12.2 Evidence of granting of Pre-existing rights

Upon request by the Commission, the contractor must, in addition to the list mentioned under Article II.12.1, provide evidence that it has the ownership or the right to use all the listed Pre-existing rights, except for the rights owned or licensed by the European Union. [***]

This evidence must include, as appropriate:

[***]

II.12.3 Copyright notice for Pre-existing rights

When the contractor retains Pre-existing rights on parts of the Results, reference must be inserted to that effect when the Result is used as set out in Article I.12.1, with the following disclaimer: '© — year — European Union. All rights reserved. Certain parts are licensed under conditions to the EU', or with any other equivalent disclaimer as the Commission may consider best appropriate, or as the Parties may agree on a case-by-case basis. This does not apply where inserting such reference would be impossible, notably for practical reasons.

II.12.4 Visibility of Union funding and disclaimer

When making use of the Results, the contractor must declare that they have been produced under a contract with the European Union and that the opinions expressed are those of the contractor only and do not represent the Commission's official position. The Commission may waive this obligation in writing or provide the text of the disclaimer.

II.13 FORCE MAJEURE

II.13.1 If a Party is affected by Force majeure, it must Notify the other Party without undue delay, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.13.2 A Party is not liable for any delay or failure to perform its obligations under the APA if that delay or failure is a result of Force majeure. The obligations affected by a Force majeure event shall be suspended and the time for performance shall be extended for a period equal to the time lost by reason of such event. If the contractor is unable to fulfil its contractual obligations owing to Force majeure, it has the right to remuneration only for the services and doses of Product actually provided.

II.13.3 The Parties must take all necessary measures to limit any damage due to Force majeure, it being specified that nothing herein shall require a Party to settle on terms unsatisfactory to such Party any strike or dispute.

II.13.4. To the extent that an event of Force majeure continues for a period [***], the Parties agree (i) to negotiate in good faith [***] of the end of that period either to (ia) resolve the event of Force majeure, if possible, or (ib) to extend the time period to resolve, eliminate or overcome such event, or (ii) to terminate the APA if such negotiations are unsuccessful. If the Force majeure event affects only one or more Vaccine Order Forms, but not the APA in its whole, then such termination shall apply only to those affected Vaccine Order Form(s). [***]

II.14 LIQUIDATED DAMAGES

II.14.1 In accordance with Article I.4.7.3, and the conditions provided for therein, if the contractor fails to deliver doses in accordance with the Delivery Schedule, the Participating Member State which delivery is subject to Late Delivery may claim liquidated damages. [***]

II.14.2 [***]

[***]

II.14.3 [***]

[***]

II.15 SUSPENSION OF THE IMPLEMENTATION OF THE APA

II.15.1 Suspension by the contractor

If the contractor is affected by Force majeure, it may suspend the provision of the services and Product under a Vaccine Order Form, as provided under Article II.13.

In accordance with Article II.13, the contractor must Notify the Commission and the Participating Member States of the suspension. The Notification must include a description of the Force majeure and state when the contractor expects to resume the provision of the Product.

The contractor must Notify the Commission and the Participating Member States as soon as it is able to resume Performance of the Vaccine Order Form, unless the Commission has already terminated the APA or the Vaccine Order Form in accordance with Article II.13.

II.15.2 Suspension by the Commission or the Participating Member State

The Commission or the Participating Member State in question may suspend the Implementation of the APA or Performance of a Vaccine Order Form (of such Participating Member State) or any part of it if the procedure for awarding the APA or a Vaccine Order Form or the Implementation of the APA proves to have been subject to Irregularities or Fraud by the contractor.

The Commission or the Participating Member State in question must Formally notify the contractor of the suspension and the reasons for it. Suspension takes effect on the date of Formal notification, or at a later date if the Formal notification so provides.

The Commission or the Participating Member State in question must Notify the contractor as soon as the verification is completed whether:

(a) it is lifting the suspension; or
(b) it intends to terminate the APA or its Vaccine Order Form under Article II.16.2(d).

[***]

II.16 TERMINATION OF THE APA

II.16.1 Termination due to failure to meet long stop dates

If:

- the contractor fails to receive a Marketing Authorisation for the Product on or before 30 April 2022, or any other later date mutually agreed upon by the Commission and the contractor in writing. [***]; or
- delivery of all the Doses does not occur by 31 December 2022 or any other later date mutually agreed upon by the Commission and the contractor in writing;

(each a "**Potential Termination Event**"), then the Commission and the Participating Member States shall Notify to contractor, within 15 days of the Potential Termination Event, whether they consider terminating this APA and the Vaccine Order Forms due to the Potential Termination Event ("**Termination Intent Notice**"). If contractor fails to remedy the situation within 30 days and the Commission and the Participating Member States do not find contractor's remedial plan acceptable, the Commission and the Participating Member States shall have the right to terminate this APA [***].

[***]

II.16.2 Other grounds for termination by the Commission and a Participating Member State

The Commission may terminate the APA or a Participating Member State may terminate its on-going Vaccine Order Form in the following circumstances:

(a) if the contractor is in material Breach of obligations [***];

[***]

(b) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation[5];

[5] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal- content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

(c) if the contractor or any Related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;

(d) if the procedure for awarding the APA or the Implementation of the APA prove to have been subject to Irregularities, Fraud or Breach of obligations;

(e) if the contractor is in a situation that constitutes a Conflict of interest or a Professional conflicting interest and the situation is not resolved in accordance with Article II.6.2;

(f) a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;

(g) in the event of Force majeure, as provided under Article II.13.4.

II.16.3 Grounds for termination by the contractor

The contractor may terminate the APA in the following circumstances:

(a) If the Commission materially fails to comply with its respective obligations

(b) In the event of *Force majeure*, as provided under Article II.13.4.

The contractor may terminate the Vaccine Order Form of a Participating Member State in the following circumstances:

(a) If the Participating Member State in question materially fails to comply with its respective obligations

(b) In the event of Force majeure, as provided under Article II.13.4.

II.16.4 Procedure for termination under Articles II.16.2 and II.16.3

A Party must Formally notify the other Party of its intention to terminate the APA or a Vaccine Order Form and the grounds for termination.

If a Party Formally notifies its intention to terminate under Articles II.16.2(a) to (f), or II.16.3(a), the other Party has [***] to cure the relevant issue or dispute the existence of such issue by submitting observations, including the measures it has taken or will take to continue fulfilling its contractual obligations.

If the terminating Party confirms that the measures the other Party has taken, or will take, cure such issue [***], the notice of termination submitted by the terminating Party shall become null and void. If the terminating Party does not provide such confirmation, and the other Party fails to cure the issue [***], the Party intending to terminate must Formally notify such Party's decision to terminate this APA or a Vaccine Order Form and the grounds for termination. [***] in the event of a dispute of the existence or cure status of the relevant issue, such dispute shall be subject to Article I.10.2 prior to any termination of this APA or of a Vaccine Order Form.

II.16.5 Effects of termination

In case of termination pursuant to Article II.16.1:

(a) No liability is incurred by any Party;

(b) The Down Payment paid to the contractor shall be refundable according to the following procedure:

(i) The contractor shall send to the Commission [***] from Notifying the Commission about the termination of the APA, a financial statement (the "**Financial Statement**"), detailing for which expenses the Down Payment has been used in relation to the purposes as set out in the APA. Expenses to be taken into account include the full amount of internal and/or external expenses which have been, or will be, incurred as well as such which have been committed by, or relate to commitments made by, the contractor at the time when the contractor Notified the Commission, [***].

(ii) In the Financial Statement, the contractor will set out such amounts as well as those amounts of the Down Payment that have neither been incurred nor committed ("**Unspent Amounts**"). Such Unspent Amounts will be reimbursed by the contractor to the Participating Member States [***] from the receipt of the Financial Statement by the Commission, it being understood that the Financial Statement and the Unspent Amounts shall be final and binding upon all Parties to the extent the Commission has not provided to the contractor a written statement of objections, specifying in reasonable detail the grounds of objections, [***] from the receipt of the Financial Statement by the Commission. The reimbursement of the Unspent Amounts shall be distributed between the Participating Member States in proportion of each Participating Member State's allocation of Doses under the APA.

(c) In addition, the contractor will transfer, upon the Commission's request to be provided [***] after the receipt of Notification about the termination, to the Commission, or a Third Party named by the Commission, any raw materials and primary components paid for with the Down Payment and not used (the "**Refundable Items**"). The contractor will also use its Best Reasonable Efforts to facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment to a Third Party selected by the Commission. Any such transfer is subject to the CMOs express agreement and any discussions about financial terms of such transfer will take place between such selected Third Party and the CMO.

[***]

The Parties must take all appropriate measures to minimise costs, prevent damage and cancel or reduce their commitments.

[***], the contractor must submit any report and any invoice for Product doses that were already delivered or in delivery in compliance with the APA at the time of termination.

II.17 INVOICES, TAXES, VALUE ADDED TAX AND E-INVOICING

II.17.1 Payment Requests, Invoices and value added tax

Payment requests and invoices shall contain the information set out in Articles I.8.1 and I.8.3.

II.18 PAYMENTS

II.18.1 Date of payment

The date of payment is deemed to be the date on which contractor receives the relevant sums on its bank account.

II.18.2 Costs of transfer

The costs of the transfer are borne as follows:

(a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
(b) the contractor bears the costs of receipt charged by its bank;
(c) the Party causing repetition of the transfer bears the costs for repeated transfer.

II.18.3 Suspension of the time allowed for payment

The Commission or the Participating Member State in question may suspend the payment periods specified in Articles I.8.1 and I.8.3 at any time by Notifying the contractor that its invoice cannot be processed. The only reason the Commission or the Participating Member State in question may cite for not being able to process an invoice is because it does not substantially comply with the invoicing process in the APA.

The Commission or the Participating Member State in question must Notify the contractor as soon as possible of any such suspension, giving the reasons for it. The Commission or the Participating Member State in question shall Notify the contractor the time limits to submit additional information or corrections or a new version of the documents.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the Notification. The remaining payment period resumes from the date on which the requested information or revised documents are received. The contractor may request the Commission or the Participating Member State in question to justify the continued suspension.

II.18.4 Interest on late payment

On expiry of the payment periods specified in Article I.8, the contractor is entitled to interest [***]. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.18.3 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.

II.19 RECOVERY

II.19.1 Recovery procedure

Before recovery, the Commission or the Participating Member State in question must Formally notify the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by Formally notifying a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note unless contractor disputes such payment.

If the contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the contractor in writing, recover the amounts due:

(a) by offsetting them against any amounts owed to the contractor by the Commission or the Participating Member State in question, provided that legal conditions for such offsetting are met;
(b) by taking legal action.

The contractor will be liable for any losses or damages caused by its late payment.

II.19.2 Interest on late payment

If the contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.4. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20 CHECKS AND AUDITS

II.20.1 The Commission and the European Anti-Fraud Office (OLAF) may check or require an audit on the Implementation of the APA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the contractor.

Such checks and audits may be initiated at any moment during business hours during the provision of the Product doses and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

Audit missions scope applies to the contractor's compliance with applicable regulatory standards insofar as relevant for the Implementation of the APA. Audit missions may not be extended to a broader audit of the contractor's activities or the contractors' contractual relations, which do not involve the Commission or the Participating Member States regarding the purpose of this APA or the Vaccines Order Forms.

II.20.2 The contractor must keep all original documents stored on any appropriate medium, including digitised originals if allowed under national law, for a period of five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

II.20.3 The contractor must grant the appropriate right of access to sites and premises where the APA is implemented, and to all information, including information in electronic format, needed to conduct such checks and audits. The contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures Notified to Commission by the contractor, and minimize disruption in contractor's operations, subject to this not creating any material obstacles for the performance of the auditor’s tasks.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

If, on the basis of the final audit findings, the Commission or a Participating Member State wishes to challenge all or part of the payments made under the APA, and the Parties cannot reach an agreement, any dispute between the Parties in this respect shall be settled under Article I.10.2.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities’ financial interests against Fraud and other Irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti- Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been Fraud, corruption or any other illegal activity under the APA affecting the financial interests of the European Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the Product doses and up to [***].

II.20.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939[6] ('the **EPPO**') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

[6] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

ANNEX I: PARTICIPATING MEMBER STATES AND ALLOCATED VOLUMES

[***]

ANNEX II: MODEL FOR VACCINE ORDER FORMS

EXPLANATORY NOTE

✓ ***Who shall send a Vaccine Order Form?***

- Each Part icipating Member State shall send to the contractor one duly completed and signed Vaccine Order in electronic format (PDF by e-mail) for its relevant allocated **Doses** as set out in Annex I (of this APA).
  - ***By when (deadline)?*** Within 10 days of the date of signature of the APA.

✓ ***To Whom and how shall the Vaccine Order Form be sent?***

- To the contractor by email at the following email address: [***], with a copy to [***]. Please always send the duly completed and signed Vaccine Order Form as a PDF attachment to the email.

✓ ***How to complete this Vaccine Order Form?***

- The relevant information in square brackets must be completed by each Participating Member State.
- Other than completing such information in square brackets, **no changes or amendments are permitted** to this model Vaccine Order Form unless explicitly agreed by the contractor and the Commission. If any such change or amendment is made, the Vaccine Order Form will be deemed invalid and not conform to the APA requirements.

✓ ***Whom to contact in case of questions re. how to complete this Vaccine Order Form?***

- Commission representatives:
  - Commission will confirm the name after signature. Please copy all communications to EC-VACCINES@ec.europa.eu
- Contractor's representatives:

[***]

[Letterhead of Government if available]

This Vaccine Order Form is submitted by:

[*The Government of [•]*] (the "**Member State**"), represented for the purposes of signing this specific order form by [*forename, surname, function, department of authorising officer*],

to:

Valneva Austria GmbH, a limited liability company ("Gesellschaft mit beschränkter Haftung") incorporated under company number [***], whose registered office is at [***] (hereinafter referred to as the "**contractor**")

The Member State and the contractor are together referred to as the "**Parties**" and each individually as a "**Party**".

WHEREAS

— The contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into an Advance Purchase Agreement for the purchase and supply of the contractor's COVID-19 vaccine for EU Member States **SANTE/2020/C3/054** (the "**APA**"), the terms of which are binding on the Participating Member States.

The APA provides that each Participating Member State will submit to the contractor a Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the Doses at the price and conditions as set out in the APA.

— In accordance with Article I.4, the Member State hereby places its order for its allocation of Doses.

Article I

Definitions

Capitalized terms used but not defined in this Vaccine Order Form shall have the meaning given in the APA.

Article II

Subject matter

1. This Vaccine Order Form is submitted by the Member State to the contractor in accordance with the terms of the APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary.

2. This Vaccine Order Form relates to the order for the Member State's full allocated Doses as set out in Annex I of the APA. The provision of this Vaccine Order Form by the Member State to the contractor constitutes a binding order by the Member State for the purchase of its full allocated Doses at the Price.

Article III

Delivery; Quality

1. Delivery Address. The Delivery Address for the Member State is as follows:

   [• - *Member State to enter location*]

2. Quality. The roles and responsibilities between the contractor and the Member States in relation to acceptance/rejection matters related to the Product doses are set out in Article I.5 of the APA.

Article IV

Invoices; Notices

1. Invoice and Payments. The contractor shall invoice the Member State in accordance with the terms of the APA. All payments to the contractor shall be made in accordance with the terms of the APA.

2. Notice. Any notice given under this Vaccine Order Form must be made in writing in English in paper or electronic format; bear the APA number and the number of this Vaccine Order Form; be made using the relevant communication details set out below with respect to the Member State and the contractor (as applicable); and be sent by email:

   Member State:

   [*Name of Member State*]
   [*Full official address of Member State*]
   [*Full name of addressee physical person (contact person)*]
   [*Function of addressee physical person (contact person)*]
   E-mail: [*complete email of addressee physical person (contact person)*]

Contractor:

Valneva Austria GmbH

To the attention of: [***]

Mail address: [***]

Email address: [***]

with a copy sent, in any case, by email to: [***]

Article V.

Entry into Force and Duration

1. This Vaccine Order Form shall become effective upon execution and delivery by the Member State to the contractor in accordance with the APA.
2. This Vaccine Order Form shall automatically expire upon delivery of the Member State's full allocated Doses as set out in the APA.
3. Expiry of the Vaccine Order Form shall be without prejudice to Article I.3.4 of the APA (*Surviving Provisions*).

Article VI.
Applicable Law and Settlement of Disputes

Article I.10 (*Applicable Law and Settlement of Disputes*) of the APA shall apply *mutatis mutandis* to this Vaccine Order Form.

(Signature page follows)

SIGNATURES

For the **Member State**,

[*forename/surname/position*]

Signature:_____

Done at [*place*], [*date*]

For acceptance of the Vaccine Order Form,

[*forename/surname/position*]

Signature: _____

Done at [*place*], [*date*]

ANNEX III: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020

Agreement

Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union1as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter "ESI" or "ESI regulation");

***

The European Commission ("the Commission")

and

The following Member States: (XXX), hereinafter referred to as "the Participating Member States"

Together referred to as "the Parties"

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participation Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

A) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and caling-up production capacity;
B) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and

C) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

ANNEX IV: LIST OF CONFIRMED AND PLANNED MANUFACTURING NETWORK PARTNERS INCLUDING THE LOCATION(S) OF MANUFACTURING

[***]

ANNEX V: TARGET PRODUCT PROFILE

At the date of signature of the APA, the current target Product profile is set out below, and can be varied by contractor during the APA as and when the Product is being developed in accordance with Article I.4.2 of the APA. For the avoidance of doubt, the final Product and related Marketing Authorisation (and notably the Product indication) will depend on the clinical trial data and acceptability of the Marketing Authorisation application by the EMA.

	Vaccine Properties
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]
[***]	+ [***]

ANNEX VI: CONTRACTOR'S INSURANCE

[***]

ANNEX VII: DETAILS OF THE UTILISATION OF THE DOWN PAYMENT

[***]

Exhibit 10.5

[***] = 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

28 October 2021 (the "**Amendment Date**")

Dear Sirs

SUPPLY AGREEMENT BETWEEN DYNAVAX, PURCHASER AND VALNEVA AUSTRIA DATED 12 SEPTEMBER 2020 (THE "AGREEMENT")

To the extent not otherwise defined in this letter (including Appendix One hereto, which is incorporated herein by this reference) ("**Amendment**"), capitalized terms used but not otherwise defined in this Amendment 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 forth in this Amendment.

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 Amendment 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: 29 October 2021

Valneva Austria GmbH

Signed: [***]

Name: [***]

Date: 29 October 2021

We agree to the above proposal.

For and on behalf of **Dynavax Technologies Corporation**

Signed: [***]

Name: [***]

Date: 10/28/2021

Attachment: Appendix One

APPENDIX ONE

1. The Parties agree and confirm that, in accordance with Section 2.5 of the Agreement, each of the Purchase Orders identified below, which collectively constitute all Purchase Orders which have been placed by Purchaser prior to the Amendment Date in respect of CpG Adjuvant which has not, as at the Amendment Date, been delivered to Purchaser, are hereby cancelled:

Purchase Order No.	**Date**
[***]	[***]
[***]	[***]

The Parties hereby confirm that Dynavax is entitled to retain all Advance Payments paid by Purchaser to Dynavax under the Agreement prior to the Amendment Date, and Purchaser shall not be entitled to any refund thereof.

2. The Parties wish to further vary the Agreement and agree that, with effect from the Amendment Date:

(a) Sections 2.2 is deleted in its entirety and replaced as follows:

"**2.2 Commitments and Orders.**

(a) Binding Purchase Order. On the Amendment Date, Purchaser has submitted a binding Purchase Order for 11kg of CpG Material, which has been accepted by Dynavax, as set out in the table below:

KG of CpG Material	**Order Deadline**	**Delivery Date**	**Final Payment paid on Delivery Date**
[***]	1 December 2021	[***]	[***]

(b) Optional Purchase Order. As soon as reasonably practicable, Dynavax shall deliver written notice to Purchaser as to whether or not Dynavax can reasonably extend the shelf life of such CpG Material [***]. If Dynavax determines not to extend such shelf life, Purchaser shall have the right to submit to Dynavax, [***], one (1) (and only one) additional Purchase Order under this Agreement [***] which Dynavax will be obliged to accept:

[***]	[***]	[***]
[***]	[***]	[***]

(c) No Additional Quantities. For clarity, the sum of the number of kilograms of CpG Material set forth in the table in Section 2.2(a), and, if applicable, the number of kilograms of CpG Material set forth in the table in Section 2.2(b) (collectively, the "**Commitment**"), represents the maximum amount of CpG Material that Purchaser has the right to order and purchase, and Dynavax is obligated to sell and supply to Purchaser, under this Agreement from and after the Amendment Date. From the Amendment Date, Purchaser shall have no right to submit, and Dynavax shall have no obligation to accept, any Purchase Order from Purchaser for CpG Material under this Agreement, other than the Purchase Orders specified in Sections 2.2(a) and 2.2(b). Should Purchaser wish to purchase from Dynavax, and Dynavax be willing to sell and supply to Purchaser, any quantity of CpG Adjuvant in excess of the Commitment, the terms and conditions of any such purchase, sale and supply, including the price of any such CpG Adjuvant, would be subject to negotiation and mutual written agreement of the Parties."

(b) Section 2.3 of the Agreement is deleted in its entirety.

(c) The first sentence of Section 2.4(a) of the Agreement is deleted in its entirety.

(d) Notwithstanding the provisions of Section 2.4(b) of the Agreement, except for the obligation set forth in Section 2.2(b) of this Amendment to deliver written notice to Purchaser regarding whether Dynavax can reasonably extend the shelf life of the CpG Material already received by Purchaser under the Agreement (as amended by this Amendment), Dynavax shall have no additional obligation to extend the shelf life of CpG Material (including CpG Material previously delivered).

(e) Section 2.5(b) of the Agreement is deleted in its entirety and replaced as follows:

"**(b)** The Parties agree that Purchaser, in its sole discretion, may cancel the Purchase Order placed under Section 2.2(a) of this Agreement by written notice to Dynavax on or before the Order Deadline (1 December 2021). If such Purchase Order is cancelled on or before the Order Deadline, Dynavax will not be required to deliver the CpG Material which is the subject of that Purchase Order, Purchaser shall not be required to pay the Final Payment for such CpG Material, and, for clarity, Purchaser shall not be entitled to any refund of the Advance Payment received by Dynavax in connection with such Purchase Order."

(f) Notwithstanding the first two sentences of Section 3.1 of the Agreement, the purchase price (and aggregate Cost per Dose) of all CpG Material supplied by Dynavax to Purchaser after the Amendment Date under Section 2.2 of the Agreement (as amended by this Amendment) is as specified in such Section 2.2.

(g) Section 3.2 of the Agreement is deleted in its entirety and replaced as follows:

"**3.2 Invoice and Payment.** In respect of the CpG Material ordered in any Purchase Order submitted by Purchaser pursuant to Section 2.2(a) or 2.2(b) of this Agreement, Purchaser is deemed to have paid, and Dynavax is deemed to have received, prior to the Amendment Date, [***] (the "**Advance Payment**"), and Dynavax will invoice Purchaser for [***] (the "**Final Payment**"), upon delivery of such CpG Material in accordance with Section 2.4(a). Purchaser shall pay each invoice, [***] by wire transfer of immediately available funds into an account designated by Dynavax. If Purchaser disputes any invoiced amount hereunder (or a portion thereof), Purchaser shall timely pay any undisputed portion of the invoiced amount in accordance with the preceding sentence and shall notify Dynavax in writing of the disputed amount, including the basis on which Purchaser disputes such amount, within [***]."

(h) Section 10.1 of the Agreement is deleted in its entirety and replaced as follows:

"**10.1 Term.** This Agreement commenced on 13 September 2020 (the "**Effective Date**") and, unless earlier terminated by the Parties pursuant to Section 10.2, will continue until the delivery by Dynavax to Purchaser in accordance with this Agreement of the quantity of CpG Material specified in Section 2.2(a), unless Purchaser timely submits a Purchase Order for the additional quantity of CpG Material specified in Section 2.2(b), in which case it will continue until the delivery by Dynavax to Purchaser in accordance with this Agreement of the quantity of CpG Material specified in Section 2.2(b)."

(i) The final sentence of Section 10.5 of the Agreement is deleted in its entirety and replaced as follows:

"Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Article 1 (Definitions), Section 2.7 (Inspection and Acceptance), Article 5 (Use of CpG Material), Article 6 (Intellectual Property), Article 7 (Confidentiality), Article 9 (Indemnification), Section 10.5 (Effects of Termination; Survival), and Article 11 (General Provisions)."

[End of Appendix One]

Exhibit 10.6

[***] = 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.

Master Supply and Commercial Manufacturing Services Agreement

between

VALNEVA AUSTRIA GMBH

Campus Vienna Biocenter 3

1030 Vienna, Austria

and

IDT BIOLOGIKA GMBH

Am Pharmapark

06861 Dessau-Rosslau, Germany

TABLE OF CONTENTS

MASTER SUPPLY AND COMMERCIAL MANUFACTURING SERVICES AGREEMENT

This Master Supply and Commercial Manufacturing Services Agreement (this "**Agreement**") is entered into as of November 26, 2021 (the "**Effective Date**") by and between:

(1) **Valneva Austria GmbH**, a company incorporated in Austria under Company Registration Number [***]x (HG Wien), whose registered office is at Campus Vienna Biocenter 3, 1030 Vienna, Austria ("**Valneva**"); and

(2) **IDT Biologika GmbH**, a company incorporated in Germany under Commercial Register Number [***], whose principal place of business is at Am Pharmapark, 06861 Dessau-Rosslau, Germany ("**IDT**").

WHEREAS

(A) Valneva is engaged in the research, development, manufacture and commercialization of certain vaccines;

(B) IDT has extensive facilities for, and experience in, developing and manufacturing vaccines and biological bulk drug products including bulk manufacturing, quality control testing, formulation, filling and freeze-drying, packaging, labelling, storage and release services to the pharmaceutical industry;

(C) Valneva may from time to time require to purchase Products (as defined herein) from IDT and IDT has the ability and desire to manufacture and supply such Product to Valneva; and

(D) Valneva and IDT now wish to enter into this Agreement to set forth the general terms and conditions on which the supply and additional service of any particular Product under a Product Schedule (as defined herein) will be carried out.

Integral Agreement

This Agreement is comprised of (i) Part A (*General Terms*), (ii) Part B (*Ways of Working*), (iii) Part C (*Definitions*) and (vi) Part D *(Additional Services)*, each of which is an integral part of this Agreement and which, taken together, and subject to the provisions of Clause 22.4, form the entirety of this Agreement.

PART A: GENERAL TERMS

1. Agreement, Product Schedules and Joint Steering Committee

1.1. Agreement: This Agreement sets out the terms and conditions under which 1) IDT agrees to Manufacture and Ship the Product(s) to Valneva and provide related services, and 2) Valneva agrees to purchase a Product(s) and related services agreed upon pursuant to a Product Schedule(s). Valneva and IDT shall enter into Product Schedules for the Manufacture and Shipment of products agreed upon. Each Product Schedule, once signed, shall be incorporated into, and form a part of this Agreement. Notwithstanding any other provision, in case of any conflict between a Product Schedule and this Agreement, the Product Schedule shall prevail, provided that any QAA applicable to one or several Product Schedules, as the case may be, shall prevail for all matters concerning quality related matters.

1.2. Capacity Reservation: IDT hereby agrees to establish (to the extent required) and reserve Manufacturing capacity as set forth in any Product Schedule ("**Capacity**") necessary to perform the Services set forth therein (the "**Capacity Reservation**") and Valneva agrees to pay IDT a fee for the Capacity Reservation as set forth in any Product Schedule ("**Reservation Fee**").

1.3. Technology Transfer:

1.3.1. [***]

1.3.2. During the Term of this Agreement, Valneva shall undertake such additional technical transfer services as are necessary and agreed with respect to a Product Schedule to enable IDT to provide the Services contemplated by such Product Schedule.

1.3.3. In the event that IDT uses its own Background IP and technologies to develop processes relating to the Product, it shall inform Valneva thereof in due time prior to implementing such Background IP into the Services, and the Parties shall discuss and agree in writing by amending this Agreement or any Product Schedule (where applicable) (i) whether such processes shall be used in relation to the Services and the Product, and (ii) any technical transfer services relating to such processes as are necessary to enable a Third Party service provider to Manufacture the Product.

1.4. QAA: Prior to the Release of any Product by IDT pursuant to this Agreement or any Product Schedule, the Parties will enter into a QAA, setting forth, as appropriate, quality assurance provisions, the respective roles and allocation of responsibilities of the Parties with respect to the applicable processes and standards and procedures for handling deviations and related matters.

1.5. Non-Exclusive: The engagement of IDT by Valneva under this Agreement and a Product Schedule shall be on a non-exclusive basis and Valneva shall at all times have the right, at its sole discretion, manufacture itself, or to engage other contract manufacturers and other suppliers in relation to the Product(s).

1.6. Duration: Valneva and IDT may enter into additional Product Schedules at any time during the Term.

1.7. Joint Steering Committee. The Parties shall establish a joint steering committee that shall be responsible for monitoring the activities under this Agreement and for making those decisions delegated to it pursuant to this Clause 1.7.

1.7.1. JSC Responsibilities. The JSC shall have non-executive oversight of and responsibility for:

(a) encouraging and facilitating ongoing communication and cooperation between the Parties with respect to each Party's obligations under this Agreement;

(b) determining mechanisms to resolve any issues, monitoring, raising, discussing and resolving any material issues, other difficulties, problems or obstacles concerning the Manufacturing, any Product Schedule or Shipment of the Products and monitoring the resolution of those issues or delay of Product;

(c) reviewing and, where appropriate, agreeing any changes to the manufacturing plan and Shipment dates

(d) reviewing and discussing Yields per Batch Manufactured and monitoring, tracking and discussing the same, and the impact and consequences of any Yield in accordance with provisions set forth in the applicable Product Schedule;

(e) provided, in each case, that any change of this Agreement, the Product Schedule, the QAA or an Exhibit needs to be formalized through an Amendment to be effective.

1.7.2. Membership of the JSC. The JSC shall comprise an equal number of representatives from each of the Parties or their Affiliates (collectively, the "**Members**"). The number of Members representing each Party at the JSC shall be three (3), or such other number as the Parties may mutually agree. Each Party may replace any or all of its Members on the JSC at any time upon written notice to the other Party provided that any replacement Members are employees or officers of that Party or that Party's Affiliates, have the appropriate skill and experience to perform the duties of a Member and sufficient seniority and authorisation on behalf of the applicable Party to make decisions arising within the scope of the JSC.

Any Member of the JSC may designate a suitable substitute who is an employee or officer of the relevant Party or that Party's Affiliates to attend and perform the functions of that Member at any meeting of the JSC. Each Party may, in its reasonable discretion, invite non-Member representatives of such Party to attend meetings of the JSC as a non-voting contributor, provided that such persons are bound by confidentiality obligations no less stringent than those of Clause 15 below.

1.7.3. Meetings of the JSC. The JSC shall meet [***], or more or less frequently as the Parties or the Members may mutually deem appropriate provided that where a dispute has been referred to the JSC for resolution the JSC shall meet within [***] of such referral in order to resolve such dispute (or sooner if required).

The JSC may meet virtually via a secured digital platform, or where necessary it may meet physically subject to observing then current social distancing guidelines and travelling restrictions. Either Party may also call a special meeting of the JSC (via a secure digital platform) upon at least [***] prior written notice to the other Party, or such shorter period as may be agreed on a meeting-by-meeting basis, if such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JSC (as applicable) no later than [***] prior to the special meeting with materials reasonably adequate to enable an informed understanding to be made by its Members. Each Party shall be responsible for its own expenses relating to such meetings. The chairperson of the JSC shall be responsible for preparing reasonably detailed written minutes of all JSC meetings.

1.7.4. Decision Making. Except as otherwise expressly provided in this Agreement, where a matter requires the consent, approval or agreement of the JSC in accordance with this Agreement, such decision shall be made by unanimous vote of a quorum of the Members [***]. The presence of at least [***] shall constitute a quorum of the JSC. The Members shall endeavour in good faith to reach agreement on any and all matters to be determined or resolved by the JSC.

Each Party shall ensure that where, in accordance with this Agreement, a matter is referred to the JSC for consent, approval or agreement, that Party's Members of the JSC appointed by it shall act reasonably and should not unreasonably withhold or delay such consent, approval or agreement.

If at any time, the JSC is unable to reach a unanimous decision within [***] (or sooner if required) after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such matter referred for resolution by an appropriate senior executive officer of each Party. Within [***] (or sooner if required) of such notice, the relevant senior executives and member shall meet and attempt to resolve the dispute by good faith negotiations.

2. Forecasting

2.1. Unless otherwise agreed in a Product Schedule, on or before the [***] of each calendar month during the Term Valneva shall provide to IDT a [***], monthly rolling Forecast of its requirements of Product. The first [***] months of each Forecast shall constitute binding commitments pursuant to each such Forecast and shall be covered by Purchase Orders pursuant to Clause 3. The remaining [***] months of the [***] Forecast shall be non-binding (except as otherwise set forth in this Agreement or a Product Schedule) and serve for planning purposes only.

2.2. Upon request by Valneva, IDT shall use Commercially Reasonable Efforts to Manufacture a quantity in excess of the binding Forecast quantities, provided that such quantity does not exceed [***].

3. Purchase Orders

3.1. Valneva shall send purchase orders for each Product to IDT, in each case consistent with the binding portion of the Forecast. Such purchase orders shall be sent no less than the calendar months before the expected delivery date as set forth in the Product Schedule. IDT shall confirm the receipt of a Firm Order as well the delivery date within [***] after receipt. IDT shall not be entitled to reject any purchase orders if the volumes therein are consistent with Valneva's binding forecast or with the applicable Minimum Purchase Commitment, whichever is higher. If, within [***], IDT has not confirmed that the delivery date set forth in the purchase order is accepted Valneva shall send a reminder. If IDT still has not confirmed that the Shipment date set forth in the purchase order is accepted within [***] after receipt of the reminder, IDT shall be deemed to have accepted such Shipment date.

3.2. Placed and confirmed purchase orders becomes "Firm Orders" and may not be altered by either Party. Any assumed or actual deviation from the confirmed Delivery date is to be communicated to Valneva as soon as possible in order to enable Valneva to take necessary action to minimize any negative effects.

4. IDT Obligations

4.1. IDT's Performance: IDT shall Manufacture, Ship and perform related services and activities set forth in each Product Schedule ("**Services**"), in accordance with the terms of this Agreement, including but not limited to the applicable:

4.1.1. Product Specification;

4.1.2. Manufacturing Specifications;

4.1.3. Purchase Order;

4.1.4. QAA; and

4.1.5. Product Schedule.

4.2. Compliance: IDT shall perform the Services in accordance with Applicable Laws and Regulations, including but not limited to GMP.

4.3. IDT Supply Commitment: IDT shall supply and Ship Product(s) to Valneva in the amount and in accordance with the timelines set forth in the relevant Product Schedule ("**Supply Commitment**"). In case IDT fails to Ship the Product on the dates agreed between the Parties due to IDT's fault and such delay remains for a period longer than [***] from Shipment Date, IDT shall pay Valneva, a late delivery fee of [***].

5. Valneva Obligations

5.1. Valneva Obligations: Valneva shall order the Product(s), provide the Valneva Materials and pay the Price set forth in the Product Schedule in accordance with the terms of this Agreement, including but not limited to the applicable:

5.1.1. Purchase Order;

5.1.2. QAA; and

5.1.3. Product Schedule.

5.2. Take-or-Pay Commitment: Valneva shall order Product in accordance with the forecast mechanism and the binding portion of the Forecast set forth in this Agreement and otherwise in accordance with the relevant Product Schedule.

5.2.1. Valneva shall 'take or pay' for its commitment under any Firm Order which are to be placed by Valneva in accordance with quantities of Product in the binding part of the Forecast ("Commitments") otherwise [***]; provided, however that, in addition to other remedies available to Valneva under this Agreement or in the relevant Product Schedule, if IDT fails to Ship all or part of the Product ordered under such Commitment, Valneva shall only be obligated to pay' [***].

5.2.2. Subject to Clause 5.2.1, upon failure of Valneva to take the Product which was subject of a Commitment, and unless IDT fails to Ship all or part of the Product ordered under such Commitment or as otherwise stated in the Product Schedule (e.g. in case of rescheduling), the amount to be paid by Valneva shall equal [***], subject always that IDT shall use Commercially Reasonable Efforts to use, return or cancel materials or Third Party services already ordered pertaining to such Firm Order.

6. Intellectual Property

6.1. Intellectual Property of Valneva: All Intellectual Property of Valneva (including all Background IP) provided to IDT by Valneva pursuant to this Agreement shall remain vested in and remain the exclusive property of Valneva or its licensors, as applicable. [***]

6.2. Licence of Valneva Intellectual Property Rights: Valneva grants to IDT a royalty-free, non-exclusive right for the Term (with no right to sub-licence, except to IDT's Affiliates) to use Valneva's Intellectual Property to the extent necessary and for the sole purpose of performing its obligations under this Agreement.

6.3. Intellectual Property of IDT: Subject to the rights and licences granted by IDT hereunder, all Intellectual Property of IDT (including all Background IP) used in the performance of this Agreement shall remain vested in and remain the sole and exclusive property of IDT or its licensors, as applicable.

6.4. Inventions:

6.4.1. Subject to Clause 6.4.2, Valneva shall own all right, title and interest in any Intellectual Property conceived, reduced to practice or otherwise made by IDT or Valneva or any other of their respective Affiliates, employees, sub-contractors, consultants or agents (either solely or jointly) in connection with the Product ("**Valneva New IP**"). IDT hereby assigns to Valneva all of IDT's right, title and interest in and to such Valneva New IP.

6.4.2. IDT shall own all right, title and interest in any Intellectual Property conceived, reduced to practice or otherwise made by IDT or any of its Affiliates employees, sub-contractors, consultants or agents, either solely or jointly, during and in the course of the Agreement, that is (a) capable of being applied to products or processes other than to, or in addition to the Product, or (b) is an Improvement of, or derivative of, any Intellectual Property of IDT ("**IDT New IP**") subject always that any IDT New IP specifically excludes the Product and/or any Valneva New IP. Valneva hereby assigns to IDT all of Valneva's right, title and interest in and to such IDT New IP (if any).

6.5. Know-How and Improvements: If Valneva provides Valneva's Know-How or other Valneva Information to IDT to enable it to Ship the Product(s) as well as to provide the Services:

6.5.1. IDT shall use such Valneva Know-How or other Valneva Information solely for the purpose of performing its obligations under this Agreement;

6.5.2. IDT shall promptly disclose to Valneva all Improvements that IDT develops or discovers during the term of this Agreement relating to the Products;

6.5.3. for the avoidance of doubt, for all Improvements in relation to Valneva's Know-How or other Valneva Information, in respect of IDT or Valneva or any of their respective Affiliates, employees sub-contractors, consultants or agents (either solely or jointly), Clause 6.4 shall apply; and

6.5.4. in relation to Improvements which are intended to be the exclusive property of IDT under Clause 6.4.2 IDT shall, and hereby does, grant to Valneva a non-exclusive, world-wide, perpetual, irrevocable, royalty-free licence, with the right to sublicense, to use such Improvements to the extent that such Improvements are necessary for the Manufacture and commercialisation of the Products.

6.6. Licence of Background IP: IDT shall, and hereby does, grant to Valneva a non-exclusive, world-wide, perpetual, irrevocable, royalty-free licence, with the right to sublicense, to use any Background IP and any Improvements of IDT that are necessary for the Manufacture and commercialization of the Products.

6.7. No Warranty: If Valneva provides Valneva Information or Know-How that represents only part of the Manufacturing processes, Product Specification, analytical methods or other data used by Valneva to manufacture the Product at any scale in Valneva's or its Affiliates' facilities or the facilities of a Third Party, no warranty is given as to the appropriateness or sufficiency of any such Valneva Information or Know-How, in relation to either the Shipment of the Product by IDT, or the performance of IDT when utilizing such Valneva Information or Know-How. However, Valneva shall be responsible for any defect of Products or delay of Shipment of Products if and to the extent this is due to the lack of appropriateness or sufficiency of any Valneva Information or Know-How provided by Valneva to IDT.

In case of a dispute with regard to the appropriateness or sufficiency of any such Valneva Information or Know-How, the Parties will discuss in good faith the root cause, remedies and costs.

6.8. Infringement: Neither Party shall do, nor authorize a Third Party to do anything that will or may infringe the other Party's Intellectual Property used in the performance of the Services under this Agreement.

6.9. Trademark. Neither Party shall acquire any rights or licence on the other Party's trademarks, unless such other Party provides prior written consent.

7. Shipment

7.1. Time of Shipment: IDT shall Ship the quantity of Product ordered under any Firm Order on the delivery date stipulated therein, and otherwise in accordance with the provisions set forth in the respective Product Schedule.

7.2. Shipment: Unless otherwise set forth in a Product Schedule, each Shipment of Product shall be [***] for collection by a carrier specified by Valneva in each respective Product Schedule and risk shall transfer to Valneva accordingly.

7.3. Transfer of Ownership of Products: Ownership, title and control to Product(s) shall pass at the same time as risk.

8. Valneva Materials

8.1. IDT Forecast: Unless otherwise agreed in a Product Schedule, on or before the [***] day of each calendar month during the Term IDT shall provide to Valneva a [***] months, monthly rolling IDT Forecast of its requirements of Valneva Materials for planning purposes.

8.2. Provision of Valneva Materials: Unless otherwise set forth in a Product Schedule, Valneva shall provide to IDT material agreed between the Parties and defined in the respective Product Schedule required for use by IDT to Manufacture the Product and perform the Services. Delivery shall be [***]. Unless otherwise set forth in the applicable Product Schedule, Valneva shall deliver or arrange for supply, at Valneva's cost, to IDT such quantities of Valneva Materials as are reasonably required for IDT to Manufacture the amount of Product pursuant to a relevant Purchase Order in accordance with the dates set forth in the IDT Forecast. IDT shall use such Valneva Materials exclusively for the Manufacturing of Product, and not for any other purpose, and shall not transfer the Valneva Materials to any Third Party. Valneva shall at all times have and retain legal title to Valneva Materials shipped by Valneva to IDT pursuant to the provisions of this Clause. Valneva shall provide to IDT supplier qualification documentation and material qualification documentation, reasonably satisfactory to the IDT QP.

8.3. Certificates: Valneva shall include with each such delivery of Valneva Material applicable GMP quality certificates.

8.4. Inspection: Upon receipt by IDT of each Shipment of Valneva Materials, IDT shall perform a [***] inspection of such Shipment and give Valneva electronic notice within [***] after receipt of any missing or damaged Valneva Materials. Thereafter, IDT shall conduct such quantitative and quality controls on the Valneva Materials as are set forth in the specifications set out in the applicable Product Schedule. Within [***] of the determination by IDT of any qualitative shortcomings in any Valneva Materials, IDT shall give Valneva electronic notice thereof.

8.5. Shortfall: In the event of failure by Valneva to provide any Valneva Materials or if there is any shortcoming or other justified claim with respect to any Valneva Materials, Valneva shall use Commercially Reasonable Efforts to replace or arrange to be replaced such quantities of Valneva Materials to which such shortcoming relates within the lead-times as set forth in the Product Schedule, unless the Parties consent to another time-period.

If Valneva Materials have not been provided or replaced within the dates set forth in the IDT Forecast or as otherwise set forth in the Product Schedule necessary for IDT to Ship the Products ordered under a Firm Order, then the Parties shall discuss in good faith any alternative solutions [***], and, absent agreement thereon, the related Firm Order shall be deemed cancelled, and IDT shall not be obligated to Ship the Product in accordance with such Firm Order. In the event of cancellation of such a Firm Order, except in the event that such shortcoming of Valneva Materials is IDT's fault, Valneva shall [***].

8.6. If Valneva continues to require Product set forth by any Firm Order cancelled pursuant to Clause 8.5, it shall notify IDT and IDT shall use Commercially Reasonable Efforts to reschedule the Manufacturing of the Product, [***] In the event that IDT is so required to reschedule a Firm Order, Valneva shall re-order such Product(s) not yet Manufactured through a new or amended Firm Order.

8.7. Provided IDT has provided Valneva with the IDT Forecast IDT shall have no liability for the failure or any delay in the Shipment of Product under a Firm Order to the extent such failure or delay is due to the failure on the part of Valneva to deliver or have delivered any Valneva Materials to IDT in accordance with this Clause 8.

8.8. IDT will have liability for Losses or damages to any and all Valneva Material in its control to the extent that such Losses or damages are the result of IDT's negligence or misconduct.

8.9. Information Provided: Prior to supplying any Valneva Materials and to the extent set forth in the applicable Product Schedule, Valneva shall send to IDT [***].

9. Valneva Equipment

9.1. [***] If new capital equipment is required during the Term of this Agreement, the Parties shall discuss in good faith the procurement of such equipment and formalize the agreement in a Work Package. [***]

9.2. Equipment Use. During the Term, IDT will hold the Valneva Equipment as a bailee only and will not permit any lien or other encumbrance to be placed against such Valneva Equipment when in IDT's care, custody, and control. IDT shall include a note in its ERP and to physically mark the Valneva Equipment as Valneva property in a manner sufficient to ensure easy identification of Valneva Equipment. Under no circumstances will IDT move Valneva Equipment from the location designated by Valneva, without Valneva's Consent, or deny Valneva, its agents or contractors access to the Valneva Equipment upon reasonable advance notice. IDT shall not be entitled to use the Valneva Equipment for purposes other than the performance of Services without prior Consent by Valneva.

9.3. Maintenance. IDT shall calibrate, clean and maintain the Valneva Equipment in accordance with IDT's standard equipment maintenance, and other operating procedures to a service fee agreed between the Parties.

9.4. Liability. Notwithstanding the foregoing provisions, IDT shall have no liability for failure to perform or for any delay in such performance to the extent such failure or delay is due to Valneva Equipment which is not fit for purpose, defective or irreparable, provided that IDT without undue delay after becoming aware of such defect or irreparable condition gives Valneva Notice thereof and provided further that such defective or irreparable condition of said Valneva Equipment is not caused by IDT's gross negligence or intentional or willful misconduct.

9.5. Ownership after Expiration. At the expiration or termination of this Agreement, IDT shall return the Valneva Equipment to Valneva or its designee [***]. In the event IDT wishes to retain the Valneva Equipment and gain ownership thereof IDT shall notify Valneva not later than [***] prior to the termination or expiration date, of its wish. Upon such notification the Parties shall negotiate in good faith the potential retention whereby IDT would pay to Valneva [***] said Valneva Equipment, which, upon the payment of the above, shall be retained by IDT and become the property of IDT. If the Parties fail to reach an agreement within [***] following termination or expiration of this Agreement, the Valneva Equipment shall be dismantled and prepared and packed suitable for shipment [***] to Valneva [***].

9.6. IDT will have liability for Losses or damages to any and all Valneva Equipment in its control to the extent that such Losses or damages are the result of IDT's negligence or misconduct.

10. Non-Conformance and Shortfall

10.1. Non-Conformance:

10.1.1. Obvious Defects: Valneva shall check Product Shipped by IDT for any Obvious Defects upon receipt of such Product, and Valneva shall inform IDT of such Obvious Defects no later than within [***] following the date of receipt of the Product at Valneva's site.

10.1.2. Latent Defects: Valneva shall inform IDT in writing in case of Latent Defects promptly upon discovery of such Latent Defects of Product but no later than within [***] following such discovery. For the sake of clarity, the receipt of information [***], provided post Shipment showing defects in the Product shall be included in the definition "Latent Defects".

10.1.3. If Valneva does not inform IDT of any Obvious Defects within the time period set forth in Clause 10.1.1 or of any Latent Defects within the time period set forth in Clause 10.1.2, the Shipped Product received by Valneva will be deemed accepted.

10.1.4. If Valneva notifies IDT that it will reject Product due to any Non-Conformance for which IDT is responsible, within the time periods set forth in Clauses 10.1.1 and 10.1.2, IDT shall use Commercially Reasonable Efforts, taking potential capacity restraints into consideration, to replace Product, at IDT's expense and at no cost to Valneva. Depending on available manufacturing capacity, IDT shall propose possible time slots for the manufacturing of replacement Product which timelines the Parties shall discuss in good faith. If Valneva concludes that the new plan for the Shipment of replacement Product is not sufficient, provided that [***], it shall cancel the relevant Firm Order immediately but no later than [***] after the presentation of the plan by IDT. In the event of the cancellation of the Firm Order, IDT shall refund [***] for the cancelled Firm Order. In the event of a cancellation by Valneva in accordance with this provision Valneva shall have no obligation to pay [***]. For clarity, subject to Clauses 10.1.6 and 10.4, any Valneva Material necessary for the Manufacture and Shipment of replacement Product shall be at IDT's expense.

10.1.5. If IDT believes that Product has been incorrectly rejected by Valneva, Valneva shall provide samples of the Product in Non-Conformance for prompt testing and analysis by an independent laboratory. Such independent laboratory shall be mutually agreed upon by the Parties. The results of such independent laboratory shall be in writing and shall be final and binding [***]. If the independent laboratory determines that the Product includes a Non-Conformance that is IDT's responsibility, IDT shall bear the costs associated with such testing and review. If the independent laboratory determines that the Product does not include a Non-Conformance that is IDT's responsibility, Valneva shall bear the costs associated with such testing and review, and any costs associated with the replacements required by Clause 10.1.6.

10.1.6. Valneva agrees that IDT shall have no liability if the Product in Non-Conformance is due to any act or omission of Valneva, any Affiliate of Valneva or any Third Party under contract with or subject to the control or direction of Valneva or any Affiliate of Valneva. If a Non-Conformance is determined to be the responsibility of Valneva, including any Product being in Non-Conformance due to Valneva's provision of incomplete or inaccurate Product and/or Manufacturing Specifications, due to improper handling of Product by Valneva, due to any defect in Valneva proprietary production processes being used by IDT in the performance of the Manufacturing, except if it is the result of IDT's improper handling of the production processes of Valneva, or due to defective Valneva Material, IDT shall Ship to Valneva, as soon as commercially reasonable, replacement Product in accordance with an amended manufacturing plan reasonably agreed to by the Parties. Valneva shall be required to pay [***].

10.2. Shortfall: If Valneva notifies IDT no later than [***] following the date of receipt of the Product at Valneva's site or the agreed Shipment date of any shortfall in quantity of the Product, which shortfall is the responsibility of IDT, IDT shall as promptly as practicable, Ship to Valneva Product in an amount corresponding to that shortfall, at no cost to Valneva. In addition, Clause 10.4 shall apply to such shortfall.

10.3. Remedies: Valneva's remedies under Clauses 10.1 or 10.2, which are subject to the liabilities and limitations set forth in Clause 10.4, shall be Valneva's sole remedy as a consequence of the Shipment of a Product in Non-Conformance or shortfall. For clarity, (i) IDT's liability to compensate Valneva for costs for Valneva Material pursuant to Clause 10.4 shall be in addition to IDT's obligation to replace or Ship Product pursuant to Clauses 10.1 or 10.2, and (ii) this Clause 10.3 shall not limit Valneva's right to terminate this Agreement or a Product Schedule for a material breach of IDT, if any Non-Conformance or shortfall shall constitute a material breach by IDT.

10.4. Losses due to a Non-Conformance: If and to the extent IDT is responsible for the Product in Non-Conformance, IDT shall be responsible for any Losses, including the costs for Valneva Materials used in respect of the Product in Non-Conformance or shortfall. For the sake of clarity, the limitation of liability set forth Clause 16 shall be applicable.

11. Product Recall

Recall of Product shall be conducted in accordance with the QAA. To the extent that a recall of Product is due to IDT's breach of this Agreement or the Shipment of Product in Non-Conformance due to IDT's fault, IDT shall be liable for all direct Losses incurred by Valneva as a result of that recall. Clause 16 shall be applicable.

12. Representations and Warranties

12.1. IDT represents, as of the Effective Date, warrants and undertakes that:

12.1.1. IDT is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

12.1.2. The Services will conform to the specifications and instructions set forth in the Product Schedule and the QAA.

12.1.3. IDT, its employees and agents, have, and will continue to have the knowledge, experience and skill to provide, and will provide, the Services in a professional and timely manner.

12.1.4. The performance of IDT's obligations to Valneva under this Agreement will not breach or be in conflict with any obligation to any Third Party, and, to the best of IDT's knowledge, does not infringe any Intellectual Property rights of any Third Party.

12.1.5. All Shipped Product, will have been Manufactured, handled, stored and transported in accordance with, as applicable (a) the QAA, (b) Applicable Laws and Regulations, (c) the Product Specification, (d) the Manufacturing Specifications; (e) all Manufactured Product will conform to the Certificate of Analysis; (f) such Product Shipped will not be adultered or misbranded; and title to such Product will pass to Valneva as provided herein free and clear of any security interest, lien, or other encumbrance.

12.1.6. All Valneva Materials and Valneva Equipment supplied by Valneva or purchased by IDT and paid by Valneva shall be handled in accordance with the Safety and Data Sheet and safety regulations as supplied by Valneva or the supplier (as the case may be), and in accordance with Applicable Laws and Regulations, including but not limited to GMP, where applicable.

Except with respect to the representations and warranties pursuant to Clauses 12.1.1 and 12.1.4, the aforementioned representations and warranties are subject to the limitation of liability set forth in Clause 16 in the event of a breach.

12.2. Valneva represents, as of the Effective Date, warrants and undertakes that:

12.2.1. Valneva is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

12.2.2. The execution, delivery or performance of this Agreement will not contravene Applicable Laws and Regulations and Valneva shall perform its obligations and responsibilities hereunder in accordance with all Applicable Laws and Regulations.

12.2.3. To the best of Valneva's knowledge, Valneva has all the rights necessary to permit IDT to perform the Services without infringing the Intellectual Property rights of any Third Party.

12.3. Promptly Inform Valneva: IDT shall inform Valneva promptly in writing of any event that to the best of IDT's knowledge may adversely affect IDT's ability to perform its obligations under this Agreement or may adversely affect the suitability of the Product for Valneva's use.

12.4. DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

13. Payment

13.1. The Price payable by Valneva in respect of a Product:

13.1.1. is set forth in each respective Product Schedule;

13.1.2. is based on the assumptions and information set out in the Product Schedule;

13.1.3. is payable in Euro.

13.2. Invoices: Subject to deviating provisions in the relevant Product Schedule, IDT shall issue an invoice to Valneva, or to an Affiliate of Valneva, issuing the relevant Firm Order on or after the date of the transfer of risk, title and ownership. Any invoiced amount shall take into account any fees and expenses and any prepayments made by Valneva which are creditable against the agreed Price as further set forth in the applicable Product Schedule. Each invoice shall contain a reference to Valneva's applicable VAT registration number to be provided to IDT, the relevant Firm Order number, and shall comply with Applicable Laws and Regulations regarding information required on a valid invoice and shall state IDT's registered Tax number. As regards Equipment the invoice shall include Valneva's registered German VAT number [***]. The Parties agree that amounts due under a Product Schedule shall, save for any creditable fees or other prepayment, not set off against another or applied to sums due as a result of the performance of other Product Schedules without the prior written consent of the other Party. Invoices shall be sent to e-mail address: [***].

13.3. Payment Period: Valneva shall pay all invoices within [***]. The payment period begins on the date of receipt of the invoice, except where Valneva has a bona fide dispute in respect of the whole or any part of the Product Delivered, in which case the terms for payment, including the payment period, will be as agreed by the Parties in resolving the dispute (or as otherwise determined under Clause 22.12).

13.4. Interest: If Valneva fails to pay any amount due to IDT under this Agreement within [***] after that payment is due, IDT shall send Valneva a written reminder to make the respective payment. If a Party fails to pay any amount due under this Agreement the other Party is entitled to charge interest until actual payment at [***] until payment is made. Such interest shall accrue on a [***] basis from the due date until the date of actual payment of the overdue amount and shall be payable on demand.

13.5. Right to Suspend: Except as set out and agreed in a Product Schedule, neither Party shall be entitled at any time to suspend the provision of the whole or any part of the Manufacture and Shipment of Product.

14. Taxes

14.1. Taxes: The Parties agree that all charges under this Agreement are inclusive of all taxes, levies, duties, contribution, withholding or impost of whatever nature (including related fines, penalties, surcharges of interest) ("**Taxes**", each "**Tax**") imposed or payable to any government, state or municipality or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world ("**Tax Authority**") except transaction taxes (e.g. value added tax, goods and service taxes, or other similar taxes) computed by reference to turnover that are required by law to be disclosed as a separate item on the relevant invoice ("**GST**") that are the responsibility of Valneva under this Agreement.

14.2. GST Invoice: Where either Party is required under this Agreement to make a supply ("**GST Supplying Party**") to the other Party ("**GST Receiving Party**") for Tax purposes, and Tax is chargeable on such supply, the GST Supplying Party shall provide the GST Receiving Party with an invoice ("**Tax Invoice**") including such particulars as are required by any law imposing Tax and such other information as required to claim any credit allowed under a law imposing Tax in respect of such supply. All Prices are exclusive of GST, which, if payable, shall be borne and paid against provision by the IDT of a valid Tax Invoice.

14.3. Excess: To the extent, in any circumstances, the GST Receiving Party has paid GST to the GST Supplying Party which it subsequently transpired was in excess of the GST actually due, the GST Supplying Party shall issue a credit note for the incorrectly invoiced items and issue a new invoice which reflects the correct GST, the net effect thereof being that the GST Supplying Party repays the excess GST amount to the GST Receiving Party.

14.4. Tax Deductions: If a deduction or withholding for or on account of Tax ("**Tax Deduction**") is required by law to be made by Valneva, the amount of payment due from Valneva to IDT shall be equal to the payment which would have been due if no Tax Deduction had been required less the Tax Deduction. Valneva shall not be required to make an increased payment to IDT for a Tax Deduction. Valneva shall co-operate reasonably with IDT to notify IDT when Valneva believes a Tax Deduction is required and in connection with any proposed actions of IDT to reduce or recover the Tax Deduction (e.g., by completing prescribed forms) provided that Valneva shall not dispense or apply a reduced rate of Tax Deduction unless IDT has provided evidence, in a form satisfactory to Valneva of authorization to do so.

14.5. Reports, Audits; Disputes; Requests for Information: [***] per calendar year, upon request by Valneva, IDT shall provide Valneva with a report confirming that IDT has an internal control framework. The Parties shall reasonably work together with respect to audits, disputes or requests for information with respect to Taxes (e.g., provision of relevant information and documents) in connection with this Agreement.

15. Confidentiality, Trade Secrets and Use of Name

15.1. Confidential Information: Neither Party shall, at any time, without the other Party's prior written consent, disclose to any Third Party any of the other Party's Confidential Information or the fact that the Shipment of Products and related Services are being conducted hereunder. Each Party shall use such Confidential Information solely for the purposes for which it was provided, i.e. for the Shipment and purchase of Products and related Services. Each Party shall take all reasonable precautions to prevent any unauthorized use or disclosure of the Confidential Information. All IDT Information is the Confidential Information of IDT. All Valneva Information is the Confidential Information of Valneva. The financial terms of this Agreement are the Confidential Information of the Parties.

15.2. Exceptions: The provisions of Clause 15.1 will not apply to any Confidential Information to the extent (i) the receiving Party can prove such information was known to it prior to the disclosure of the Confidential Information by the disclosing Party (ii) the receiving Party can prove was lawfully obtained from a Third Party without any obligation of confidentiality to the disclosing Party; (iii) is or becomes part of the public domain other than through any act or omission of the receiving Party; or (iv) is independently developed by the receiving Party without use of or reference to the disclosing Party's Confidential Information, as evidenced by the receiving Party's business records. Notwithstanding anything to the contrary, the Parties agree that nothing in this Agreement shall release the other Party from any obligations of confidentiality and non-use under any Manufacturing Services Agreement or other agreement entered into between the Parties.

15.3. Required Disclosure: Notwithstanding other provisions of this Agreement, a Party may disclose Confidential Information of the other Party to the extent and to the Persons required under Applicable Laws and Regulations, provided that, and to the extent permitted by Applicable Laws and Regulations (including, if applicable to Valneva, the securities laws and regulations in the United States and/or France), such Party (a) first gives prompt notice of such disclosure requirement to the other Party so as to enable the other Party to seek any limitations on or exemptions from such disclosure requirement, (b) reasonably cooperates at the other Party's request and expense in any such efforts by the other Party, and (c) only discloses that portion of such Confidential Information as is legally required.

15.4. Authorized Disclosure: Notwithstanding other provisions of this Agreement, a Party may also disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary to its and its Affiliates' officers, directors, employees, agents, consultants, contractors, licencees, sublicencees, legal and financial advisors, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement or the Product Schedule; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement. For clarity, and in furtherance of the foregoing, a Party may disclose Confidential Information of the other Party to any Person that intends to execute, or has executed a written definitive agreement with Valneva that pertains to the research, development, Manufacture or commercialization of the Product(s).

15.5. Return of Confidential Information: Upon the earlier of the termination of this Agreement or at a Party's request for any reason at any time, the other Party shall (a) immediately cease all use of all Confidential Information disclosed thereunder and (b) promptly, at the requestor's instruction, either return to the requestor or destroy all Confidential Information disclosed thereunder, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to the requestor the completion of such return and/or destruction, provided, however, that such Party may retain one copy solely for archival purposes.

15.6. Publicity: Neither of the Parties shall use the name of any other Party for promotional purposes without the prior written consent of the Party whose name is proposed to be used, nor shall either Party disclose the existence or substance of this Agreement except as required by Applicable Laws and Regulations. In particular, the Parties shall not make any publications, presentations, or public disclosures related to this Agreement and the subject matter thereof without the other Party's prior review and written approval.

15.7. Trade Secrets: Prior to the Effective Date and during the term of this Agreement or any Product Schedule, Valneva has, or may transfer to IDT Valneva trade secrets. In addition to the statutory rights under the German Trade Secret Act (*Gesetz zum Schutz von Geschäftsgeheimnissen*) the following shall apply:

15.7.1 [Intentionally omitted]

15.7.2. IDT hereby covenants that it (a) shall not disclose, transfer or provide access to any Trade Secrets to any person or entity except to its designated personnel that have a need to know ("Designated Personnel") for the purpose of Supplying the Products and performing relating Services under this Agreement and any Product Schedule without Valneva's prior written consent; (b) shall hold all Trade Secrets in strict confidence; (c) shall not reproduce any Trade Secrets beyond the extent reasonably necessary to perform its obligations under this Agreement or any Product Schedule; and (d) shall use at least the same degree of care (and in any event reasonable care) to maintain the secrecy and security of disclosed Trade Secrets as it uses to protect its own trade secrets. IDT hereby covenants that it shall not use any Trade Secrets transferred by Valneva hereunder for any purpose other than as expressly permitted by this Agreement and any Product Schedule.

15.7.3. Without limiting the generality of Clause 15.7 above, to safeguard the Trade Secrets, IDT agrees and covenants to take the following additional protective measures:

(a) IDT shall not permit or authorize any person or entity other than the Designated Personnel to access any embodiments of any Trade Secrets.

(b) The documents containing Trade Secrets ("**Trade Secret Documents**") shall be identified by Valneva and marked appropriately by IDT as "Trade Secret of Valneva" or as "Valneva Property" or as otherwise agreed between the Parties. The Trade Secret Documents shall be identified in an Appendix to the Product Schedule. Trade Secret Documents shall be saved at Valneva's SharePoint only and Valneva shall be responsible for the access authorization, logs etc. to such documents.

(c) The Trade Secret Documents shall not be sent by email or other non-secure electronic transmission, but rather via a secure file server provided by Valneva.

(d) Designated Personnel of IDT shall use the Valneva Trade Secrets for the Manufacturing of Valneva Product(s) and shall specifically not use any Valneva Trade Secrets to develop or perform any activities relating to another vaccine that is sold for the same indication and is the same type of vaccine as the relevant Valneva Product. Relevant Valneva Product shall mean the Product for which the Trade Secret has been transferred.

(e) IDT shall record and investigate, and promptly report to Valneva, all unauthorized attempts to gain access to the Trade Secrets. IDT shall promptly share with Valneva the results of all such investigations. Valneva shall conduct periodical security reviews to ensure compliance with the security requirements set forth in this Agreement.

(f) In the course of an Audit according to Clause 25.7 Valneva shall have the right to audit any facility at which IDT practices or that contains any Trade Secrets to determine IDT's compliance with the provisions of this Agreement. During each such audit, IDT shall permit Valneva or its representative (i) to access all Valneva records reasonably required to verify such compliance, and (ii) to conduct any inspection reasonably required to verify such compliance.

(g) This Section 15.7.2 shall supersede any prior agreement between the Parties.

16. Liability

16.1. No Exclusion or Limitation: Nothing in this Agreement limits or excludes the liability of either Party towards the other Party (and each Party shall retain unlimited liability) for any claims to the extent arising out of, relating to, or covered by any of the following: (i) personal injury or death of the other Party's personnel caused by negligence, (ii) fraud or fraudulent misrepresentation, (iii) willful misconduct, or (iv) any other liability that by law cannot be excluded or limited.

16.2. Excluded Types of Loss: Except for liability to which Clause 16.1 applies, neither Party nor any of its Affiliates or (sub)licencees shall be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any indirect, incidental, consequential, special, punitive, remote, exemplary or speculative damages, including loss of profits, or other damages that are speculative or not reasonably foreseeable as a proximate result of the breach by a Party of any of its representations, warranties or covenants under this Agreement. This Clause 16.2 shall not apply (a) to Valneva's obligation to take-or-pay the Firm Order as set forth in Clause 5.2, (b) in the event of a Party's breach of its obligations under Clause 15, (c) to the extent any such damages are required to be paid to a Third Party as part of a claim for which a Party provides indemnification under this Clause 16, or (d) fraud.

16.3. Limits of Liability: Subject to Clause 16.1, IDT's liability to Valneva under or in connection with this Agreement or the Product Schedules shall, [***], in no event exceed [***]. This Clause 16.3 shall not apply (a) in the event of a IDT's breach of its obligations under Clauses 4 or 15 or (b) for the avoidance of doubt, in the event the relevant claim or damage is caused by IDT's willful misconduct or fraud.

16.4. If any limitation of liability shall be deemed invalid by the governing law, then such liability shall be limited to the extent permitted by that law.

17. Indemnity

17.1. Indemnification by Valneva: In addition to the strict liability provisions set forth in Clause 16.1, Valneva shall indemnify, defend and hold harmless IDT, its Affiliates, and their respective directors, officers, employees and agents (the "**IDT Indemnitees**") for any Third Party claims, including reasonable attorneys' fees for defending those claims, arising out of:

17.1.1. the negligence or willful misconduct of Valneva or an Valneva Indemnitee;

17.1.2. Valneva's breach of this Agreement, including without limitation, any representations, warranties and covenants herein; and

17.1.3. personal injury, illness or death, or loss or damage to Third Party property resulting from the use of the Product, except where such personal injury, illness or death, or loss or damage results from IDT's failure to perform as set forth in Clause 17.2.3, and

17.1.4. actual or alleged infringement of any Third Party's Intellectual Property rights related to IDT's use of Valneva's Intellectual Property, Valneva Information or Valneva Confidential Information provided by Valneva and used by IDT in performing the Services in accordance with this Agreement,

17.1.5. For the sake of clarity, except in each case subject to Clause 16.1 Valneva expressly agrees that it will also be liable for and indemnify IDT against all claims of an Affiliate of Valneva and of any Third Party not satisfied by IDT's insurance and/or by IDT's limited liability set forth in Clause 16.3.

17.2. Indemnification by IDT: In addition to the strict liability provisions set forth in Clause 16.1, and subject to the limitation of liability provisions set forth in Clause 16.3 IDT shall indemnify, defend and hold harmless Valneva, its Affiliates, and their respective directors, officers, employees and agents (the "**Valneva Indemnitees**") for any Third Party claims, including reasonable attorneys' fees for defending those claims, arising out of:

17.2.1. the negligence or willful misconduct of IDT, or an IDT Indemnitee,

17.2.2. IDT's breach of this Agreement, including without limitation, any representations, warranties and covenants herein,

17.2.3. personal injury, illness or death, or loss or damage to Third Party property resulting from IDT's failure to perform the Services in accordance with the requirements of this Agreement, and

17.2.4. actual or alleged infringement of any Third Party's Intellectual Property rights arising from IDT utilizing any process, method, specifications or information in the performance of the Shipment of Product and performance of related Services or otherwise from the Services supplied under this Agreement (other than to the extent arising as a result of the lawful and correct use of any Valneva Technology in accordance with this Agreement).

17.3. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification:

17.3.1. promptly notifying the indemnifying Party in writing of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such written notice within a reasonable period shall not relieve the indemnifying Party of its obligations under this Clause 17 except to the extent, if any, the indemnifying Party is prejudiced by such failure,

17.3.2. allowing the indemnifying Party, if the indemnifying Party so requests, to conduct and control the defence of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense); provided, that the indemnifying Party shall promptly provide and continuously maintain such defence,

17.3.3. cooperating with the indemnifying Party in the defence of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense) and

17.3.4. not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

18. Insurance

18.1. Valneva: [***]. In case Valneva lacks such an insurance, Valneva will use best efforts to obtain such insurance policy, with a per claim limit and an aggregate limit which is customary in the marketing of vaccines. Without limiting the preceding sentence, Valneva shall provide IDT with at least [***] Notice prior to termination of or reduction in said coverage.

18.2. IDT: IDT will maintain, at all times during the Term of this Agreement and for a period of [***] thereafter, a general third party liability insurance including Products liability insurance policy, with a per claim limit of at least [***], and an aggregate limit of at least [***]. In addition, IDT shall maintain an environmental liability insurance policy in accordance with the EU Directive 2004/35/EC, as amended. Without limiting the preceding sentence, IDT shall provide Valneva with at least [***] Notice prior to termination of or reduction in said coverage.

18.3. Property Insurance. Either Party will ensure to have adequate insurance coverage for physical damage on "All Risks" basis of its own property used for the provision of Services and the Manufacture of Product hereunder.

18.4. Responsibility for Premiums. Each Party shall be solely responsible for paying the premiums under its respective insurance policies.

19. Term and Termination

19.1. Term of the Agreement: This Agreement shall commence on the Effective Date and shall end on the fifth (5^{th}) anniversary of the Effective Date unless sooner terminated in accordance with the terms hereof (the "**Term**"). The Term may be extended upon written agreement by Valneva and IDT. Any uncompleted Product Schedules shall continue notwithstanding the expiry of this Agreement provided that for such Product Schedules the terms and conditions of this Agreement shall apply.

19.2. Term of Product Schedule: Each Product Schedule shall remain in force for the period set forth in the Product Schedule, unless terminated earlier under Clause 19.

19.3. Termination for Convenience: Subject to the payment of any Capacity Reservation Fee (if and to the extent applicable) and the fees in accordance with Clause 5.2.2, this Agreement or a Product Schedule may be terminated by Valneva at any time upon [***] prior written notice to IDT, either in whole, or in part with respect to any Product Schedule.

19.4. Force Majeure: Each Party acknowledges and agrees that time is of the essence in respect of the Manufacture and Shipment of Product(s) and the performance of related Services. If either Party anticipates any delay in the timelines specified in any Product Schedule, due to a Force Majeure, it shall promptly notify the other Party in writing. Unless the relevant Party is able to eliminate an anticipated Force Majeure or is able to cure an actual Force Majeure event within [***] from the point in time when such Force Majeure was discovered, the Parties shall promptly meet and discuss in good faith the actions necessary to mitigate or eliminate the consequences of such Force Majeure. Should the Force Majeure not be capable of cure or remedy, the other Party shall be entitled to (at its discretion) immediately terminate this Agreement upon written notice, either in whole, or in part with respect to all or a portion of any Product Schedule.

19.5. Material Breach: This Agreement or a Product Schedule may be terminated by either Party, either in whole, or in part with respect to all or a portion of any Product Schedule, upon the material breach of this Agreement by the other Party, which material breach continues un-remedied for [***] after delivery to the non-breaching Party of notice of the material breach.

19.6. Insolvency Events: This Agreement and all Product Schedule may be terminated by either Party immediately upon written notice to the other Party in the event the other Party suffers an Insolvency Event.

19.7. All Product Schedules: If either Party has the right to terminate under Clauses 19.5 or 19.6, that Party may at its sole discretion elect to also terminate all other Product Schedules, and each relevant Valneva Affiliate may at its sole discretion elect to terminate all of its Affiliate Product Schedules (where applicable).

19.8. Change of Corporate Control: Each Party shall notify the other Party at the earliest opportunity of a possible Change of Corporate Control of those legal entities which handle this Agreement and/or a Product Schedule.

19.9. Accrued Liabilities upon Termination: Valneva shall pay for all Products and Services ordered by Valneva in any Firm Order up to the date of Termination. In addition, Valneva shall be responsible for payment to IDT of [***]. In addition, Valneva shall pay for [***].

19.10. Valneva Property. In the event of termination of this Agreement for whatever cause, in addition to the other obligations of the Parties hereunder, IDT shall return to Valneva or to the Valneva's designee, at Valneva's cost and expense and upon Valneva's request, no later than [***] after receipt of Valneva's request all of such Valneva property, including, but not limited to any Valneva Materials and Product ordered by Valneva under a Firm Order and all Valneva proprietary information, in IDT's possession, except to the extent required to be retained by Applicable Laws and Regulations or to comply with Valneva's continuing obligations hereunder.

19.11. Survival of Rights and Obligations: The expiration or termination of this Agreement or a Product Schedule shall be without prejudice to any rights or obligations that may have accrued prior to such expiration or termination. Notwithstanding expiration or termination of this Agreement for any reason, the rights and obligations under Clauses 6, 9.5, 9.6, 10, 11, 14 to 18, 19.7, 19.9, 19.10, 21, 0 and Part C will survive.

20. Assignment, Transfer and Subcontracting

20.1. Assignment: Neither Party may assign its rights and/or delegate or subcontract its obligations under this Agreement, except as expressly provided in this Agreement, whether by operation of law or otherwise, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that Valneva shall have the right, without such consent, to assign this Agreement or any or all of its rights, and/or delegate or subcontract any or all of its obligations, hereunder to any of its Affiliates or any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of its business to which this Agreement relates. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns. Any attempted assignment, delegation or subcontracting in violation of this Clause 20.1 shall be void and of no effect.

20.2. Subcontracting: IDT shall not subcontract its obligations under this Agreement to any Person (including any Affiliate) without the prior written consent of Valneva it being understood that the consent shall be deemed given for the sub-contractors which are set forth in the QAA. Such consent shall not relieve IDT from any liability or obligation under this Agreement and IDT shall be responsible for the acts or omissions of its subcontractors as fully as if they were its own. IDT's subcontractors shall comply with all the applicable terms and conditions of this Agreement. IDT shall be liable for any breach of its obligations under this Agreement resulting from actions and/or omissions of its Third Party subcontractors, unless otherwise agreed in the Product Schedule.

21. Notices

21.1. Form of Notice: Any notices given hereunder shall be sent by email (with a confirmation copy sent via courier) or via courier to the following addresses (or such other address as a Party may designate as a notice address in a prior written notice to the other Party) and shall be deemed delivered when received (or if received on a weekend or holiday, [***]) as follows. This Clause 21.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

21.2. Address for Notice:

IDT	[***]	[***]
	[***]	[***]
Valneva	[***]	[***]
	[***]	[***]

22. General

22.1. Relationship of Parties: All employees and agents of IDT that perform Services under this Agreement are employees and agents, respectively, of IDT and not Valneva during the Term and shall at all times be directed solely by IDT. IDT is acting in the capacity of independent contractor hereunder and not as employee of Valneva.

22.2. Waivers: No failure or delay by any Party in enforcing any provision of this Agreement shall be deemed a waiver of that Party's rights to later enforce that provision or any other provision of this Agreement. To be effective any waiver must be in writing and signed by the waiving Party. No single or partial exercise of any right or remedy provided under this Agreement shall prevent or restrict the further exercise of that or any other right or remedy.

22.3. Severability: If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, llegal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deleted. Any modification to or deletion of a provision or part-provision shall not affect the validity and enforceability of the rest of this Agreement.

22.4. Entire Agreement: This Agreement, the Product Schedule(s) and the QAA constitute the entire agreement between the Parties, and supersedes all prior agreements, arrangements and understandings between them, whether written or oral, with respect to the subject matter hereof.

22.5. Supremacy. To the extent there are any inconsistencies or conflicts between this Agreement and a given Product Schedule, the Product Schedule shall control unless otherwise expressly agreed to in writing by the Parties. References herein to this "Agreement" shall be deemed to include any Product Schedule entered into pursuant hereto, subject to the preceding sentence. As to quality control and quality assurance matters, the Quality Agreement shall control.

22.6. No Reliance: Each Party confirms that it is not relying on any statement, assurance, warranty or representation (whether made innocently or negligently) of the other Party except as specifically set out in this Agreement. This Clause 22.6 is not intended to limit or exclude liability for fraud or fraudulent misrepresentation.

22.7. Amendments and Modifications: Any amendment or modification of this Agreement must be in writing and signed by authorised representatives of both Parties it being understood that signatures through the DocuSign or an equivalent system shall be valid. Each Agreement formed by the entry into a Product Schedule or an Affiliate Product Schedule may only be amended or modified by way of the authorised representative of the relevant entities signing an amendment or modification to the relevant Product Schedule or Affiliate Product Schedule.

22.8. Third Parties: The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons except as otherwise provided in this Agreement. No one other than a Party to this Agreement, their successors and permitted assigns, has any right to enforce any of its terms.

22.9. Performance Through Affiliates: Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

22.10. Counterparts: This Agreement may be executed in two counterparts, each of which will be deemed an original and all of which will together be deemed to constitute one agreement. The Parties agree that the execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defence or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

22.11. Governing Law: The interpretation and construction of this Agreement shall be governed by and construed in accordance with the law of the Federal Republic of Germany, with exclusion of the [***] without giving effect to its conflicts of law provisions.

22.12. Dispute Resolution.

22.12.1. If a Party has a dispute with the other Party, then the Party raising the dispute may send a Notice of the dispute (the "**Notice of Dispute**") to the other Party. The Notice of Dispute must thoroughly describe the basis for the dispute.

22.12.2. With respect to a Notice of Dispute, the Parties, through appropriately senior executives who are authorized to resolve the dispute on behalf of their respective companies shall first meet and attempt to resolve the dispute in face-to-face or telephonic negotiations. This first attempt at resolution shall occur within [***] upon receipt of Notice of Dispute by a Party of such dispute.

22.12.3. If no resolution is reached through the Representatives within [***] of the first attempt to resolve the dispute, each Party is entitled to have the dispute be resolved by binding arbitration before [***]. All disputes arising in connection with this Agreement or its validity shall be finally settled in accordance with the Arbitration Rules of the International Chamber of Commerce, without recourse to the ordinary courts of law. Notwithstanding the forgoing any dispute relating to the scope, validity, enforceability or infringement of any patents or trademarks shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

22.12.4. The venue for any arbitration under this Article shall be [***] and the language of the proceedings (including all documentation) shall be [***].

22.12.5. No information concerning an arbitration, beyond the names of the Parties and the relief requested, may be unilaterally disclosed to a Third Party by any Party unless required by law. Any documentary or other evidence given by a Party or witness in the arbitration shall be treated as confidential by any party whose access to such evidence arises exclusively as a result of its participation in the arbitration, and shall not be disclosed to any Third Party (other than a witness or expert), except as may be required by law.

22.12.6. In any arbitration hereunder, subject to contrary direction by the arbitrators if, in their judgment particular circumstances require broader pre-hearing disclosures and investigation, discovery prior to hearing shall presumptively be limited to [***] and to [***].

22.12.7. The Parties irrevocably agree that a final judgment in any arbitration proceeding relating to this Agreement shall be conclusive (except for manifest error) and shall be enforceable in any court having jurisdiction thereof, provided, however, that the arbitrators shall not have authority to alter any explicit provision of this Agreement.

22.13. Equitable Relief: A breach by either Party of the confidentiality obligations in Clause 15 may cause irreparable damage and the non-breaching Party may not be adequately compensated by monetary damages. In the event of a breach, or threatened breach, of those obligations, the non-breaching Party shall be entitled to seek from any court of competent jurisdiction equitable relief, whether preliminary or permanent, without the need to show irreparable harm or the inadequacy of monetary damages as a remedy and without the requirement of having to post a bond or other security. Nothing in Clause 22.12 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

22.14. Interpretation: Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to include the Person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Clauses and Parts shall be construed to refer to Clauses and Parts of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) all references to a number of days, unless otherwise specified, such number refers to calendar days, (i) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by email, written agreement, letter, approved minutes or otherwise (but excluding instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."

PART B: WAYS OF WORKING

23. General Principles

23.1. General Principles: The Parties represent that they: (a) will perform this Agreement and operate its business in compliance with all Applicable Laws and Regulations, (b) commit to ethical standards consistent with basic principles of corporate responsibility and integrity, human rights and work standards, environmental standards and anticorruption requirements, particularly as they are set forth in the 10 principles of the UN Global Compact (https://www.unglobalcompact.org/what-is-gc/mission/principles) (c) will not take any action that will cause the other Party to be in breach of any Applicable Laws and Regulations for the prevention of fraud, bribery and corruption, racketeering, money laundering or terrorism, and product safety.

23.2. Data Privacy. Each Party is responsible for complying with applicable data protection legislation. Within this Agreement each Party determines the purposes and the means of its processing of personal data and each Party is therefore an independent data controller for such processing.

Valneva's processing of personal data is described in its Privacy Policy published on its website https://www.valneva.com/en/legal/privacy-policy.

24. Compliance.

24.1. Compliance: Each Party recognizes the other Party's commitment to working only with partners who embrace standards of ethical behavior that are consistent with those set forth in in Clause 23 and operate its business in compliance with all laws and regulations applicable thereto. Each Party will use reasonable efforts to cause its personnel, Affiliates, suppliers and subcontractors performing Services under this Agreement to comply with those expectations.

24.2. Debarment: Both Parties represent, warrant and undertake that they are not on any applicable official national or international sanctioned party lists and that performance of this Agreement will not violate applicable embargo regulations. The relevant Party has the right to conduct screening checks of the other Party, including verification of its identity, full name, country location and address, against official national and international sanctioned party lists and embargo regulations.

24.3. Termination: A breach by a Party of this Clause 24 shall give the other Party the right to terminate this Agreement with immediate effect. Further claims of the terminating Party shall remain unaffected. In addition, the Party in breach of this Clause 24 shall indemnify, defend and hold the other Party, its Affiliates, and their employees, directors and officers harmless from any and all liabilities, costs, and damages resulting from such breach.

25. Regulatory Matters and Audits

25.1. Filings with Regulatory Authorities: Unless otherwise consented by the Parties, as between the Parties, Valneva is entitled to file, and shall have the sole responsibility for filing, all documents with the applicable Regulatory Authorities and taking any other actions that may be required or necessary in order to obtain Regulatory Approval of the Products. IDT shall, upon Valneva's Request,, provide Valneva with reasonable assistance and cooperation in connection with making such filings with Regulatory Authorities. Unless otherwise agreed in any Product Schedule, such services and fees thereof, are described in Part D "Additional Services" of this Agreement. For the sake of clarity, Valneva shall be solely responsible for the compliance of the Manufacturing with the marketing authorization and the dossier, especially but not limited to the agreed upon Manufacturing Specifications, Product Specification, raw materials and manufacturing instructions (e.g. master batch records).

25.2. Licences and Certificates: IDT will ensure that any and all permits, licences, registrations, and approvals required by Applicable Laws and Regulations in connection with the Manufacture of the Product hereunder have been obtained and that such permits, licences, registrations, and approvals will be maintained during the Term of this Agreement. IDT will maintain the IDT Facility in a state of repair and operating efficiency consistent with industry standard practices and all Applicable Laws and Regulations.

25.3. Communications with Regulatory Authorities: Without undue delay but in any event within [***] of any contact with, or after receipt of any communication from, a Regulatory Authority that may be reasonably expected to affect the Manufacture of the Product or the performance of Services hereunder, including in connection with an audit by said Regulatory Authority of the IDT Facilities, each Party shall forward to the other Party a copy or description of the same and shall confer with the other Party with respect to the best means to comply with any new or modified requirements of such Regulatory Authority. IDT shall provide Valneva with a copy of all draft responses for comment as soon as possible and shall consider Valneva's comments in good faith. Valneva shall submit any comments on said draft responses within [***] or within such longer period as agreed by the Parties. In case Valneva receives questions and queries from a Regulatory Authority concerning IDT, Valneva shall forward to IDT such questions and queries and IDT shall respond as soon as possible at Valneva's costs which fees are set forth in the Part D "Additional Services".

25.4. Documentation: IDT will maintain complete and accurate documentation of all quality control procedures and any other data required under applicable GMP and other requirements of any Regulatory Authority in connection with the Manufacturing, storage, and Shipment of Product. IDT will provide Valneva with copies of such documentation in English language and in accordance with the terms of the QAA or otherwise upon Valneva's Request.

25.5. Regulatory Authority Inspection: IDT will permit Regulatory Authorities to conduct inspections relating to the Product and will cooperate fully in connection with such inspections pursuant to applicable provisions of the QAA.

With respect to any such Regulatory Authority inspection that relates solely to the Product, IDT will invoice to Valneva a fee equal to [***] and [***]. IDT shall Notify Valneva of the results of the inspection within a reasonable period after receipt of such results.

25.6. Regulatory Authority Change: In the event that any Regulatory Authority requires Valneva to change the Product Specification, IDT shall use Commercially Reasonable Efforts to accommodate any Request from Valneva relating thereto which change will be set forth in a formal amendment to the relevant Product Schedule. In the event that any Regulatory Authority requires IDT to change the Facilities or any process or activity that affects the Manufacture of the Product, Valneva shall use Commercially Reasonable Efforts to accommodate any Notice from IDT relating thereto. Unless otherwise provided in the Product Schedule, the costs incurred and fees charged of any such change shall be borne by the Party requesting the change, provided, however, that the costs of any change of IDT's Facilities required by any Regulatory Authority in connection with any submission for Regulatory Approval by Valneva or otherwise relating to activities of Valneva or affecting matters other than general, not Product related GMP shall be the responsibility of Valneva.

25.7. Right of Audit: Valneva or its representatives shall have the right, upon reasonable advance Notice and during IDT's normal business hours, to perform due diligence on the IDT Facilities including on-site audit of the IDT Facilities, which audit will cover Valneva Materials, Other Materials, Equipment and other Valneva Product (including intermediates relating thereto), operations, quality systems, EHS systems and Manufacturing Process and any and all records and documentation relating to the Products and Manufacturing Process solely to ascertain compliance with the terms of this Agreement, QAA and the respective Product Schedule. Valneva, solely at its own cost and expense, will also have the right, subject to IDT's Consent and at a mutually agreeable time, to conduct general inspections for "mock" pre-approval audits upon reasonable Notice to IDT, and the Parties agree to cooperate in such "mock audits" prior to Regulatory Approval of the Product(s).

Each Party will disclose to the other Party all relevant findings resulting from any audit it performs hereunder.

25.8. Audit Fee: The Parties agree that Valneva shall pay IDT a fee for the pre-qualification audit, any Valneva audit which occur more frequently than [***], and any Third Party audits. Such fee shall be at a rate of [***].

26. Corrective and Preventative Action

26.1. Corrective and Preventative Action: If any findings arising out of an audit performed by Valneva or its authorized agents related to the Product require Corrective and Preventative Action ("**CAPA**"), IDT will develop a plan and determine the appropriate CAPA for implementation. IDT will share such plan and CAPA with Valneva and the Parties will discuss corrective measures and fees, if applicable, in good faith.

26.2. Disagreements: If there is any disagreement regarding audit findings, proposed CAPA and/or implemented CAPA, or whether a CAPA is required or whether a proposed CAPA adequately addresses an audit finding, the quality assurance representatives of Valneva and IDT will attempt in good faith to resolve any such disagreement. If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not [***]) the matter shall be decided by the IDT QP.

27. Person-in-Plant

27.1. Person in Plant: Upon the Request of Valneva, and with the related costs, expenses and IDT fees to be borne by Valneva as set forth in the Part D "Additional Services", IDT shall permit one (1) named employee of Valneva, its Affiliates or its designee (the "**Valneva Representative**") to be present at such areas of the IDT Facilities where the Product is Manufactured, during normal working hours, it being understood that the PIP does not have access to the clean rooms. IDT shall provide the Valneva Representative with reasonable office space (including necessary furniture and Internet access) within the IDT Facilities during the Term. For clarity, any named employee of Valneva, its Affiliates or its designee that is supporting IDT, upon request by IDT, in the Manufacture of Product(s) shall not be included in the definition of a "Valneva Representative" and IDT shall consequently not charge any fees to such supporting representative of Valneva.

27.2. Scope: Notwithstanding the foregoing, the scope of the activities of the Representative shall be limited to:

27.2.1. observing and monitoring the Services;

27.2.2. reviewing the Raw Materials, Valneva Materials, Equipment and work-in-progress relating to the Manufacture of Product;

27.2.3. inspecting records (excluding any financial records) that IDT is required to keep and to make available to Valneva in accordance with the QAA and this Agreement; and

27.2.4. participating in discussions between the Parties relating to Valneva's requirement of Product, scheduling of the Manufacture and Delivery of Product.

28. Continuous Improvement and Change Procedure

28.1. Regulatory Changes, Improvements, Efficiencies and Savings: Both Parties shall in the course of the Manufacturing of Products and performance of related Services inform the other Party of any efficiencies, savings and environmental improvements, including but not limited to improvements to the Manufacture of the Product ("**Improvement**"). In case one Party suggests an Improvement, the other Party shall take such Improvement into consideration and, if applicable, subject to an amendment to this Agreement, the QAA or the Product Schedule, use Commercially Reasonable Efforts to implement such an Improvement. In case any Regulatory Authority requests a change, such change shall be implemented by IDT upon Valneva's request.

28.2. Change Procedure: Any Improvement or change (e.g. changes to the Product or the Manufacturing process, Manufacturing facilities or sub-contractors or materials used by IDT to Manufacture the Product) shall be subject to the change control procedure set out in the QAA prior to implementation.

28.3. Costs of Change: All costs for any change of, especially but not limited to, the Manufacturing process, Manufacturing facilities, sub-contractors or materials shall be discussed in good faith between the Parties, it being understood that, as a general rule, the costs of such change shall be distributed as follows:

28.3.1. [***];

28.3.2. [***];

28.3.3. [***]; or

28.4. Benefits of Change: [***].

PART C: DEFINITIONS

Definitions: In this Agreement:

Affiliate	means, with respect to a Party, any Person that Controls, is Controlled by or is under common Control with such Party from time to time.
Agreement	has the meaning set out in the preamble of this Agreement.
Applicable Laws and Regulations	means all national, supra-national, federal, state, local, foreign or provincial laws, rules, directives, regulations, including but not limited to GMP as well as any guidance, guidelines and requirements of any Regulatory Authorities, including but not limited to export controls and economic sanctions, and any established industry codes of practice, in effect from time to time applicable to the activities performed by IDT under this Agreement.
Arbitration Notice	has the meaning set out in Clause 22.12.3.
Arbitrators	has the meaning set out in Clause 22.12.3.
Batch	has the meaning set forth in each respective Product Schedule.
Commercially Reasonable Efforts	means with respect to the obligations of a Party under this Agreement, that level of efforts which would typically be required to carry out such obligations in a diligent, expeditious and sustained manner using efforts and resources, including reasonably necessary personnel and financial resources, companies of comparable size and resources typically devote to similar obligations.
Background IP	means all Intellectual Property, results, data, inventions and information necessary to perform the activities under the Agreement (i) owned by a Party (or owned by a Third Party licensor but licensed to a Party with the right to disclose or sub-license) prior to the date that the Product Schedule comes into effect or (ii) developed by a Party during the Term independently of the Services performed under a Product Schedule and without the use of or reliance upon the other Party's Intellectual Property or Confidential Information. Background IP may be specified in the Product Schedule.
Business Day	means any Monday, Tuesday, Wednesday, Thursday or Friday that is not a public holiday in Austria or Saxony-Anhalt, Germany.
Capacity	has the meaning set out in Clause 1.2.
Capacity Reservation	has the meaning set out in Clause 1.2.
Capacity Reservation Fee	has the meaning set out in Clause 1.2.
Certificate of Analysis	means the certificate of analysis to accompany all cGMP-manufactured Product delivered to Valneva as set out in the QAA.
GMP	Shall have the same meaning as defined in the QAA.
Change in Law	means any change in any Applicable Laws and Regulations that: (i) impacts on the Product, (ii) comes into force after the date that the Product Schedule came into effect, and (iii) was not known about, and could not reasonably have been known about, before that date.

Change of Corporate Control	means with respect to a Party an event in which: (i) any other Person or group of Persons acquires Control of such Party, or (ii) the Party enters into a merger, consolidation or similar transaction with any other Person or group of Persons in which such Party is not the surviving entity.
Confidential Information	means any and all data and information, whether or not marked as "confidential" and/or "proprietary" including results relating to the Product(s), any Manufacturing process, and/or to processes or cell lines, of a confidential nature not generally known to the public before its disclosure that is learned, created by, disclosed to or becomes known by a Party under this Agreement, whether disclosed in written, oral, electronic or any other form, including Know-How, operational methods, processes, formulae, samples, cell banks, Product Specification(s), analytical methods as well as any details of commercial, business, technical, pharmaceutical, scientific and industrial nature, and also business plans and strategy, research and development including but not limited to pre-clinical studies and current and future clinical trials, relationships with Third Parties, technology, Trade Secrets, Intellectual Property rights, know-how, proprietary information, inventions (whether or not patentable), patent applications, licenses, software, programs, prototypes, designs, analysis codes, discoveries, techniques, methods, ideas, concepts, data, engineering and manufacturing information, diagrams, drawings, schematics, blue prints, parts lists, and samples, and financial information, and also the confidential information of any Third Party which is lawfully disclosed by or on behalf of a Party to the other Party. The cell lines are proprietary to Valneva and used in the Shipment of Products and the performance of related Services and constitute Confidential Information of Valneva.
Control	means: (i) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (ii) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person, or (iii) in the case of a partnership, control of the general partner, and "**Controls**" and "**Controlled**" shall be construed accordingly.
Dispute	has the meaning set out in Clause 22.12.2.
Documents	means reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, computer programs and documents, computer information storage means, samples of material, other graphic or written data and any other media on which Know-How can be stored.

Effective Date	has the meaning set out in the preamble of this Agreement.
EMA	means the European Medicines Agency.
FDA	means the USA Food and Drug Administration.
FMD	has the meaning set out in Clause 28.
Firm Order	has the meaning set forth in Clause 3.
Force Majeure	means any unforeseeable, exceptional situation or event beyond the control of the Parties that prevents either of them from fulfilling any of their obligations under this Agreement and/or any Product Schedule. The situation or event must not be attributable to a breach of this Agreement or any Product Schedule on the part of the Parties or on the part of its subcontractors. Such events include fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other employment disturbances (whether involving the workforce of the non-performing party or of any other person) or acts, omissions or delays in acting by any governmental authority.
Forecast	has the meaning set forth in Clause 2.1.
IDT	has the meaning set out in the preamble of this Agreement.
IDT Forecast	has the meaning set forth in Clause 8.1.
IDT Indemnitees	has the meaning set out in Clause 17.1.
IDT Information	means all data and information related to or comprised in Intellectual Property, as well as other proprietary or confidential information in relation to IDT's general business operations and Manufacturing processes and trade secrets, which is owned or controlled by IDT or its Affiliates and which IDT or its Affiliates are entitled to disclose.
IDT QP Release Statement	means a statement or certificate signed by the IDT QP, confirming that the Manufacturing of Product described therein has been performed in accordance with the Manufacturing Specifications.
Improvement	means any invention, improvement, discovery, extension of Know-How, upgrading or modification and all other Intellectual Property rights (whether patentable or not) arising during this Agreement made, generated, developed or arising from, or related directly or indirectly to, the Confidential Information. Improvements include any manufacturing processes, any new indication, dosage forms, formulations or delivery systems, but exclude Inventions;
Ineligible Person	has the meaning set out in Clause 24.
Insolvency Event	means that a Party: (i) suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due, (ii) is the subject of a petition, notice, resolution or order for its winding up, (iii) has an administrator, administrative receiver or receiver appointed over it or its assets or is the subject of any formal step taken as part of the process of making such an appointment, (iv) has assets that a creditor or encumbrancer has attached or taken possession of, or in respect of which a distress, execution, sequestration or other such process is levied or enforced on or sued against, or (v) is subject to any similar event or proceeding in any jurisdiction.

Intellectual Property	means Know-How, Patent Rights, trademarks, service marks, trade names, design rights, copyright (including rights in computer software) and any similar or equivalent rights or property or forms of protection in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.
Invention	means any invention, improvement, discovery, extension of Know-How, upgrading or modification and all other Intellectual Property (whether patentable or not) arising during this Agreement made, generated, developed or arising from, or related directly or indirectly to each Product Schedule.
JSC	means the joint steering committee established by the Parties in accordance with Clause 1.7.
Know-How	means technical information, data and other information which is not in the public domain including: (i) information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries, (ii) practices and instructions of, and scientific, analytical and technical data and studies for, synthesis, manufacturing, pharmaceutical processing, formulation, packaging, labelling, storage and transportation, and (iii) non-clinical and clinical data and studies. Know-How includes Documents containing Know-How. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public. Know-How includes any rights including trade secrets, copyright, database or design rights protecting such Know-How.
Latent Defect	defects which could not have been ascertained by Valneva by the exercise of reasonable diligence.
Losses	means any and all liabilities, claims, demands, causes of action, damages (included but not limited to damages caused by the handling and storage), loss, costs and expenses, including interest, penalties, reasonable professional fees and reasonable lawyers' fees on a solicitor client basis together with disbursements.

Manufacture or Manufacturing or Manufactured	shall mean all operations in the manufacture of the Product to Valneva hereunder in accordance with the Specifications, the relevant Product Schedule, this Agreement and the QAA.
Non-Conformance	means any non-compliance of the Products with the Product Specifications, or Product not Manufactured in accordance with GMP, as specified in this Agreement, the Product Schedule, and/or the QAA.
Obvious Defect	Defects, including but not limited to damages to, and shortages of Product Shipped, which may be ascertained by visual inspection by Valneva on receipt of the Product by the exercise of reasonable diligence.
Other Materials	means materials that IDT shall procure which are required in order to perform its obligations in accordance with the terms of this Agreement and any Product Schedule.
Parties	means Valneva and IDT, and "**Party**" means either of Valneva or IDT.
Patent Rights	mean patent applications and patents (including but not limited to inventions, utility models and industrial designs), inventors' and authors' certificates, improvement patents, and patents of addition and administrative protection (such as pipeline protection) and all foreign counterparts of them in any and all countries, and including any divisional applications and patents, re-filings, renewals, continuations, continuations-in-part, extensions (including patent term extensions), reissues, re-examinations, substitutions, confirmations, registrations, revalidation, importation and additions, and any equivalents in any and all countries, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them in any and all countries.
Person	means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a Regulatory Authority.
Price	means the amount payable from time to time for a Product, as determined in accordance with the terms of this Agreement and the relevant Product Schedule.
Product	means the product to be Manufactured by IDT under this Agreement and as described in greater detail in the relevant Product Schedule.
Product Schedule	means a schedule completed and entered into between the Parties for the Manufacture, Release and Shipment of a validated Product,
Purchase Order	means a purchase order with a unique number issued by Valneva (or an Affiliate of Valneva) stating quantities of the Product that Valneva commits to purchase from IDT and IDT commits to Manufacture and Deliver to Valneva and the required Delivery date.
QAA	means the Quality Assurance Agreement entered into by the Parties and/or their Affiliates from time to time, or where a quality assurance agreement has not been entered into, the agreed specification and quality requirements relating to a Product.

Regulatory Authority	means FDA, MHRA and EMA or any court or government body, whether national, supra-national, federal, state, local, foreign or provincial, including any political subdivision, including any department, commission, board, bureau, agency, or other regulatory or administrative governmental authority or instrumentality, and further including any quasi-governmental person or entity exercising the functions of any of these in each case having jurisdiction in any country or other jurisdiction in which the applicable Product is Manufactured, distributed, marketed, or sold as are expressly set forth in the Product Schedule.
Release	means the time when the IDT QP signs the IDT QP Release Statement.
Services	has the meaning set out in Clause 4.1.
Shipment or **Ship** or **Shipped**	means Product shipped, or the shipment of Product fulfilling the requirements of the agreed upon Incoterm.
Specifications	means the procedures, requirements, standards, quality control testing and other data and the scope of Services set forth in (i) the master batch record and/or master packaging batch record applicable to the Product, (ii) the QAA, (iii) the Products Schedule, and (iv) any additional specifications.
Taxes or **Tax**	has the meaning set out in Clause 14.1.
Term	has the meaning set out in Clause 19.1.
Third Party	means any Party other than Valneva, IDT or their respective Affiliates.
Trade Secrets	means the trade secrets listed in a Product Schedule, as amended from time to time.
Valneva Equipment	means capital equipment 1) supplied by Valneva to IDT, or 2) purchased by IDT and paid by Valneva, necessary for the Manufacture of the Product or the performance of the Services.
Valneva Indemnitee	has the meaning set out in Clause 17.2.
Valneva Information	means all data and information related to or comprised in Intellectual Property as well as other proprietary or confidential information in relation to Valneva's and its Affiliates' general business operations, technology and products, the Product or their Manufacture or packaging, or trade secrets which is owned or controlled by Valneva or its Affiliates and which Valneva or its Affiliates are entitled to disclose.
Valneva Materials	means any materials supplied by Valneva and/or its Affiliates and/or its agents to IDT for use exclusively in performing the Manufacturing of Product(s) and performing the Services, as listed in each respective Product Schedule.

PART D: ADDITIONAL SERVICES

Item	Description	Service Fee per Order Unit in €	Order Unit	Remarks
1	[***]			
	[***]	[***]	[***]	
	[***]	[***]		[***]
	[***]	[***]	[***]	
	[***]	[***]	[***]	
2	[***]	[***]		
3	[***]	[***]		
4	[***]	[***]		
5	[***]	[***]		
6	[***]	[***]		
7	[***]	[***]		[***]
9	[***]	[***]		
9	[***]	[***]		

The services and related costs set forth herein are in addition to the Manufacturing and related Services under this Agreement and the Product Schedule.

Execution

This Agreement is executed as of the Effective Date by the authorized representatives of the Parties.

SIGNED for and on behalf of

Valneva Austria GmbH

Date: 29 November 2021

By:

Name: [***]

Title: [***]

Date: 29 November 2021

By:

Name: [***]

Title: [***]

SIGNED for and on behalf of

IDT Biologika GmbH

Date: 26 November 2021

By:

Name: [***]

Title: [***]

Exhibit 10.7

SUPPLY PRODUCT SCHEDULE PRODUCT VLA2001_FINAL

[***] = 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 SARS-Cov-2 (DRUG BULK PRODUCT)

This Product Schedule (this "**Product Schedule**") is entered into as of November 26, 2021 ("**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 shall be incorporated into this Product Schedule.

This Product Schedule concerns (i) the Manufacturing, Release and Shipment of [***] Batches of Product (as defined below) of Valneva's proprietary vaccine candidate VLA2001 for SARS-CoV-2 in calendar year 2022 for which IDT reserved capacity in accordance with the VLA2001 Manufacturing Services Agreement between the Parties with the effective date [***] ("**MSA**") and this Product Schedule and which quantity shall be ordered by Valneva in accordance with this Product Schedule, and (ii) the call option for Valneva to request the Manufacturing, Release and Shipment of further Batches in calendar year 2023.

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 "**Batch**" shall mean the output of a series of manufacturing steps in accordance with the Specification(s) [***] of Product.

2.2 "**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.

2.3 **"Expected Yield"** shall be defined in Clause 5.4.

2.4 **"Firm Supply Commitment"** shall be defined in Clause 6.3.

2.5 "**Product**" means the fully formulated bulk drug product material Manufactured in accordance with and conforming to the Specifications set forth in **Appendix A** attached hereto.

2.6 **"Shipment"** shall be defined in Clause 8.1.

2.7 **"Late Delivery Fee"** shall be defined in Clause 8.7.

2.8 "**Price**" means the price for the Products as set out in Clause 10.1 to this Product Schedule.

2.9 "**QAA**" means the Quality Assurance Agreement entered into between the Parties and signed on [***], 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).

Any capitalized terms used but not defined in this Project Schedule shall have the meanings ascribed to them in the Master Agreement.

3. RESERVATION FEE, CAPACITY RESERVATION AND RESERVATION PERIOD

3.1 In the MSA the Parties agreed that IDT would commit to reserve the required capacity at IDT's production facilities in Dessau-Rosslau sufficient to secure the Manufacture of certain Batches of Bulk Drug Product (as defined in the MSA) for commercial supply. In accordance therewith, the Parties hereby agree that IDT will reserve capacity necessary for the Manufacture of a total of [***] Batches of Product during calendar year 2022 ("**Capacity Reservation**").

3.2 The Parties acknowledge that the Parties agreed in the MSA that Valneva shall make a total payment of [***] to IDT upon [***] (the **"Capacity Reservation Fee"**) and that a certain portion of the Capacity Reservation Fee accounted for IDT's verified external recruitment costs. The Parties further acknowledge that the Capacity Reservation Fee less the recruitment costs shall be credited proportionally, as set forth in Clause 10.2 below, against Batches of Product purchased**.**

3.3 The Capacity Reservation Fee paid by Valneva and credited in accordance with Clause 10.2 below, shall be non-refundable, except in case IDT fails to provide all or part of the capacity which is to be reserved pursuant to this Product Schedule, in which event IDT shall refund to Valneva [***]. Such refund shall be in addition to any other remedy available to Valneva under this Product Schedule and/or under the Master Agreement due to IDT's failure to Manufacture, Release and Ship Product under the 2022 Firm Orders.

4. TERM AND TERMINATION OF PRODUCT SCHEDULE

4.1 This Product Schedule shall enter into effect on November 26, 2021 ("**Effective Date")** and shall remain in effect until 31 December 2023, or as otherwise agreed upon between the Parties, unless terminated earlier by either Party as permitted under the Master Agreement ("**Term**").

4.2 Should IDT fail to deliver [***] successful PPQ Batches Manufactured under the Manufacturing Services Agreement between the Parties effective as of [***] ("**MSA**") on or before [***], then Valneva shall have the right to terminate this Product Schedule, subject to Clause 11.3, without incurring any liabilities. The shipment of the last of the [***] PPQ Batches under quarantine on or before [***] shall be decisive for the determination of the timely delivery.

4.3 In addition to the termination provisions set forth in Clause 19 of the Master Agreement and above, Valneva shall have the right to terminate any outstanding Batches ordered in accordance with **Appendix B** but not Shipped to Valneva by [***]. For clarity, Valneva shall have no obligation to pay any cancellation fee according to Clause 5.2.2 of the Master Agreement.

5. MANUFACTURING TERMS AND YIELD

5.1 Valneva Background IP: IDT acknowledges and agree that the manufacturing process pertaining to the Product is Valneva Background IP. The Parties do not anticipate that IDT will use any of its Background IP in the Manufacturing of Product, however in case there is such a need, Clause 1.3.3 of the Master Agreement shall apply.

5.2 Manufacturing Plan. The Manufacturing activities to be performed for the supply of the Firm Purchase Orders until certain weeks for calendar year 2022 are set forth in the manufacturing plan ("**Manufacturing Plan**") attached hereto as **Appendix B**. The Manufacturing activities to be performed until certain months for the supply of Product related to the Batches Called, upon Valneva's exercise of the option as defined in Clause 6.2, are set forth in the manufacturing plan for calendar year 2023 attached hereto as **Appendix G** ("**2023 Manufacturing Plan**").

5.3 Specifications including Master Batch Record. IDT shall Manufacture the Product in accordance with the requirements set forth in the Master Agreement and in accordance with the master batch records. The Product shall comply with the Specifications described in **Appendix A-1** and the expectations set forth in **Appendix A-2** ("**Valneva Expectations**"). The Valneva Expectations shall only be relevant if and to the extent they are part of the marketing authorization of the Product. The compliance of Product Shipped by IDT with the Valneva Expectations shall be tested by Valneva. In case of Regulatory Authorities requests revisions or additions to the Specifications set forth in Appendix A-1 and/or the Valneva Expectations such revisions shall be agreed upon and implemented in accordance with Clause 25.6 of the Master Agreement. IDT warrants that the Product (1) shall comply with the Specifications for the Product and (2) shall be Manufactured in accordance with GMP in effect at the time of Manufacture.

5.4 Yield. After finalization of the Manufacture of the first [***] Batches, the Parties will review actual yields of each Batch ("**Actual Yield**") and calculate the average yield according to the Yield Calculation (**Appendix E**), which will become the "**Expected Average Yield**". Thereafter, on a regular basis, after the Manufacture and Shipment of each following [***] Batches, within [***] of such Shipment, the Actual Yield of each Batch of Product of that [***] Batches and the Expected Average Yield shall be reconciled and reported to the JSC. If upon reconciliation the Actual Yields in average for the applicable [***] Batches are above [***] of the Expected Average Yield, Valneva shall pay the Batch Price of Product set forth in Clause 10.1 below. If IDT fails to meet the Expected Average Yield by [***] or more in that period, then IDT will credit Valneva with [***].

The Parties shall determine and discuss in good faith the minimum formulation volume and the minimum titer per Batch ("**Minimum Yield**") after the successful production of the [***] consecutive PPQ batches in accordance with the MSA and in addition the Specifications defined in **Appendix A-1** and **Appendix A-2**. Batches with lower yields than the Minimum Yield shall be considered a Product in Non-Conformance and Clause 10 of the Master Agreement shall apply to such Product in Non-Conformance.

6. FIRM PURCHASE ORDERS FOR 2022, CALL OPTION FOR DOSES IN 2023 AND SUPPLY COMMITMENT

6.1 Firm Purchase Orders for Manufacture and Shipment in 2022: Valneva herewith orders [***] Batches of Product to be Manufactured by IDT in calendar year 2022 as further set forth in **Appendix B ("Firm Purchase Orders")**.

6.2 Call Option for Calendar Year 2023: Valneva has the right to request the Manufacture of between [***] and [***] Batches to be Manufactured and Shipped by IDT to Valneva in calendar years 2022 and 2023 in accordance with the 2023 Manufacturing Plan (**Appendix G**) ("**Call Option**") and undertakes to notify IDT as follows:

Number of Batches Called for Manufacturing	**Call Option Date**	**Capacity Slot Fee**
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

On [***] the Call Option expires and Valneva has to pay a capacity slot fee of [***] unless Valneva has exercised the option in accordance with the table above. For clarity, Valneva has the right, at its own discretion, not to exercise the Call Option on or before [***] without any liabilities. Valneva shall inform IDT in writing not later than by [***] in case Valneva does not wish to exercise the Call Option whereby the Call Option will expire upon notice.

[***]

IDT shall Manufacture the amount of Batches called for ("**Batches Called**") in accordance with the indicated call option dates ("**Call Option Dates**") set forth above in accordance with the 2023 Manufacturing Plan (**Appendix F**). For clarity, if and to the extent IDT has to Manufacture replacement Product related to the Firm Purchase Orders after the initially planned Manufacturing slots according to **Appendix B**, the 2023 Manufacturing Plan shall start at an accordingly later time and the Manufacturing Dates shall be shifted accordingly. IDT will reserve Manufacturing capacity for the applicable Batches Called and will Manufacture and Ship such Batches covered by Valneva's Purchase Orders in accordance with the 2023 Manufacturing Plan.

6.3 Firm Supply Commitment: IDT hereby commits to Manufacture and Ship to Valneva [***] Batches in accordance with the Manufacturing Plan set forth in **Appendix B** and for calendar year 2023 IDT commits to Manufacture and Ship the amount of Batches Called by Valneva in accordance with Clause 6.2 above, provided that the PPQ runs, which are essential part of the transfer, have been manufactured successfully by IDT **("Firm Supply Commitment")**. If one or several PPQ runs are not successful, the Parties shall discuss in good faith an amendment to the **Appendices B** and **G**, taking the new manufacturing dates due to the delayed delivery of the PPQ batches into consideration, subject always that if PPQ runs are not successful on or after [***], Clause 4.1 above shall apply.

6.4 In accordance with Clause 5.2 of the Master Agreement, Valneva shall 'take or pay' for its Firm Purchase Orders for 2022 and for the amount of Batches Called in 2023 in accordance with Clause 6.2 above. In addition to Clause 5.2 of the Master Agreement the following shall apply: If IDT fails to provide all or part of the capacity which is to be reserved pursuant to this Product Schedule and IDT's Firm Supply Commitment, IDT shall refund to Valneva [***] and Valneva's obligations to 'take and pay' for its Firm Purchase Order shall cease.

7. FORECAST AND ORDER PROCEDURES

7.1 Forecasts: The Parties agree that there will be no forecasting process for the calendar years 2022 and 2023.

7.2 Purchase Orders: On or before the [***] following each calendar quarter Valneva shall provide to IDT Purchase Orders covering Valneva's purchases of the Product during the following calendar quarter pursuant to its Firm Purchase Orders set forth in **Appendix B** or any Batches Called as set forth in **Appendix G**, as the case may be.

Without modifying or limiting IDT's obligations hereunder to Manufacture and Ship Product or Valneva's obligations to purchase Product, IDT, without undue delay, will send to Valneva a written confirmation of each Purchase Order that complies with the terms of this Product Schedule or inform Valneva of a noncompliant Purchase Order and, thereafter, if the Purchase Order is noncompliant, Valneva will promptly issue a compliant Purchase Order. Unless any Purchase Order is rejected by IDT within [***] after IDT's receipt, said Purchase Order shall be deemed to have been accepted by IDT. Notwithstanding anything to the contrary, IDT is not permitted to reject Purchase Orders to the extent they are consistent with the Firm Purchase Orders or any Batches Called.

8. REPORTING, SHIPMENT AND LATE DELIVERY FEE

8.1 Reporting: IDT shall provide Valneva with the following reports:

On the date of finalization of the Manufacture of a Batch, and in any event not later than the date of Shipment of Product, IDT shall provide Valneva with a report including Valneva Materials used during the Manufacture together with the Actual Yield in litres of such a Batch ("**Consumption Report**"),and

Not later than by [***] in any calendar month, IDT shall provide Valneva with a stock report listing all Valneva Material that remains unused by IDT at the last day of the of the foregoing calendar month. Such stock report shall be sent to the email address: [***].

8.2 Shipment under Quarantine: The Product shall be Shipped to Valneva under quarantine [***] following the Manufacturing together with the Written Statement (defined below) and otherwise in accordance with the QAA ("**Shipment under Quarantine**"). For the sake of clarity, at the time of such Shipment under Quarantine no testing results will be available to Valneva. For further clarification, IDT shall invoice the Price upon Shipment under Quarantine. IDT shall inform Valneva including sending an email to the following email-address: [***] upon Shipment of the Product.

Further Processing post Shipment: Upon Shipment, IDT shall provide Valneva with a written statement that, based on the documentation available at the date of Shipment, the Product has been Manufactured in accordance with GMP and that no critical deviations occurred during Manufacture ("**Written Statement**"). After Shipment Valneva shall be solely responsible for the further processing of Product Shipped under Quarantine and assume losses which occur thereafter due to such further processing of Product except in case Product is determined to be in Non-Conformance after Shipment (e.g. test results received after Shipment) and such Non-Conformance is caused by IDT's wilful intent.

8.3 Terms of Shipment: Furthermore, the following terms apply to Shipment:

Incoterm	[***]
Packaging Requirements	As specified in the Specifications
Labelling Requirements	As specified in the Specifications

8.4 Commercial Documentation: IDT shall Ship the Products to Valneva ready for sale/export with the necessary documentation, including export documentation in accordance with the applicable Incoterms it being understood that no IDT QP Release Statement is available on the date of the Shipment.

8.5 Quality Assurance Documentation: IDT shall provide the IDT QP Release Statement and any other documentation as set out in the QAA without undue delay after the Shipment.

8.6 Risk and Title: Risk in the Products shall pass to Valneva in accordance with Clause 8.3. Title and ownership shall transfer at the same time as risk.

8.7 Delays: In case IDT fails to Ship the Product [***] following the Manufacturing in accordance with **Exhibit B** or **Appendix G** ("**Shipment Date**") for reasons due to IDT's fault, and such delay remains for a period longer than [***], IDT shall pay Valneva, a late delivery fee ("**Late Delivery Fee**") of [***], up to a maximum of [***].

8.7.1 If the delay remains for a period longer than [***], Valneva shall have the right to cancel the Purchase Order pertaining to the Batche(s) delayed. In the event of the cancellation of the Firm Order, 1) IDT shall pay the Late Delivery Fee to Valneva in accordance with Clause 8.7 above, and 2) Valneva shall have no obligation to pay any cancellation fee according to Clause 5.2.2 of the Master Agreement.

8.7.2 In case of delays and the successive cancellation of a Purchase Order pertaining to a Shipment of Non-Conforming Product, Clause 10 of the Master Agreement apply.

9. SUPPLY AND STOCK MANAGEMENT

9.1 The Parties agree that IDT shall Ship the Products within [***] after the Manufacturing and hence no storage capacity is needed. If necessary, the Parties shall discuss the storage of Product in good faith which storage shall be subject to IDT's standard storage fees according to **Appendix D**.

10. PRICE AND PAYMENT

10.1 The Price per Batch shall be [***], and (ii) [***], in each case [***].

10.2 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	[***]
Pro rata credit of Capacity Reservation Fee	The Capacity Reservation Fee paid (or payable) according to Clause 3.2 above less the verified recruitment costs shall be credited proportionally against the invoices for the Shipment of the number of Batches which correspond to the Capacity Reservation. For the sake of clarity, subject to Clause 3.3, if and to the extent, for any reason outside IDT's scope of responsibility, Valneva does not order the Product corresponding to such Batches to be Manufactured in the applicable Reservation Period in accordance with this Product Schedule and the Master Agreement, IDT shall be entitled to retain the relevant part of the Capacity Reservation Fee.

11. SUPPLY OF VALNEVA MATERIALS AND OTHER MATERIALS

11.1 In this Clause:

Valneva Materials	mean the materials shown in **Appendix C "Valneva Materials".**
Valneva Materials Forecast	Valneva Materials shall be procured by Valneva in accordance with the IDT Forecast for Valneva Materials set forth in Clause 8.1 of the Master Agreement**.**
Other Materials	has the meaning described in Clause 11.3.
Certification	means the act of approving (accepting) quality control results provided in the Certificate of Analysis by Valneva in relation to specific Valneva Materials, eliminating the need to undertake some, or all, quality control tests.

11.2 Supply of Valneva Materials: Valneva, at its sole cost and expense, shall supply Valneva Materials to IDT in accordance with this Product Schedule and the Master Agreement and in accordance with the IDT Forecast.

11.3 Other Materials: IDT shall procure all other materials required in order to perform its obligations in accordance with the terms of this Product Schedule ("**Other Materials**"). All Other Materials used by IDT shall comply with the standards set out in, and shall be inspected by IDT in accordance with the QAA. IDT shall use Commercially Reasonable Efforts to procure Other Materials in due time before Manufacture, however IDT shall not be responsible for any delays in the procurement of such Other Material or any failure of a supplier to deliver Other Materials or third party testing services if IDT used Commercially Reasonable Efforts in the procurement process and to the extent the delay or non-delivery is not otherwise due to IDT's fault. In case Other Materials have not been consumed and used in the Manufacturing of Batches, in case of termination or expiration of this Product Schedule or the Agreement and in case Valneva has not exercised the Call Option any and all Other Materials shall be delivered to Valneva not later than within [***] post termination or expiration or receipt of notice that Valneva will not exercise the Call Option. In such case Valneva shall pay [***] ("**Termination Fee**"). For clarity, any 2022 Advance Payment according to Clause 11.5 or 2023 Advance Payment according to Clause 11.6 remaining for the 2022 and 2023 Manufacturing Plan shall be deducted from the Termination Fee (also in case of Call Option not exercised). For the avoidance of doubt, any Advanced Payment not credited against an invoice will be paid back to Valneva.

11.4 Other Materials Provided by Valneva: The Parties acknowledge that Valneva has materials on stock which may be used to Manufacture Batches in 2022 instead of using Other Materials procured by IDT ("**Valneva Other Materials**"). Valneva shall have the right to request and the Parties shall discuss in good faith IDT's use of Valneva Other Material to Manufacture Batches in 2022 which Valneva Other Materials shall be provided by Valneva as Valneva Material. The Parties shall agree on the usage of Valneva Other Materials and the addition of the Valneva Other Materials to the Valneva Material (**Appendix C**) for a limited time in an Amendment to this Product Schedule and in particular an amended **Appendix C**. For clarity, such Other Materials procured from Valneva shall be excluded from the definition of Termination Fee.

11.5 Advance Payment for the 2022 Manufacturing Plan. Valneva shall pay [***] on or after the Effective Date to finance the procurement by IDT of the Other Materials which is needed to Manufacture the Batches in accordance with **Appendix B** ("**2022 Advance Payment**"). IDT shall credit the 2022 Advanced Payment against the [***] last Batches delivered to Valneva in accordance with **Appendix B** in a way that with the invoice for the last Batch the 2022 Advanced Payment shall be consumed.

11.6 Advance Payment for the 2023 Manufacturing Plan. IDT shall procure Other Materials required for the fulfilment of the 2023 Manufacturing Plan as set forth in **Appendix H** right after the Effective Date and then on a quarterly basis following the Effective Date. Valneva shall make an initial advanced payment for such Other Materials in the amount set forth in **Appendix H** on or after the Effective Date and thereafter on a quarterly basis for the Other Materials to be procured in the following quarter **("2023 Advance Payments")**. The 2023 Advanced Payments shall be credited against the [***] last deliveries of Batches Called in a way that with the invoice for the last Batch shipped in 2023 the 2023 Advanced Payment shall be consumed.

11.7 Wastage and Loss: IDT shall use Commercially Reasonable Efforts to minimize wastage of Valneva Materials and Other Materials.

11.8 Keep Separate: IDT shall separate all Valneva Materials and mark such Materials appropriately or as otherwise set forth in the Master Agreement.

11.9 Inventory Stock Count. In addition to Clause 25.7, Valneva and/or its representatives shall, have the right to attend the regular stock count on Valneva Materials performed by IDT. IDT shall provide Valneva with notice on such stock count not later than [***] in advance. Such inventory stock count shall be free of charge to Valneva.

11.10 Quality and Testing: IDT shall manage quality control, inspection and testing of Valneva Materials according to the relevant specifications and test methods. IDT shall certify sources of Valneva Materials according to IDT procedures and GMP. If Certification is applied for Valneva Materials, IDT shall at the minimum perform identity testing to mitigate quality and safety, health and environmental risks. Valneva will upon the result of such investigation handle any claims against the suppliers of the Valneva Materials.

12. RECALLS

12.1 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.

13. MISCELLANEOUS

13.1 Confidentiality and Trade Secrets. Clause 15 of the Master Agreement (Confidentiality and Trade Secrets) shall be incorporated hereby by reference. Trade secrets relevant to this Product Schedule is attached hereby as **Appendix F**.

13.2 Approved Services Provider: IDT acknowledges and agrees that IDT have been approved by the European Commission ("**EC**") as a services provider to Valneva. IDT shall provide Valneva with all corporate documents, regulatory licences requested by the EC necessary for such approval without undue delay after receipt of request.

13.3 Access to Information. In addition to Clause 17 of the Master Agreement the Parties hereby agree that in case a Third Party brings any action against Valneva, the European Commission or any Participating Member State pertaining to the Product, IDT shall give Valneva, or an independent expert, access to reasonable information necessary for Valneva to assess liabilities. This information shall include data generated relevant to the Manufacturing of the Product including quality control data.

13.4 Checks and audits. The Parties acknowledge that the European Commission ("**EC**") and the European Anti-Fraud Office ("**OLAF**") may check or require an audit on Valneva and its subcontractors ("**EC Audit**"). IDT hereby agrees to abide by the provisions set forth in this Clause 13.4.

An EC Audit may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that such auditor may not be a competitor of IDT or any other conflict of interest exists.

EC Audits may be initiated at any time during business hours during the Term this Project Schedule and up to [***] years starting from the payment of the last Purchase Order issued under this Project Schedule.

The EC Audit procedure is initiated on the date of receipt of the letter sent by Valneva and/or the European Commission, and Valneva and/or the European Commission shall provide a reasonable prior notice to IDT. EC Audits are carried out on a confidential basis.

EC Audit missions scope applies to IDT's compliance with applicable regulatory standards insofar as relevant for the Manufacture and Shipment of Product under the Master Agreement and this Product Schedule. EC Audit missions may not be extended to a broader audit of IDT's activities or IDT's contractual relations, which do not involve Valneva.

IDT must grant the appropriate right of access to sites and premises where the Product is Manufactured for, and Shipped to Valneva, and to all information, including information in electronic format, needed to conduct such checks and audits. IDT must use its Commercially Reasonable Efforts to ensure that the information is readily available at the moment of the EC Audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Valneva and/or the European Commission by IDT, and minimize disruption in IDT's operations, subject to this not creating any material obstacles for the performance of the auditor's tasks.

On the basis of the findings made during an EC Audit, a provisional report is drawn up. Valneva or its authorised representative must send the provisional report to IDT, and IDT has [***] following the date of receipt to submit observations. IDT shall receive a final report within [***] following the expiry of the deadline to submit observations.

If, on the basis of the final EC Audit findings, Valneva wishes to challenge all or part of the payments made under the Master Agreement and/or this Product Schedule, and the Parties cannot reach an agreement, any dispute between the Parties in this respect shall be settled under Clause 22.12 of the Master Agreement.

In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the European Commission in order to protect the European Communities' financial interests against Fraud and other Irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti- Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been Fraud, corruption or any other illegal activity under the Master Agreement and this Product Schedule affecting the financial interests of the European Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during hours during the Term of this Project Schedule and up to [***] years starting from the payment of the last Purchase Order issued under this Project Schedule.

The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939 ('the **EPPO**') have the same rights as Valneva and the European Commission, particularly right of access, for the purpose of checks, audits and investigations.

13.5 Conflict of Interest and Professional Conflicting Interests. IDT must use Commercially Reasonable Efforts to prevent any situation of Conflict of Interest.

IDT must notify Valneva as soon as possible of any situation that could constitute a Conflict of Interest during the Term of this Project Schedule. IDT must immediately take action to rectify the situation.

If the action is not sufficient, Valneva may require IDT to take further action within a specified deadline which shall be reasonable taking into account the context of the situation.

IDT shall have the possibility to complete a rectification of the conflicting situation within a period of [***] or a shorter period if the urgency of the situation requires such shorter period.

13.6 Disclosure by the European Commission. IDT acknowledges that the European Commission, along with other agencies and offices of the European Union (collectively, the "**European Institutions**"), are subject to requirements under Regulation (EC) 1049/2001, which may require the European Institutions to disclose information to Third Parties on request. The European Commission commits itself to assess any request for access to a document that relates to the Master Agreement and this Project Schedule according to the exclusions or exceptions set forth in Regulation (EC) 1049/2001.

13.7 The Parties agree that 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 EU free of charge.

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: 29 November 2021	Date: 26 November 2021

SIGNED for and on behalf of **Valneva Austria GmbH**	
By:	
Name: [***]	
Title: [***]	
Date: 29 November 2021	

Appendix A-1 – Manufacturing Specifications and Product Specifications

[***]

[***]

Appendix A-2 – Valneva Expectation

[***]

Appendix B – Manufacturing Plan, Firm Purchase Orders (2022)

[***]

Appendix C - Valneva Materials to be supplied in accordance with the IDT Forecast

[***]

Appendix D - Storage Fees pertaining to Product in accordance with Section 9.1

[***]

Appendix E – Expected Yields and Yield Calculation

[***]

Appendix F - Valneva Trade Secrets

[***]

Appendix G –2023 Manufacturing Plan

[***]

Appendix H – Other Materials for 2023 Manufacturing Plan

[***]

Exhibit 10.13

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE: J

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO	5. PROJECT NO. *(If applicable)*
P00001	See Blk. 16C	See Block 14	

6. ISSUED BY CODE

DLA TROOP SUPPORT
MEDICAL SUPPLY CHAIN PHARM FSA
700 ROBBINS AVENUE
PHILADELPHIA PA 19111
USA
Initiator [***]
PCPQBC3 Tel 215-737-3978 FAX 215-737-3276 Email [***]

7. ADMINISTERED BY *(if other than Item 6)* CODE SPE2DP

DLA TROOP SUPPORT
MEDICAL SUPPLY CHAIN PHARM FSA
700 ROBBINS AVENUE
PHILADELPHIA PA 19111
USA

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State, and Zip Code*)

VALNEVA USA, INC
910 CLOPPER RD STE 160S
GAITHERSBURG MD 20878-1361
USA

CODE 43FM1 FACILITY CODE

(X)	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (*SEE ITEM 11*)
X	10A. MODIFICATION OF CONTRACT/ORDER NO. SPE2DP-20-D-0005
	10B. DATED (*SEE ITEM 13*) 2020 Sep 09

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered, solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers ☐ is extended ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:

(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers, FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify Authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (*Specify type of modification and authority*) FAR 52.217-9 Option to Extend the Term of the Contract and mutual agreement

E. IMPORTANT: Contractor ☐ is NOT, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

See Continuation Sheet

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
[***] [***]		[***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ [***]	Aug 30, 2021	/s/ [***]	9/2/2021
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

NSN 7540-01-152-8070
Previous Edition Unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA FAR (48 CFR)

/s/ [***]
[***] 31 AUG 2021
[***]

A. Option 1 is hereby exercised effective for the period of September 2, 2021 through September 1, 2022.

B. Option Year 1 quantities are hereby changed from [***] doses minimum and [***] doses maximum to [***] doses minimum and [***] doses maximum.

C. Valneva will hereby provide [***] on all Option Year 1 delivered quantities in lieu of the contractually agreed upon [***].

D. Valneva's letter dated 8/30/21 is hereby incorporated by reference.

E. All other terms and conditions remain the same.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE: J

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO	5. PROJECT NO. *(If applicable)*
P00002	See Blk. 16C	See Block 14	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(if other than Item 6)*	CODE
DLA TROOP SUPPORT MEDICAL SUPPLY CHAIN PHARM FSA 700 ROBBINS AVENUE PHILADELPHIA PA 19111 USA Initiator [***] PCPQBC3 Tel 215-737-3978 FAX 215-737-3276 Email [***]		DLA TROOP SUPPORT MEDICAL SUPPLY CHAIN PHARM FSA 700 ROBBINS AVENUE PHILADELPHIA PA 19111 USA	SPE2DP

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State, and Zip Code*)	(X)	9A. AMENDMENT OF SOLICITATION NO.
VALNEVA USA, INC 910 CLOPPER RD STE 160S GAITHERSBURG MD 20878-1361 USA		9B. DATED (*SEE ITEM 11*)
		10A. MODIFICATION OF CONTRACT/ORDER NO. SPE2DP-20-D-0001
CODE 43FM1 FACILITY CODE	X	10B. DATED (*SEE ITEM 13*) 2019 JAN 15

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered, solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers ☐ is extended ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:

(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers, FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify Authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (*Specify type of modification and authority*) Mutual Agreement of the Parties via phone call 7/1/21

E. IMPORTANT: Contractor ☐ is NOT, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

See Continuation Sheet

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
[***] [***]		[***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ [***]	Aug 30, 2021	/s/ [***]	9/2/2021
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

/s/ [***]
[***] 31 AUG 2021
[***]

A. Valneva will provide [***] replacement doses of Japanese Encephalitis Vaccine (JEV), at no additional cost to the government, for any JEV product from the subject contract that expired [***] at the Defense Logistics Agency (DLA) depot locations. These replacement doses shall not be delivered prior to September 2023. All doses must be received by [***]. The JEV doses shall be delivered with [***]. Shipment and delivery will be coordinated between Valneva and DLA prior to any doses being delivered to DLA Distribution Susquehanna Pennsylvania (DDSP).

B. All other terms and conditions remain the same.

VALNEVA USA, INC.
910 Clopper Road, Suite 160S
Gaithersburg. MD 20878, *USA*

[***]
[***]
Contracting Officer
Defense Logistics Agency – Troop Support BY EMAIL
Business Opportunities Office
Bldg. 36, 2nd Floor, Room 2035
700 Robbins Avenue
Philadelphia, PA 19111-5092

Re: Option Year 1 Under DLA Contract No. SPE2DP-20-D-0005 For Japanese Encephalitis Virus, Purified, Inactivated Vaccine

Dear [***],

As discussed, Valneva USA, Inc. ("Valneva") has set forth below the revisions to DLA Contract No. SPE2DP-20-D-0005 (the "Contract") that will be implemented with the exercise of the first Option Year for the period of August 24, 2021 through August 23, 2022 under the Contract as agreed to between DLA and Valneva. Specifically:

1. Valneva will provide [***] replacement doses at no cost to DLA should any of the doses purchased during the base year of the Contract expire. DLA will be required to return the expired doses, [***], to Valneva within [***] of the expiry date. Valneva will ship replacement doses, [***], to DLA upon receipt of notice from DLA, provided that DLA notifies Valneva at least [***] prior to the expected delivery date for the replacement doses.

2. Valneva will provide [***] expiry dating on all Option Year 1 delivered quantities to DDSP [***].

3. The minimum quantity for Option Year 1 will be revised from [***] to [***] doses. The maximum quantity for Option Year 1 will be revised from [***] to [***]. Doses are packaged in quantities of [***] so quantities must be divisible by [***].

4. The following delivery schedule will apply:

Month/Year	Doses
08/21	[***]
09/21	[***]
10/21	[***]
11/21	[***]
12/21	[***]
01/22	[***]
02/22	[***]
03/22	[***]
04/22	[***]
05/22	[***]
06/22	[***]
07/22	[***]
08/22	[***]

T +1 301-556-4500
F +1 301-556-4501
www.valneva.com

As noted above, no doses to be shipped from January to June 2022. For orders above the minimum guaranteed quantities, Valneva will agree to deliveries at DLA's discretion provided that DLA (a) provides Valneva with [***] lead time for each order and (b) each order is equal to or in excess of the minimum order quantity set forth in FAR Clause 52.216-19, Order Limitations. The dates above are proximate. Valneva will work with DLA to accommodate minor revisions as reasonably necessary.

5. DLA will provide monthly utilization reports to Valneva of doses distributed at the lowest level permissible but in no event no lower than the national level.

6. All other terms and conditions remain the same.

Per past practices, Valneva would appreciate if DLA would incorporate this letter by reference into the Option Year 1 modification for clarity.

Thank you for your assistance in this matter.

[***] = 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.

Best regards,

[***]
[***]
VALNEVA USA, INC.
(A VALNEVA SE AFFILIATE)
910 Clopper Rd. Suite 160S
Gaithersburg, MD 20878
U.S.A.
E [***]
T [***]
M [***]

[***] = 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.

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 24, 2022

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 24, 2022

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, 2021, 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.

By: /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, 2021, 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/ 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.*