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As confidentially submitted to the Securities and Exchange Commission on February 24, 2021.
This Amendment No. 1 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Valneva SE
(Exact name of registrant as specified in its charter)

France	**2836**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

Valneva SE
6 rue Alain Bombard
44800 Saint-Herblain, France
+33 2 28 07 37 10
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act.

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 7(a)(2)(B) of the Securities Act. ☐

Calculation of Registration Fee

Title of Each Class of Securities to be Registered(1)(2)(3)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee(4)
Ordinary shares, €0.15 nominal value per share	$	$

(1) All ordinary shares in the U.S. offering will be in the form of American Depositary Shares, or ADSs, with each ADS representing ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby are being registered pursuant to a separate registration statement on Form F-6.

(2) Includes ordinary shares, which may be in the form of ADSs, which the underwriters have an option to purchase. See “Underwriting.”

(3) Includes ordinary shares that are being offered in the European offering, but which may be resold from time to time in the United States in transactions requiring registration under the Securities Act or an exemption therefrom.

(4) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

† 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.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject To Completion, Dated , 2021.

PRELIMINARY PROSPECTUS

Ordinary Shares

(Consisting of Ordinary Shares in the Form of American Depositary Shares to be sold in the United States and Ordinary Shares to be sold outside of the United States)

This is a public offering of ordinary shares of Valneva SE, which consists of (i) a public offering in the United States of ordinary shares in the form of American Depositary Shares, or ADSs, each representing the right to receive ordinary shares, which we refer to as the "U.S. offering," and (ii) a concurrent offering of ordinary shares outside the United States exclusively offered to "qualified investors," as such term is defined in article 2(e) of Regulation (EU) No. 2017/1129 of the European Parliament and Council of June 14, 2017, which we refer to as the "European offering." We refer to the U.S. offering and the concurrent European offering as the "global offering." These ordinary shares are being offering directly or in the form of ADSs which may be evidenced by American Depositary Receipts, or ADRs.

This is our initial public offering of our ADSs in the United States and no public market exists for our ADSs. We intend to apply to list our ADSs on the Nasdaq Global Market under the symbol "VALN." Our ordinary shares are listed on Euronext Paris under the symbol "VLA."

The final offering price per ADS in U.S. dollars and the corresponding offering price per ordinary share in euros will be determined through negotiations between us and the representatives of the underwriters for the offering, and by reference to the prevailing market prices of our ordinary shares on Euronext Paris after taking into account market conditions and other factors.

On , 2021, the last reported sale price of our ordinary shares on Euronext Paris was € per ordinary share, equivalent to a price of $ per ADS, assuming an exchange rate of €1.00 = $, the exchange rate on , 2021.

We are an "emerging growth company" as defined under U.S. federal securities laws and, as such, will be subject to reduced public company reporting requirements for this prospectus and future filings.

Investing in our ADSs and ordinary shares risks. See "Risk Factors" beginning on page 13 to read about factors you should consider before buying our ordinary shares or ADSs.

Neither the Securities and Exchange Commission, or SEC, nor any U.S. state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER ORDINARY SHARE	PER ADS	TOTAL
Offering price	€	$	$
Underwriting commissions(1)	€	$	$
Proceeds, before expenses, to Valneva SE	€	$	$

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

To the extent that the underwriters sell more than ordinary shares (which may be in the form of ADSs), the underwriters have the option to purchase, within 30 days from the date of this prospectus, up to an additional shares from us at the initial price to the public.

The total number of ordinary shares (including ordinary shares in the form of ADSs) to be sold in the U.S. offering and the European offering (including upon exercise of the underwriters' option to purchase, within 30 days from the date of this prospectus, additional ordinary shares and ADSs) is subject to reallocation between them.

The underwriters expect to deliver the ADSs to the purchasers in the offering on or about , 2021.

Goldman Sachs & Co. LLC **Jefferies** **Guggenheim Securities** **Bryan, Garnier & Co.**

Prospectus dated , 2021.

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We are responsible for the information contained in this prospectus and any free-writing prospectus we prepare or authorize. We and the underwriters have not authorized anyone to provide you with different information, and we and the underwriters take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than its date.

For investors outside the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus must inform themselves about, and observe any restrictions relating to, the global offering of the ADSs and ordinary shares and the distribution of this prospectus and any free writing prospectus outside the United States.

We are incorporated in France, and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the U.S. Securities and Exchange Commission, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Presentation of Financial Information

We maintain our books and records in euros and we prepare our consolidated financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. However, our consolidated financial statements are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the IASB. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States. Our financial statements included in this prospectus are presented in euro and, unless otherwise specified, all monetary amounts are in euro. All references in this prospectus to "$," "U.S. dollars," and "dollars" means U.S. dollars and all references to "€" and "euro," mean euro, unless otherwise noted. Unless otherwise indicated, certain euro amounts contained in this prospectus have been translated into U.S. dollars at the rate of €1.00 to $1.2230, which was the noon buying rate of the Federal Reserve Bank of New York on December 31, 2020, the last business day of our fiscal period ended December 31, 2020. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of euro at the dates indicated. Throughout this prospectus, references to ADSs mean ADSs or ordinary shares represented by such ADSs, as the case may be.

Implications of the FAST Act

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are not required to file our financial information for the year ended December 31, 2018 because we expect to file our financial information for the year ended December 31, 2020 in our registration statement when it is first publicly filed. While the financial information for the year ended December 31, 2018 is otherwise required by Regulation S-X, it will not be required to be included in the Form F-1 filing at the time of the contemplated offering.

Market, Industry and Other Data

Unless otherwise indicated, information contained in this prospectus 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 prospectus is reliable and is based on reasonable assumptions, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Risk Factors."

Trademarks and Service Marks

"Valneva," the Valneva logo, "IXIARO," "JESPECT," "DUKORAL" and other trademarks or service marks of Valneva SE appearing in this prospectus are the property of Valneva or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus 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 prospectus 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.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our ordinary shares (including ordinary shares in the form of ADSs). You should read the entire prospectus carefully, including "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus before making an investment decision. Unless otherwise indicated or the context otherwise requires, "Valneva," "the company," "our company," "we," "us" and "our" refer to Valneva SE and its consolidated subsidiaries, taken as a whole.

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 in undergoing clinical trials VLA15 targets the six most prevalent serotypes, or variations, of Borrelia in North America, where approximately 300,000 Americans 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. To our knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials and we believe that it is differentiated from other clinical stage chikungunya vaccine candidates since VLA1553 is the only candidate that targets long-term protection with a single administration.

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 vaccine candidate for COVID-19 in clinical trials in Europe. We believe that, if approved, our vaccine, as an inactivated virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could offer sustained protection despite mutations of the virus. In September 2020, we entered into a collaboration with the government of the United Kingdom, pursuant to which the government has ordered 60 million doses of VLA2001 for delivery in the second half of 2021 and 40 million doses for delivery in 2022 and has the option to purchase up to 90 million doses thereafter through 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion. We do not currently have the right to use the specific strain of the virus used in VLA2001 for commercial purposes and are in the process of seeking a commercial agreement.

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.

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 three BioSafety Level 3 research and development 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.

Company History and Team

We are a public company listed on 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. Over the course of this experience, members of our management team have supported the submission of over 40 INDs and 20 NDAs/BLAs and have contributed to the development of 17 approved products.

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:

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 two Phase 2 clinical trials of VLA15 in over 800 healthy adults and 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 anticipated to commence in the first quarter of 2021. The dosing of the first subject in this trial will trigger a milestone payment from Pfizer of $10 million. Together with Pfizer, we expect that our Phase 3 clinical trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the pivotal, placebo-controlled field efficacy trial that we are planning for the 2023 tick season. We expect to report initial data, based on the first tick season of the trial, by the end of 2023. If the results from these clinical trials are positive, we are targeting submitting a biologics license application, or BLA, and marketing authorization application in the second half of 2024. VLA15 has received Fast Track designation from the FDA.
- **VLA1553 –** a vaccine candidate against the chikungunya virus, 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, to our knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials. Additionally, when compared to other chikungunya assets that are being evaluated in clinical trials, we believe that VLA1553 has a number of advantages, including the fact that it is the only candidate designed to require a single administration. Based on the data generated in our Phase 1 clinical trial in which we observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants, which results were sustained after 12 months, as well as our discussions with regulators, VLA1553 has advanced to a Phase 3 clinical trial, in which we have achieved over 80% enrollment as of February 2021 and for which we expect to complete recruitment in the first half of 2021 and report initial data in mid-2021. VLA1553 received Fast Track designation from the FDA and PRIME designation from the European Medicines Agency. 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, subject to agreement with FDA that this surrogate endpoint is reasonably likely to predict protection from chickungunya 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 sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher.

- **VLA2001 –** a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. Our inactivated whole virus vaccine candidate is currently being evaluated in the Phase 2 portion of a fully-enrolled Phase 1/2 clinical trial. Although vaccines against SARS-CoV-2 have already been approved, 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 September 2020, we announced a collaboration with the UK government, which has the option to purchase up to 190 million doses through 2025. We expect to report initial data in April 2021 and, if the results are positive, we would initiate a pivotal Phase 2/3 trial, which could support an initial regulatory approval in the second half of 2021. We began production of VLA2001 in January 2021 in parallel with clinical development in order to optimize the timeline for potential deliveries of VLA2001.

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, 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 €94.1 million in the year ended December 31, 2019 and €30.8 million in the nine months ended September 30, 2020. Sales in 2020 have been 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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options.
- **DUKORAL –** an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and/or heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. We acquired DUKORAL in 2015 and recorded €31.5 million of revenues in the year ended December 31, 2019 and €13.2 million in the nine months ended September 30, 2020. Sales in 2020 have been 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.

Background to Vaccine Development

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.
- ***Inactivated vaccines***. Inactivated vaccines use a version of the disease-causing virus or bacteria that has been destroyed with chemicals, heat or radiation.
- ***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 so they can be applicable to people with weakened immune systems.
- ***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.

These approaches 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. Therefore, 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.

Our Strengths

Our vision is to build a leading vaccines company with a portfolio of specialized assets targeting diseases with limited preventive or therapeutic treatment options where our vaccines can contribute unique or differentiated prophylactic solutions. We believe that the following strengths will allow us to continue to deliver on this vision and build on our leading position as a vaccine focused biotechnology company:

- **Highly specialized and targeted approach to development of unique prophylactic vaccines.**
- **Advanced pipeline of differentiated clinical-stage assets designed to address large target populations.**

- **Product development and regulatory expertise with clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization.**
- **Highly developed, nimble and sophisticated manufacturing infrastructure.**
- **Two commercialized vaccines, specialist sales infrastructure and distribution rights for third-party vaccines which help to fund our clinical development efforts.**
- **Highly experienced leadership team with track record of success in the vaccine space.**

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.**
- **Seek regulatory approval for, and commercialize, VLA1553 as a prophylactic vaccine candidate against chikungunya virus.**
- **Advance VLA2001 through clinical development for the prevention of COVID-19.**
- **Drive sales through our established commercial infrastructure and continue to fund our research and development pipeline and manufacturing platform.**
- **Opportunistically pursue strategic partnerships to maximize full potential of our clinical and commercial portfolios.**
- **Deepen our pipeline of pre-clinical and clinical programs to develop new vaccines addressing diseases with significant unmet need.**

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, in Livingston, Scotland, Solana, Sweden and Vienna, Austria, which are qualified by various regulatory authorities. Our manufacturing center in Livingston is currently being expanded to include two additional product units in connection with our COVID-19 vaccine partnership with the UK government. Our manufacturing network has been operating and producing licensed vaccines for more than 10 years and we believe that we have the expertise and capability to produce most types of viral or bacterial vaccines.

Risks Associated with our Business

An investment in our ordinary shares (including ordinary shares in the form of ADSs) involves a high degree of risk. Any of the factors set forth under "Risk Factors" may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our securities. Among these important risks are 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.
- Even if this global offering is successful, 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.
- Our COVID-19 vaccine candidate is at an early stage of development and will require substantial financial resources and we may ultimately be unsuccessful in our efforts to develop and successfully commercialize a COVID-19 vaccine. We do not currently have the right to use the specific strain of the virus used in VLA2001 for commercial purposes and are in the process of seeking a commercial agreement.
- 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, or 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 on our manufacturing facilities as the sole source of manufacturing for our products and for certain of our product candidates.
- The terms of our debt 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.

For additional information about the risks we face, please see the section of this prospectus titled "Risk Factors."

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates; (iii) 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 (iv) the last day of the fiscal year ending after the fifth anniversary of the global offering.

We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and intend to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. Accordingly, the information that we provide shareholders and holders of our ADSs may be different than you might obtain from other public companies.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Since International Financial Reporting Standards, or IFRS, makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

Implications of Being a Foreign Private Issuer

We are also considered a "foreign private issuer" under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and

procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, members of our Management Board and Supervisory Board and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our members of the Management Board or Supervisory Board are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies.

Corporate Information

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 principal executive offices are 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 prospectus and does not constitute a part of this prospectus.

We intend to make our reports and other information filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act available, free of charge, through our website, as soon as reasonably practicable after those reports and other information are electronically filed with or furnished to the SEC. 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.

THE GLOBAL OFFERING

Ordinary shares (including ordinary shares in the form of ADSs) offered by us	ordinary shares, consisting of ordinary shares represented by American depositary shares, or ADSs, offered in the U.S. offering and ordinary shares offered in the European offering. The total number of ordinary shares to be sold in the U.S. offering and European offering is subject to reallocation between these offerings.
Option to purchase additional ordinary shares (including ordinary shares in the form of ADSs) in the global offering	We have granted the underwriters an option for a period of 30 days from the date of this prospectus, to purchase up to an aggregate of additional ordinary shares (which may be in the form of ADSs).
Ordinary shares (including ordinary shares in the form of ADSs) to be outstanding after the global offering	ordinary shares (or ordinary shares if the underwriters exercise their option in full)
American Depositary Shares	Each ADS represents ordinary shares, nominal value €0.15 per share. The depositary will be the holder of the ordinary shares underlying the ADSs, and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and all holders and beneficial owners of ADSs issued thereunder. You may surrender your ADSs to the depositary for cancellation to receive the ordinary shares underlying your ADSs. The depositary will charge you a fee for such a cancellation. To better understand the terms of the ADSs, you should carefully read the section in this prospectus titled "Description of American Depositary Shares." We also encourage you to read the deposit agreement, which is filed as an exhibit to the Registration Statement that includes this prospectus.
Depositary	Citibank, N.A.
Use of proceeds	We estimate that we will receive net proceeds from the global offering of approximately $ million (€ million), based on an assumed offering price of $ per ADS, or € per ordinary share, the closing price of our ordinary shares on Euronext Paris on , 2021, after deducting estimated underwriting commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the global offering, together with our existing resources, to fund further development of our Lyme, chikungunya and COVID-19 vaccine candidates, to advance our pre-clinical vaccine candidate programs and for working capital and general corporate purposes. See "Use of Proceeds" for more information.
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in the ordinary shares or ADSs.
Proposed Nasdaq Global Market symbol for our ADSs	"VALN"
Euronext Paris trading symbol for our ordinary shares	"VLA"

The number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering is based on 90,950,048 ordinary shares outstanding as of December 31, 2020 and excludes:

- 43,750 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*), including 3,125 ordinary shares issued upon exercise of equity awards subsequent to December 31, 2020;
- 4,975,831 ordinary shares issuable upon exercise of outstanding stock options, including 790,075 ordinary shares issued upon exercise of stock options subsequent to December 31, 2020;
- 2,027,848 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,075,822 ordinary shares issuable upon full vesting and conversion of outstanding Free Convertible Preferred Shares; and
- ordinary shares that may be issued in the future under our share-based compensation plans and other delegations of authority from our shareholders.

Except as otherwise noted, the information in this prospectus assumes no exercise by the underwriters of their option to purchase additional ordinary shares (which may be in the form of ADSs) and no exercise of warrants, vesting of free ordinary shares or other equity awards or conversion of preferred shares subsequent to December 31, 2020.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated statement of income (loss) data for the years ended December 31, 2019 and 2020 have been derived from our audited consolidated financial statements as of and for the year ended December 31, 2019 included elsewhere in this prospectus. 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, as of and for the year ended December 31, 2019 for purposes of the confidential submission with the Securities and Exchange Commission of a draft registration statement in connection with a proposed Nasdaq listing. However, our consolidated financial statements are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the IASB.

The following summary condensed consolidated statement of income (loss) data for the nine months ended September 30, 2019 and 2020 and summary condensed statement of financial position data as of September 30, 2020 have been derived from our unaudited interim condensed consolidated financial statements as of September 30, 2020 and for the nine months ended September 30, 2019 and 2020 included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements as of September 30, 2020 and for the nine months ended September 30, 2019 and 2020 were prepared in accordance with IAS 34, Interim Financial Reporting, the standard of IFRS applicable to interim financial statements.

Our historical results and the results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2020 or in the future. You should read this summary data together with our financial statements and related notes beginning on page F-1 of this prospectus, as well as the sections of this prospectus titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information included elsewhere in this prospectus.

Consolidated Statement of Income (Loss) Data:

€ in thousands (except per share data)	Year ended December 31,		Nine Months ended September 30,	
	2020	2019	2020	2019
Product sales	€	€129,511	€ 45,874	€ 86,409
Revenues from collaboration, licensing and services		(3,315)	12,974	(5,015)
Total revenues	€	€126,196	€ 58,848	€ 81,394
Cost of goods and services		(52,781)	(37,249)	(35,517)
Research and development expenses		(38,022)	(51,767)	(23,238)
Marketing and distribution expenses		(24,145)	(13,772)	(17,064)
General and administrative expenses		(18,398)	(19,285)	(12,988)
Other income and expenses, net		6,338	10,733	4,165
Operating profit (loss)	€	€ (811)	€(52,493)	€ (3,247)
Finance income		1,449	299	1,900
Finance expense		(3,082)	(11,051)	(2,272)
Result from investments in associates		1,574	(16)	1,695
Profit (loss) before income tax	€	€ (870)	€(63,262)	€ (1,924)
Income tax		(874)	928	(510)
Profit (loss) for the period	€	€ (1,744)	€(62,334)	€ (2,434)
Earnings (losses) per share – basic	€	€ (0.02)	€ (0.69)	€ (0.03)
Earnings (losses) per share – diluted	€	€ (0.02)	€ (0.69)	€ (0.03)

Consolidated Statement of Financial Position Data:

€ in thousands	As of September 30, 2020	
	Actual	As Adjusted(1) (2)
Cash and cash equivalents	€156,178	€
Total assets	450,185	
Total liabilities	373,457	
Total shareholders' equity	76,728	

(1) The as adjusted summary statement of financial position data reflects our issuance and sale of a total of ordinary shares (consisting of ADSs and ordinary shares) in the global offering at an assumed offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, after deducting estimated underwriting commissions and estimated offering expenses payable by us.

(2) The as adjusted summary statement of financial position data is illustrative only and will change based on the actual offering price and other terms of the offering determined at pricing. Each $1.00 (€) increase or decrease in the assumed offering price of € per ordinary share ($ per ADS) would increase or decrease the as adjusted amount of each of cash and cash equivalents, total assets and total shareholders' equity by approximately € million, assuming that the number of ADSs and ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares (including ordinary shares in the form of ADSs) we are offering. Each increase or decrease of 1,000,000 ordinary shares (including ordinary shares in the form of ADSs) offered by us would increase or decrease the as adjusted amount of each of cash and cash equivalents, total assets and total shareholders' equity by € million, assuming that the assumed offering price remains the same, and after deducting estimated underwriting commissions and estimated offering expenses payable by us.

RISK FACTORS

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 €62.3 million and €2.4 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated net loss of €231.5 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 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 approval for and commercialize our product candidates. We are currently substantially dependent on sales of our two commercial products, DUKORAL and IXIARO, for revenue. Our product candidates, including our Lyme, chikungunya, and COVID-19 vaccines, have not received and may not receive regulatory approval. Unless and until we obtain this regulatory approval in order to commercialize our product candidates, the likelihood and amount of our future operational losses will depend, in part, on the 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 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 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 COVID-19 pandemic, for example because a COVID-19 vaccine is not available as quickly as expected, our revenues will be significantly adversely affected, and we may not be able to continue the development of our vaccine candidates against chikungunya or Lyme disease 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 be used by travelers.

Even if this global offering is successful, 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 September 30, 2020, we had total assets of €450.2 million, including cash and cash equivalents of €156.2 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of September 30, 2020, together with the proceeds from this offering, will fund our current operating plans through at least . 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 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 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 COVID-19 pandemic continues to evolve rapidly and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, 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. See "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares."

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 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 at an early stage of development and will require substantial financial resources and we may ultimately be unsuccessful in our efforts to develop and successfully commercialize a COVID-19 vaccine.

In response to the recent outbreak of COVID-19, the disease caused by the virus SARS-CoV-2, we are pursuing a vaccine candidate, VLA2001, to address the disease. Our testing and development of VLA2001 is in early stages, and we may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.

We are committing substantial financial resources, particularly research and development expenses, investment in our manufacturing facilities and personnel, to the development of a potential vaccine for COVID-19, which may cause delays in or otherwise negatively impact our other development programs and continued commercialization of our current products, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. 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 the 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 these or 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. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our potential vaccine candidates, if developed, may not be sufficiently effective. If we do not successfully develop VLA2001 and receive regulatory approval, or if we fail to successfully commercialize VLA2001 if approved, we may not be able to achieve a return on our investment.

In addition, other parties have developed and are developing vaccines for COVID-19, some of which have already received regulatory approval and begun distribution in our target markets. Several of these other parties are much larger than we are and have access to larger pools of capital, including government funding, and broader manufacturing infrastructure. Additionally, VLA2001 is an inactivated virus vaccine candidate and other parties are also developing this type of vaccine candidate against COVID-19. The earlier market entry of these other vaccines, and their actual or perceived efficacious or success relative to our own, may lead to diversion of funding away from us, decreased demand for VLA2001 if approved and difficulty in finding participants for our clinical trials. All of these factors could substantially impact our ability to complete the development of, commercialize, and profit from our COVID-19 vaccine candidate. See “Business—Competition” for further discussion on COVID-19 vaccine competition.

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 are obligated to manufacture and supply a COVID-19 vaccine 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. Pursuant to the terms of the UK Supply Agreement, the UK Authority has an option to purchase additional doses of a COVID-19 vaccine. The UK Authority may not chose to exercise such option, and we may not realize the full economic potential of this agreement. In addition, pursuant to the terms of the UK Supply Agreement, the UK Authority may terminate the agreement for a variety of reasons. The UK Authority’s termination of the UK Supply Agreement would substantially harm our business, financial condition, prospects and results of operations. See “Business—Material Agreements—UK Supply Agreement” for further detail on the terms of this agreement.

Finally, we are developing our COVID-19 vaccine using a specific virus strain obtained from the National Institute for Infectious Diseases “Lazzaro Spallanzani” IRCCS, or INMI, in Italy through a biological material transfer agreement between us and INMI as the representative of the European Virus Archive goes Global. The terms of this agreement prohibit the use of the virus strain for commercial purposes and require us to negotiate a separate agreement with

INMI before any such commercial use may begin. We initiated the process of negotiating a commercial agreement in June of 2020. In November of 2020, the Italian Ministry of Health referred us to the World Health Organization, or the WHO, as the party from which to obtain the commercial rights following the Italian government's donation of the same virus strain to the WHO's newly formed globally agreed system for sharing pathogen materials and clinical samples. We contacted the WHO in December of 2020 and continue to be in contact with INMI, the WHO and the Italian Ministry of Health regarding the commercial agreement. It will take some time to determine the applicable terms, including price, for the commercial agreement and we cannot predict how long this process may take. We cannot provide assurance that we will have obtained the required commercial agreement in time to begin commercializing our COVID-19 vaccine immediately following regulatory approval, if such approval is received. A substantial delay in agreeing on terms for commercial use of this virus strain in our COVID-19 vaccine could have an adverse impact on our ability to fulfil our obligations under the UK Supply Agreement and other agreements, the predictability of our financial results and on our financial condition, reputation and results of operations. Furthermore, failure to obtain the required commercial agreement or another agreement allowing for commercialization of our COVID-19 vaccine could substantially impair our business strategy and could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

In February 2020, we entered into an $85 million 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 September 30, 2020, 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 will 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, 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.

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 for two of our products, we may not be able to obtain regulatory approval for 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 Europe, the United States or any other geographies until we or our collaborators receive regulatory approval from the European Medicines Agency, or the EMA, FDA, or applicable regulatory agency. The time required to conduct clinical trials and obtain approval or other marketing authorizations by the EMA, 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. 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 Europe, 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 EMA, 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 it may object to elements of our clinical development program, requiring their alteration.

Of the large number of products in development, only a small percentage successfully complete the EMA'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 EMA, 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 EMA, 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 EMA, 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 EMA, 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. If we are unable to successfully commercialize our product candidates, 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 or having successfully advanced through earlier clinical trials. As a result, interim, “top-line” and preliminary data that we may publish are subject to the risk that one or more of the reported clinical outcomes may materially change as clinical trials progress and such data should be viewed with caution until final data are available.

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 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 EMA, FDA or other comparable regulatory authority, and we may never receive such approvals. The time required to obtain approval by the EMA, 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 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, which may require new or additional trials;
- decisions made by us or requirements imposed by regulators to conduct additional clinical trials or abandon product development programs; or
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease, which already caused us to delay initiation of the Phase 3 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 EMA, 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 EMA FDA or any other regulatory authority. Further, we, the EMA, 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, that we are exposing participants to unacceptable health risks, or if the EMA, 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 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, thereby delaying or preventing 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 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 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 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 EMA, 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 in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

We are aware of companies with Japanese encephalitis vaccines as well as cholera vaccines. If and when these vaccines expand commercialization into 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. See "Business—Competition" for discussion of our competitors. 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;
- 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 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, if the agency supervising pharmaceutical products in Canada, which is our principal market for DUKORAL, were to reassess DUKORAL's indications, this could have a significant negative impact on our sales.

In addition, biopharmaceutical manufacturers and their facilities are subject to ongoing review and periodic inspections by the EMA, 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 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 EMA'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 Europe, 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 EMA's, FDA's and other regulatory authorities' ability to exercise its

regulatory authority. If these executive actions impose constraints on the EMA'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 or 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.

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 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. 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 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 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. 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.

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. We have had discussions with the FDA about utilizing this pathway for our VLA1553 program, but there is no guarantee that the FDA will agree with the surrogate marker for protection that we are planning to utilize. 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.

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.

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 or 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) 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 such information regarding its relationships with 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 judicial and congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA's mandated medical device tax and "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminates the health insurer tax. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case but it is unclear when a decision will be made. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 also unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA.

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 2030. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 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 on September 24, 2020 providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. The Interim Final Rule has not been finalized and is subject to revision and challenge. For example, on December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against the implementation of this interim final rule. The likelihood of implementation of the Trump administration reform initiatives is uncertain, particularly in light of the new U.S. presidential administration.

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 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, particularly as a result of the new presidential administration. 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 of December 9th, 2017 on Transparency, the Fight Against Corruption and the Modernization of the Economy (Sapin II2 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.

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 Europe or the United States, or from selling or importing products that infringe our patents in and into Europe 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 Europe, 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 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 Europe, 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. See “Business—Intellectual Property—Trademarks” for a discussion of the co-existence agreement.

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 "Business—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. 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 significantly raise our cost of producing it. 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 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 the adjuvant used in our COVID-19 vaccine candidate 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 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 manufacturing of our COVID-19 vaccine candidate in sufficient quality and quantity, which would delay or prevent us from developing and commercializing this product candidate.

We do not have experience manufacturing on the large scale that would be required for our COVID-19 vaccine candidate, if approved. We may be unable to successfully increase the manufacturing capacity for such product candidate in a timely or cost-effective manner, or at all, as needed for our commercialization efforts, if approved. Quality issues may also arise during scale-up activities. If we are unable to successfully scale up the manufacture of our COVID-19 vaccine candidate in sufficient quality and quantity, it would result in a material adverse impact on our business, prospects, financial condition and results of operations.

We rely on our manufacturing facilities as the sole 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 and will be the sole source of clinical materials for our chikungunya and COVID-19 vaccine candidates. Our manufacturing facility in Solna, Sweden, is the sole source of commercial quantities of DUKORAL. The destruction of either of these facilities by fire or other catastrophic events would prevent us from manufacturing the relevant product and supplying our customers or clinical trial centers, which would result in a material adverse impact on our business, prospects, financial condition and results of operations.

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

We are reliant on 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 addition, 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. 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 EMA, 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 EMA, 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 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 Europe, 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 Europe, 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.

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, 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.

The manufacturing of our products and product candidates present technological, logistical and regulatory risks, each of which may adversely affect our business.

The manufacturing of biological materials is technologically and logistically complex and heavily regulated by the EMA, FDA and other regulatory authorities. The manufacturing of our products and product candidates present many risks, including, but not limited to, the following:

- we may experience delays and technical issues, fail to successfully manufacture, or experience capacity shortfalls for the manufacture of our vaccines;
- it may not be technically feasible to scale up an existing manufacturing process to meet demand or such scale-up may take longer than anticipated; and
- 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.

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.

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 including his knowledge of manufacturing. 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 in the merger. We are discussing potential settlement agreements. 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, 2019 appearing elsewhere in this prospectus 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.

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, or 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 COVID-19 pandemic and future outbreaks of the disease. The COVID-19 pandemic is resulting 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.

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 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.

While the potential economic impact brought by, and the duration of, the 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 pandemic of COVID-19 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 will need to hire new employees and expand our use of service providers.

As of December 31, 2020, we had 581 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.

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, as we did with the potential vaccine for

COVID-19, 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, 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. 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 draft guidance from the EDPB on such supplementary technical, organizational and/or contractual measures appears to 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 member states 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 EEA. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains unclear. For example, it is still unclear whether transfers of data from the EEA to the United Kingdom will take place on the basis of an adequacy decision or whether we will need to implement appropriate safeguards as required by the GDPR. For the meantime, under the post-Brexit Trade and Cooperation Agreement, or the Trade and Cooperation Agreement, between the European Union and the United Kingdom, it has been agreed that transfers of personal data to the United Kingdom from European Union Member States will not be treated as "restricted transfers" to a non-EEA country for a period of up to six months from January 1, 2021. This will also apply to transfers to the United Kingdom from EEA Member States, assuming those Member States accede to the relevant provision of the Trade and Cooperation Agreement. Although the current maximum duration of the extended adequacy assessment period is six months it may end sooner, for example, in

the event that the European Commission adopts an adequacy decision in respect of the United Kingdom, or the United Kingdom amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/ Data Protection Act 2018 without the consent of the European Union (unless those amendments or decisions are made simply to keep relevant United Kingdom laws aligned with the European Union's data protection regime). Unless the European Commission adopts an adequacy decision in respect of the United Kingdom prior to the expiry of the extended adequacy assessment period, from that point onwards the United Kingdom will be an "inadequate third country" under the GDPR and transfers of data from the EEA to the United Kingdom will require an "transfer mechanism," such as the standard contractual clauses. 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, CCPA 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 European Union 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 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 €5.7 million and €2.6 million for the nine months ended September 30, 2020 and 2019, respectively. Our French Research Tax Credits were €0.8 million and €1.3 million for the nine months ended September 30, 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 €457 million as of December 31, 2019. 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.

On December 22, 2017, President Trump signed into law the Tax Act, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. While we have reflected the expected impact of the Tax Act in our financial statements in accordance with our understanding of the Tax Act and available guidance, the ultimate effects of the Tax Act remain uncertain. The U.S. Department of Treasury may issue regulations and guidance that may significantly impact how the Tax Act applies to us, and components of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The foregoing items may and result in changes may have an adverse impact on our results of operations, cash flows and financial condition.

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 FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition.

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 2018, 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. The ADSs being offered in the U.S. offering will be 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.

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, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in the ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of the 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 ADSs will appreciate in value or even maintain the price at which our shareholders have purchased them. Investors seeking cash dividends should not purchase the ADSs.

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. See “Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares” for further details on the limitations on our ability to declare and pay dividends and the taxes that may become payable by us if we elect to pay a dividend.

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.

If you purchase ADS in this global offering, you will experience substantial and immediate dilution.

If you purchase ADS in this global offering, you will experience substantial and immediate dilution of € ($) per ordinary share in the net tangible book value after giving effect to the global offering at an offering price of $ per ADS (corresponding to € per ordinary share in the European private placement), because the price that you pay will be substantially greater than the net tangible book value per ADS or ordinary share, as applicable, that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial offering price when they purchased their ordinary shares. You will experience additional dilution upon exercise of any outstanding equity warrants (*bons de souscription d'actions*), stock options, upon the vesting of free ordinary shares (*actions ordinaires gratuites)* or upon conversion of convertible preferred shares or if we otherwise issue additional ordinary shares or ADSs below the offering price. For a further description of the dilution that you will experience immediately after this global offering, see "Dilution."

In addition, in the future, we may issue additional ADSs, ordinary shares, or other equity or debt securities convertible into ordinary shares, or seek additional capital through a variety of means, including public or private equity. Any such issuance or financings could result in substantial dilution to our existing securityholders and could cause the price of our ADSs to decline.

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

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs in the public market after the 90-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of the ADSs could decline significantly and could decline below the offering price. Upon completion of the global offering, based on the number of ordinary shares outstanding as of , 2021, we will have outstanding ordinary shares, including ordinary shares represented by ADSs, approximately of which are subject to a contractual restriction on selling for up to 90 days, subject to customary exceptions. As of the date of this prospectus, the exercise of all our instruments convertible into ordinary shares would enable the subscription of new ordinary shares, representing approximately % of the diluted share capital. Goldman Sachs & Co. LLC and Jefferies LLC may waive the lock-up agreements entered into in connection with this offering prior to the expiration thereof in their sole discretion. See "Underwriting."

After the lock-up agreements pertaining to this offering expire, and based on the number of ordinary shares outstanding upon completion of this global offering, including ordinary shares represented by ADSs, additional ordinary shares will be eligible for sale in the public market, all of which ordinary shares are held by members of the Management Board and of the Supervisory Board and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, the ordinary shares subject to subscription under our instruments convertible under shares will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the ordinary shares in the public market could have an adverse effect on the market price of the ADSs. See "Shares and ADSs Eligible for Future Sale" for a more detailed description of sales that may occur in the future. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ordinary shares and ADSs could decline substantially.

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

Following this global offering and after the ADSs begin trading on the Nasdaq Global Select Market, our ordinary shares will continue to be listed on Euronext Paris. Trading of the ADSs or ordinary shares in these markets will take 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 dual listing on the value of our ordinary shares and the ADSs. However, the dual listing of our ordinary shares and the 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 headquarters 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 "Management—Corporate Governance Practices" and "Description of Share Capital."

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 prospectus 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. See "Enforcement of Civil Liabilities."

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. See "Limitations Affecting Shareholders of a French Company";
- 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. See "Limitations Affecting Shareholders of a French Company";
- 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; see the section of this prospectus titled "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares";
- 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 will require, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year starting with the end of the first full fiscal year after the completion of the global offering. However, 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," which may be up to five fiscal years following the date of this global offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not.

Our management has not completed an assessment of the effectiveness of our internal control over financial reporting, and our independent registered public accounting firms have not conducted an audit of our internal

control over financial reporting. In conjunction with preparing our consolidated financial statements as of and for the year ended December 31, 2019 for this offering, 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 herein, 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 begun to develop a remediation plan to address these material weaknesses and strengthen our controls in these areas. While we are working to remediate the material weaknesses as quickly and efficiently as possible, we cannot at this time provide the expected timeline in connection with implementing our remediation plan and we do not expect the remediation to be complete at the time of completing our audit for the year ending December 31, 2020. These remediation measures may be time-consuming and costly, and might place significant demands on our financial and operational resources.

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. For more information, see "Limitations Affecting Shareholders of a French Company."

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 in the U.S. offering will not be directly holding our ordinary shares.

A holder of ADSs will not be treated as one of our shareholders and will not have direct shareholder rights, unless he withdraws the ordinary shares underlying his ADSs. French law governs our shareholder rights. The depositary, through the custodian or the custodian's nominee, will be the holder of the ordinary shares underlying ADSs held by purchasers of ADSs in the U.S. offering. Purchasers of ADSs in the U.S. offering will have ADS holder rights. The deposit agreement among us, the depositary and purchasers of ADSs in the U.S. offering, as an ADS holder, and all other persons directly and indirectly holding ADSs, sets out ADS holder rights, as well as the rights and obligations of us and the depositary.

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. See the section of this prospectus titled "Description of American Depositary Shares."

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 will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and will not be 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 will be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

The audit report included in this prospectus is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, our investors are deprived of the benefits of such inspection.

Our independent registered public accounting firm that issues the audit report included in our prospectus filed with the SEC, as auditors of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States), or the PCAOB, is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Because our auditors are located in France, a jurisdiction where the PCAOB is currently unable to conduct inspections due to the expiration of the cooperative arrangement with the French audit authority in December 2019 and the application of French privacy and data security laws, our auditors are not currently inspected by the PCAOB. Inspections of other firms that the PCAOB has conducted outside of France have identified deficiencies in those firms' audit procedures and quality control procedures. While we understand that the PCAOB is in discussions with relevant French authorities in order to permit the PCAOB to resume inspections in France, the current inability of the PCAOB to conduct inspections of auditors in France makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside France that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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 will be subject to their 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 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 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. For an overview of our corporate governance practices, see "Management—Corporate Governance Practices."

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) the last day of the fiscal year ending after the fifth anniversary of our initial public offering of the ADSs.

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, 2021. 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. Immediately following the closing of this global offering, approximately 15% of our outstanding ordinary shares (including ordinary shares in the form of ADSs) will likely be held by U.S. residents (assuming that all purchasers in the U.S. offering 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, 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 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 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. If we are a PFIC for any taxable year during which a U.S. holder (as defined below under "Material United States Federal Income Tax and French Tax Considerations—Material U.S. Federal Income Tax Considerations") 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 believe that a PFIC for the taxable year ending December 31, 2020. 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, including this 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 the section of this prospectus titled "Material United States Federal Income Tax and French Tax Considerations—Material U.S. Federal Income Tax Considerations."

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

We have broad discretion in the use of the net proceeds from this global offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds that we receive from this offering as well as of our existing cash, cash equivalents short-term investments and non-current financial assets, and we may spend or invest these funds in a way with which our shareholders or holders of our ADSs disagree. Our failure to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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

It is likely that the price of our ordinary shares and ADSs will 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, 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 of 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 of a strategic alliance or the inability to establish additional strategic alliances;
- 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 COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak 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, 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.

There has been no prior market for our ADSs and an active and liquid market for our securities may fail to develop, which could harm the market price of the ADSs.

Prior to this global offering, while our ordinary shares have been listed on Euronext Paris since 2013, there has been no public market on a U.S. national securities exchange for our ordinary shares or ADSs. Although our ADSs have been approved for listing on the Nasdaq Global Select Market, an active trading market for the ADSs may never develop or be sustained following this global offering. The initial offering price of the ADSs was determined through negotiations between us and the underwriters. This offering price may not be indicative of the market price of our ordinary shares or ADSs after this global offering. In the absence of an active trading market for the ADSs, investors may not be able to sell their ADSs at or above the offering price or at the time that they would like to sell.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, particularly the sections of this prospectus titled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements. All statements other than present and historical facts and conditions contained in this prospectus, 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 prospectus, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- timing and expected outcomes of clinical trials and pre-clinical studies;
- 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 compliment other COVID-19 vaccines, particularly in special target populations;
- 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 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;
- our expected use of proceeds of the global offering; and

- other risks and uncertainties, including those listed in the section of this prospectus titled “Risk Factors.”

You should refer to the section of this prospectus titled “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 prospectus 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 the global offering.

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 prospectus, 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 prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the Registration Statement of which this prospectus is a part 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.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the global offering of approximately $ million (€ million), assuming an offering price of $ per ADS (€ per ordinary share), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, after deducting estimated underwriting commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase additional ordinary shares (including ordinary shares in the form of ADSs). If the underwriters exercise their option in full, we estimate that we will receive net proceeds from the global offering of approximately $ million (€ million) after deducting estimated underwriting commissions and estimated offering expenses payable by us.

Each $1.00 (€) increase or decrease in the assumed initial offering price of $ per ADS (€ per ordinary share) would increase or decrease our net proceeds from the global offering by $ million (€ million), assuming the number of ordinary shares (including ordinary shares in the form of ADSs), as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares (including ordinary shares in the form of ADSs) we are offering. An increase or decrease of 1,000,000 ordinary shares (including ordinary shares in the form of ADSs) offered by us would increase or decrease the net proceeds to us by $ million (€ million), assuming that the assumed initial offering price remains the same and after deducting estimated underwriting commissions and estimated offering expenses payable by us. The actual net proceeds payable to us will adjust based on the actual number of ordinary shares (including ordinary shares in the form of ADSs) sold by us, the actual initial offering price and other terms of the global offering determined at pricing.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to $ million to fund further development of our Lyme VLA15 vaccine candidate through ;
- approximately $ million to $ million to fund further development of our chikungunya VLA1553 vaccine candidate through ;
- approximately $ million to $ million to fund further development of our COVID-19 VLA2001 vaccine candidate through ;
- approximately $ million to $ million to advance our pre-clinical vaccine candidate programs; and
- any remaining amounts to fund working capital and general corporate purposes.

We expect to use the remainder of any net proceeds from the global offering, together with a portion of our cash and cash equivalents, for general corporate purposes. We currently have no specific plans as to how the net proceeds from the global offering will be allocated beyond the uses specified above and therefore management will retain discretion with respect to the use of the net proceeds of the global offering. We may also use a portion of the net proceeds to acquire, license or invest in complementary technologies or businesses. However, we currently have no agreements or commitments to complete any such transaction.

As of December 31, 2020, we had cash and cash equivalents of € million. We believe our cash and cash equivalents, together with the net proceeds of the global offering, will be sufficient to fund our operations through at least . We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect.

The expected use of the net proceeds from the global offering and time horizon for the use of our funds represent our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of the global offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our vaccine candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the global offering.

Pending our use of the net proceeds from the global offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

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. See “Description of Share Capital” for more information.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2020 on an actual and on an as adjusted basis to reflect the issuance and sale of ordinary shares (including ordinary shares in the form of ADSs) in the global offering at an assumed initial offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, after deducting estimated underwriting commissions and estimated offering expenses payable by us.

Our capitalization following the global offering will be adjusted based on the actual initial offering price and other terms of the global offering determined at pricing. The table should be read in conjunction with the information contained in "Use of Proceeds," "Summary Consolidated Financial Data," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our consolidated financial statements and the related notes included elsewhere in this prospectus.

€ in thousands	**As of September 30, 2020**	
	Actual	**As Adjusted**
Cash and cash equivalents	€ 156,178	€
Liabilities—current portion	201,936	
Liabilities—non-current portion	171,521	
Total liabilities	€ 373,457	€
Share capital	13,643	
Share premium	244,946	
Other reserves	49,629	
Retained earnings (accumulated deficit)	(169,156)	
Profit (loss) for period	(62,334)	
Total shareholders' equity	€ 76,728	€
Total capitalization	€ 450,185	€

Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, would increase or decrease each of as adjusted cash and cash equivalents, total shareholders' equity and total capitalization by approximately € million ($ million), assuming that the number of ordinary shares (including ordinary shares in the form of ADSs) offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares (including ordinary shares in the form of ADSs) we are offering. Each increase or decrease of 1,000,000 ordinary shares (including ordinary shares in the form of ADSs) offered by us would increase or decrease each of as adjusted cash and cash equivalents, total shareholders' equity and total capitalization by approximately € million ($ million), assuming that the assumed offering price remains the same, and after deducting estimated underwriting commissions and estimated offering expenses payable by us.

The number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering is based on 90,950,048 ordinary shares outstanding as of December 31, 2020 and excludes:

- 43,750 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*), including 3,125 ordinary shares issued upon exercise of equity awards subsequent to December 31, 2020;
- 4,975,831 ordinary shares issuable upon exercise of outstanding stock options, including 790,075 ordinary shares issued upon exercise of stock options subsequent to December 31, 2020;
- 2,027,848 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);

- 2,075,822 ordinary shares issuable upon full vesting and conversion of outstanding Free Convertible Preferred Shares; and
- ordinary shares that may be issued in the future under our share-based compensation plans and other delegations of authority from our shareholders.

DILUTION

If you invest in the ordinary shares or ADSs in this global offering, your ownership interest will be diluted to the extent of the difference between the offering price per ordinary share or ADS paid by you and the as adjusted net tangible book value per share after the global offering. Our net tangible book value as of December 31, 2020 was € million ($ million), or € per ordinary share (equivalent to $ per ADS), based on the exchange rate in effect as of December 31, 2020. Net tangible book value per share is determined by dividing (i) our total assets less our intangible assets and our total liabilities by (ii) the number of ordinary shares outstanding as of December 31, 2020, or ordinary shares.

After giving effect to our sale of ordinary shares (including ordinary shares in the form of ADSs) in the global offering, assuming an offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, and after deducting estimated underwriting commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at December 31, 2020 would have been € million ($ million), or € per ordinary share (equivalent to $ per ADS). This amount represents an immediate increase in net tangible book value of € per ordinary share ($ per ADS) to our existing shareholders and an immediate dilution in net tangible book value of € per ordinary share ($ per ADS) to new investors.

The following table illustrates this dilution on a per ordinary share and per ADS basis:

	As of December 31, 2020	
	Per Ordinary Share	Per ADS
Assumed initial offering price	€	$
Historical net tangible book value per ordinary share or ADS	€	$
Increase in net tangible book value per ordinary share or ADS attributable to new investors participating in the global offering		
As adjusted net tangible book value per ordinary share or ADS after the global offering		
Dilution in as adjusted net tangible book value per ordinary share or ADS to new investors participating in the global offering	€	$

Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, would increase or decrease our as adjusted net tangible book value by approximately € million ($ million), or approximately € per ordinary share ($ per ADS), and the dilution to new investors participating in this global offering would be approximately € per ordinary share ($ per ADS), assuming that the number of ordinary shares (including ordinary shares in the form of ADSs) offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares (including ordinary shares in the form of ADSs) we are offering. An increase in the number of ordinary shares (including ordinary shares in the form of ADSs) offered by us by 1,000,000 would increase the as adjusted net tangible book value by approximately € million ($ million), or € per ordinary share ($ per ADS), and the dilution to new investors participating in this global offering would be € per ordinary share ($ per ADS), assuming that the initial offering price remains the same, and after deducting estimated underwriting commissions and estimated offering expenses payable by us. Similarly, a decrease in the number of ordinary shares (including ordinary shares in the form of ADSs) offered by us by 1,000,000 would decrease the as adjusted net tangible book value by approximately € million ($ million), or € per ordinary share ($ per ADS), and the dilution to new investors participating in this global offering would be € per

ordinary share ($ per ADS), assuming that the initial offering price remains the same, and after deducting estimated underwriting commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual offering price, the number of ordinary shares (including ordinary shares in the form of ADSs) offered by us and other terms of this global offering determined at pricing.

If the underwriters exercise in full their option to purchase additional ordinary shares (which may be in the form of ADSs), the as adjusted net tangible book value after the global offering would be € per ordinary share ($ per ADS), the increase in the as adjusted net tangible book value to existing shareholders would be € per ordinary share ($ per ADS), and the dilution to new investors participating in this global offering would be € per ordinary share ($ per ADS).

The following table sets forth consideration paid to us in cash for ordinary shares purchased from us by our existing shareholders (translated into U.S. dollars at an exchange rate of €1.00 = $) and by new investors participating in this global offering based on an assumed offering price of € per ordinary share ($ per ADS), the last reported closing price of our ordinary shares on Euronext Paris on , 2021, and before deducting estimated underwriting commissions and estimated offering expenses payable by us.

	Ordinary Shares or ADSs Purchased from Us		Total Consideration		Average Price per Ordinary Share/ADS
	Number	Percent	Amount	Percent	
Existing shareholders		%		%	
New investors					
Total		**100.0%**		**100.0%**	

If the underwriters exercise their option to purchase additional ordinary shares (which may be in the form of ADSs) in full, the number of ordinary shares held by the existing shareholders after this global offering would be reduced to % of the total number of ordinary shares (including ordinary shares in the form of ADSs) outstanding after the global offering, and the number of ordinary shares (including ordinary shares in the form of ADSs) held by new investors participating in this global offering would increase to % of the total number of ordinary shares (including ordinary shares in the form of ADSs) outstanding after the global offering.

The number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering is based on 90,950,048 ordinary shares outstanding as of December 31, 2020 and excludes:

- 43,750 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*), including 3,125 ordinary shares issued upon exercise of equity awards subsequent to December 31, 2020;
- 4,975,831 ordinary shares issuable upon exercise of outstanding stock options, including 790,075 ordinary shares issued upon exercise of stock options subsequent to December 31, 2020;
- 2,027,848 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,075,822 ordinary shares issuable upon full vesting and conversion of outstanding Free Convertible Preferred Shares;
- ordinary shares that may be issued in the future under our share-based compensation plans and other delegations of authority from our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated statement of income (loss) data for the years ended December 31, 2019 and 2020 have been derived from our audited consolidated financial statements as of and for the year ended December 31, 2019 included elsewhere in this prospectus. 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 as of and for the year ended December 31, 2019 for purposes of the confidential submission with the Securities and Exchange Commission of a draft registration statement in connection with a proposed Nasdaq listing. However, our consolidated financial statements are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the IASB.

The following summary condensed consolidated statement of income (loss) data for the nine months ended September 30, 2019 and 2020 and summary condensed statement of financial position data as of September 30, 2020 have been derived from our unaudited interim consolidated condensed financial statements as of September 30, 2020 and for the nine months ended September 30, 2019 and 2020 included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements as of September 30, 2020 and for the nine months ended September 30, 2019 and 2020 were prepared in accordance with IAS 34, Interim Financial Reporting, the standard of IFRS applicable to interim financial statements.

Our historical results and the results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2020 or in the future. You should read this summary data together with our financial statements and related notes beginning on page F-1 of this prospectus, as well as the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information included elsewhere in this prospectus.

Selected Statement of Income (Loss) Data:

€ in thousands (except per share data)	**Year ended December 31,**		**Nine Months ended September 30,**	
	2020	**2019**	**2020**	**2019**
Product sales	€	€ 129,511	€ 45,874	€ 86,409
Revenues from collaboration, licensing and services		(3,315)	12,974	(5,015)
Total revenues	€	€ 126,196	€ 58,848	€ 81,394
Cost of goods and services		(52,781)	(37,249)	(35,517)
Research and development expenses		(38,022)	(51,767)	(23,238)
Marketing and distribution expenses		(24,145)	(13,772)	(17,064)
General and administrative expenses		(18,398)	(19,285)	(12,988)
Other income and expenses, net		6,338	10,733	4,165
Operating profit (loss)	€	€ (811)	€ (52,493)	€ (3,247)
Finance income		1,449	299	1,900
Finance expense		(3,082)	(11,051)	(2,272)
Result from investments in associates		1,574	(16)	1,695
Profit (loss) before income tax	€	€ (870)	€ (63,262)	€ (1,924)
Income tax		(874)	928	(510)
Profit (loss) for the period	€	€ (1,744)	€ (62,334)	€ (2,434)
Earnings (losses) per share – basic	€	€ (0.02)	€ (0.69)	€ (0.03)
Earnings (losses) per share – diluted	€	€ (0.02)	€ (0.69)	€ (0.03)

Consolidated Statement of Financial Position Data:

€ in thousands	As of September 30, 2020
Cash and cash equivalents	€ 156,178
Total assets	450,185
Total liabilities	373,457
Total shareholders' equity	76,728

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements.

Our audited consolidated financial statements as of and for the year ended December 31, 2019 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, except they are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information. The audit report from Deloitte & Associés and PricewaterhouseCoopers Audit on the consolidated financial statements expresses a qualified opinion due to this departure from IAS 1 and includes an explanatory paragraph referring to the adoption of IFRS 16 Leases.

Our Unaudited Interim Condensed Consolidated Financial Statements as of September 30, 2020 and for the Nine Months Ended September 30, 2020 and 2019 have been prepared in accordance with IAS 34 Interim Financial Reporting as issued by the IASB.

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

Overview

We are a specialty vaccine company focused on the prevention of infectious diseases with significant unmet medical need through the development and commercialization of prophylactic vaccines. We take a specialized and highly 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 unique deep understanding of the science of vaccines, including our expertise across multiple vaccine approaches, as well as our established capabilities around vaccine development, to develop a prophylactic solution to these diseases. We have leveraged our expertise to both 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 North America, where approximately 300,000 Americans 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. To our knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials and we believe that its is differentiated from other clinical stage chikungunya vaccine candidates since VLA1553 is the only candidate that targets long-term protection with a single administration.

We are also advancing VLA2001, a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus that causes COVID-19, into Phase 1/2 clinical trials in order to address the urgent, global need for billions of doses of vaccines. VLA2001 is currently the only inactivated vaccine candidate for COVID-19 in clinical trials in Europe. We believe that our vaccine, if approved, could offer benefits in terms of

safety, cost, ease of manufacture and distribution compared to currently approved vaccines and, as an inactivated virus vaccine, could offer sustained protection despite mutations of the virus. In September 2020, we entered into a collaboration with the government of the United Kingdom, pursuant to which the government has ordered 60 million doses of VLA2001 for delivery in the second half of 2021 and 40 million doses for delivery in 2022 and has options to order 90 million additional doses for supply between 2023 and 2025. If the options are exercised in full, the contract could generate revenue of up to €1.4 billion.

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 some countries, prevention of diarrhea caused by enterotoxigenic *Escherichia coli*, or ETEC, the leading causes of travelers' diarrhea. All references to IXIARO in this Management's Discussion and Analysis of Financial Condition and Results of Operations 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 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. Our capital strategy is to leverage our commercial business for non-dilutive funding sources to complement equity capital. As of September 30, 2020, we had €156.2 million in cash and cash equivalents.

As of September 30, 2020, we had accumulated a net loss of €231.5 million. Our operating losses were € million and €0.8 million for the years ended December 31, 2020 and 2019, respectively, and €52.5 million and €3.2 million for the nine months ended September 30, 2020 and 2019, respectively. Our net losses were € million and €1.7 million for the years ended December 31, 2020 and 2019, respectively, and €62.3 million and €2.4 million for the nine months ended September 30, 2020 and 2019, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We currently have no preferred shares outstanding. In June 2020, we repurchased all of our outstanding preferred shares for an aggregate purchase price of €0.2 million.

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 under the heading "Risk Factors" included elsewhere in this prospectus.

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 three segments: commercialized vaccines, 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 74.8%, 91.3% and 91.9% of our revenues for the nine months ended September 30, 2020 and 2019 and the year ended December 31, 2019, respectively. For the nine months ended September 30, 2019 and the year ended December 31, 2019, this excluded the effect of €(10.7) million negative revenue related to the June 2019 mutual agreement to terminate our Strategic Alliance Agreement, or SAA, with GlaxoSmithKline Biologicals SA, or GSK, 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 3.2% and 2.6% of our revenues for the nine months ended September 30, 2020 and 2019, respectively, excluding the effect of the SAA termination agreement. 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 financial impact on the consolidated financial statement as of and for the nine months ended September 30, 2020.

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 nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. According to the World Tourism Organization, 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 82% decrease in arrivals in January to October 2020.

While COVID-19 has adversely affected sales of our travel vaccines to the general public, sales of IXIARO to the U.S. Department of Defense, which purchases our Japanese encephalitis vaccine for military personnel being deployed to endemic regions, have remained relatively consistent 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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options. For the nine months ended September 30, 2020 and 2019, 36.5% and 36.7% of our total product sales were from sales of IXIARO to the Department of Defense.

Revenues from Collaboration, Licensing and Services

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 September 30, 2020, we have recognized €68.1 million as (discounted) refund liabilities. An additional €43.0 million are treated as contract liabilities and will be realized within the next 12 months. In addition, €4.0 million were recognized as revenues from collaboration, licensing and services. €2.9 million in contract costs are included in other assets as of September 30, 2020.

In September 2020, we entered into a collaboration with the government of the United Kingdom, pursuant to which the government ordered 60 million doses of VLA2001 for delivery in the second half of 2021 and has the

option to purchase up to 130 million doses thereafter through 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion. Our inactivated SARS-CoV-2 vaccine is expected to have a two dose regimen.

We also derive revenues from our technologies and services. Revenues from our technologies consists of revenues from our EB66 cell line and vaccine adjuvant IC31, and 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.

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 €51.8 million and €23.2 million for the nine months ended September 30, 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 anticipate research and development costs in 2021 will continue to increase, as we recently commenced the Phase 3 clinical trial for our chikungunya vaccine (VLA1553) and our ongoing Phase 2 clinical trial for our Lyme vaccine candidate (VLA15). Under our agreement with Pfizer, we are obligated to contribute 30% of all Lyme vaccine candidate development costs.

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 September 2020, 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.

We plan to manufacture our COVID-19 vaccine candidate at our facilities in Livingston, Scotland. As part of our broader COVID-19 response, we plan to further invest in our manufacturing facilities in Livingston, Scotland and Solna, Sweden. The UK Government is obligated 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. This will partially cover the expenditures related to the expansion of our Livingston, Scotland facility. As the facility could potentially be used solely for manufacturing our COVID-19 vaccine candidate over a certain period of time, there is no refund obligation.

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 options to employees.

Grants

We seek grants from governmental agencies and non-governmental organizations to partially offset our increasing research and development costs. Grant income, which is recorded in other income, increased from nil to €4.6 million for the nine months ended September 30, 2020 as compared to the prior year period. In July 2019, we entered into a funding agreement with the Coalition for Epidemic Preparedness Innovations, or CEPI. Under this funding agreement, we are eligible to receive up to $23.4 million (paid in a series of six-month tranches) for vaccine manufacturing and late-stage clinical development of a single-dose live attenuated vaccine against chikungunya (VLA1553) in return for equitable access to project results. We are obligated to pay CEPI up to $7.0 million in commercial and related milestones. See “Business—Material Agreements—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, 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. In addition, as a result of COVID-19, for the nine months ended September 30, 2020, €5.3 million 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. We have continued to incur employee-related expense, though sales and marketing employee productivity is significantly decreased. However, we have been able to repurpose many of our highly-skilled employees to work on our COVID-19 response program. The COVID-19 pandemic is resulting 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. The effects of government-imposed quarantines and work-from-home policies, including the evolving nature of such policies, may still negatively impact productivity and production.

Sales in the remainder of 2020 and in 2021 are expected to continue to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its December 2020 report, the United Nations World Tourism Organization, or UNWTO, predicted that international travel, as measured by international arrivals, would rebound in 2021, based on the assumptions of a gradual reversal of the pandemic, the rollout of a COVID-19 vaccine, significant improvement in traveler confidence and major lifting of travel restrictions by the middle of 2021, as well as a large pent-up demand after months of closed borders and

travel bans. Recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels by mid-2023 to end of 2024. If international travel does not resume as quickly or as much as planned, 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 the section of this prospectus titled “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, or CODM. 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.
- “**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.
- “**Technologies and services**” — services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements.

As of January 1, 2020, 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 three operational segments based on estimated level of activities supporting the three segments. 56.0% of previously unallocated general and administrative costs were allocated to commercialized products, 36.5% to vaccine candidates and 7.5% to technologies and services using a combination of revenues and full-time employees as the basis to allocate costs to the segments. Marketing and distribution costs previously reported under corporate overhead have been fully allocated to the commercialized products. The purpose of this change was to reduce the corporate overhead costs and to reflect the way our CODM monitors the performance of the segments. The operating profit (loss) is the measure that is reported to the CODM. Segment reporting information for earlier periods has been restated to conform to these changes.

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 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 year ended December 31, 2019 included elsewhere in this prospectus.

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.

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, such as for CROs, and other contracted research and development activities, as well as for raw materials, relate to our Lyme vaccine candidate (VLA15), our chikungunya vaccine candidate (VLA1553) and, in the first nine months of 2020, our COVID-19 vaccine candidate (VLA2001). 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 September 30, 2020, we had capitalized research and development expenses recorded as intangible assets in an aggregate amount of €1.8 million.

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. Driven by our chikungunya vaccine candidate having progressed into Phase 3 clinical development in 2020, we expect incremental costs for preparation of market access and launch activities of this vaccine during the years to come.

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 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 need to 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 at their fair value 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 “Business—Material Agreements—CEPI Funding Agreement” 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. 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 Pound, 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 nor joint-control over BliNK, but rather hold a significant influence in BliNK in accordance with IAS 28.3, and therefore the investment is consolidated using the equity method according to IAS 28.16.

Income Tax

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

Results of Operations

Overview

Results of Operations—Consolidated

Our results of operations for the nine months ended September 30, 2020 and 2019 and the years ended December 31, 2020 and 2019 are summarized in the table below.

€ in thousands	**Nine months ended September 30,**		**Year ended December 31,**	
	2020	**2019**	**2020**	**2019**
	(unaudited)			
Product sales	45,874	86,409		129,511
Revenues from collaboration, licensing and services	12,974	(5,015)		(3,315)
Total revenues	**58,848**	**81,394**		**126,196**
Cost of goods and services	(37,249)	(35,517)		(52,781)
Research and development expenses	(51,767)	(23,238)		(38,022)
Marketing and distribution expenses	(13,772)	(17,064)		(24,145)
General and administrative expenses	(19,285)	(12,988)		(18,398)
Other income and expenses, net	10,733	4,165		6,338
Operating profit (loss)	**(52,493)**	**(3,247)**		**(811)**
Finance income	299	1,900		1,449
Finance expenses	(11,051)	(2,272)		(3,082)
Result from investments in associates	(16)	1,695		1,574
Profit (loss) before income tax	**(63,262)**	**(1,924)**		**(870)**
Income tax	928	(510)		(874)
Profit (loss) for the period	**(62,334)**	**(2,434)**		**(1,744)**

Results of Operations—By Segment

The following table presents our results of operations by segment for the nine months ended September 30, 2020 and 2019:

€ in thousands	Commercialized products		Vaccine candidates		Technologies and services		Corporate overhead		Total	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Product sales	45,874	86,409	—	—	—	—	—	—	45,874	86,409
Revenues from collaboration, licensing and services	1	95	3,988	(10,552)	8,986	5,441	—	—	12,974	(5,015)
Revenues	**45,875**	**86,505**	**3,988**	**(10,552)**	**8,986**	**5,441**	**—**	**—**	**58,848**	**81,394**
Cost of goods and services	(30,775)	(32,172)	—	—	(6,474)	(3,344)	—	—	(37,249)	(35,517)
Research and development expenses	(2,160)	(2,589)	(49,070)	(19,700)	(537)	(949)	—	—	(51,767)	(23,238)
Marketing and distribution expenses	(13,260)	(16,164)	(451)	(709)	(62)	(191)	—	—	(13,772)	(17,064)
General and administrative expenses	(11,740)	(7,613)	(6,136)	(4,246)	(1,410)	(1,130)	—	—	(19,285)	(12,988)
Other income and expenses, net	76	7	10,138	3,585	118	326	401	248	10,733	4,165
Operating profit (loss)	**(11,983)**	**27,973**	**(41,531)**	**(31,621)**	**620**	**153**	**401**	**248**	**(52,493)**	**(3,247)**

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

€ in thousands	Commercialized products		Vaccine candidates		Technologies and services		Corporate overhead		Total	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Product sales		129,511		—		—		—		129,511
Revenues from collaboration, licensing and services		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		(22,989)		(895)		(261)		—		(24,145)
General and administrative expenses		(10,599)		(6,150)		(1,650)		—		(18,398)
Other income and expenses, net		7		7,709		484		(1,861)		6,338
Operating profit (loss)		**44,376**		**(42,717)**		**(609)**		**(1,861)**		**(811)**

Revenue

Consolidated Revenue

Revenue decreased by €22.5 million, or 27.7%, to €58.8 million for the nine months ended September 30, 2020 compared to €81.4 million for the nine months ended September 30, 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 revenues from collaboration, licensing and services related to entering into our collaboration with Pfizer. Our total revenues for the nine months ended September 30, 2019 include a negative revenue of €(10.7) million related to the June 2019 mutual agreement to end the Strategic Alliance agreement, originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively), 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	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Commercialized products(1)	45,875	86,505		129,674
Vaccine candidates	3,988	(10,552)		(10,516)
Technologies and services	8,986	5,441		7,038
Total revenues	**58,848**	**81,394**		**126,196**

(1) Commercial products revenues consisted of €129.5 million and €86.4 million of product sales and €0.2 million and €0.1 million of revenues from collaboration, licensing and services for the year ended December 31, 2019 and for nine months ended September 30, 2019, respectively. For the nine months ended September 30, 2020, the full amount of €45.9 million relates to product sales.

Product Sales

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
IXIARO	30,824	64,200		94,144
DUKORAL	13,172	19,782		31,471
Third-party products	1,878	2,427		3,896
Total product sales	**45,874**	**86,409**		**129,511**

Product sales decreased by €40.5 million, or 46.9%, from €86.4 million in the nine months ended September 30, 2019 to €45.9 million in the nine months ended September 30, 2020. In the nine months ended September 30, 2020, IXIARO product sales were €30.8 million, a decrease of €33.4 million, or 52.0%, compared to €64.2 million in the nine months ended September 30, 2019. For DUKORAL, in the nine months ended September 30, 2020, product sales decreased to €13.2 million, a decrease of €6.6 million, or 33.4%, compared to €19.8 million generated in the nine months ended September 30, 2019. Sales of IXIARO and DUKORAL decreased primarily 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 nine months ended September 30, 2020, third-party product sales decreased to €1.9 million, a decrease of €0.5 million, or 22.6%, compared to €2.4 million in the nine months ended September 30, 2019. This decrease was primarily a result of the COVID-19 pandemic, as travel restrictions significantly reduced demand for one of the third-party products we sell, Vivotif, and which was partly offset by increased sales of influenza vaccines in the nine months ended September 30, 2020.

In the year ended December 31, 2019, IXIARO product sales were €94.1 million, largely driven by demand in the United States, mainly by military personnel through our supply agreement with the Department of Defense, as well as on the private market. In the year ended December 31, 2019, DUKORAL product sales were €31.5 million, driven by strong sales performance in Canada, and, to a lesser extent, product sales to European countries other than Germany. In the year ended December 31, 2019, third-party product sales totaled €3.9 million, driven by sales of Vivotif and influenza vaccines.

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	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
United States (military)	16,733	31,726		47,975
United States (non-military)	1,770	11,363		15,725
Canada	8,619	15,864		24,396
Nordics	3,093	7,627		11,027
Germany	7,042	5,652		10,345
United Kingdom	1,758	6,351		8,594
Austria	1,348	1,732		2,668
Other Europe	2,244	4,112		4,961
Rest of world	3,267	1,982		3,819
Total product sales	**45,874**	**86,409**		**129,511**

Total product sales in the United States decreased by €24.6 million, or 57.1%, from €43.1 million in the nine months ended September 30, 2019 to €18.5 million in the nine months ended September 30, 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 €7.2 million, or 45.7%, from €15.9 million in the nine months ended September 30, 2019 to €8.6 million in the nine months ended September 30, 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. Typically DUKORAL sales are strongest in the first and the fourth quarter of the year being the main travel season for Canadians. Germany's increased revenues in during the nine months ended September 30, 2020 compared to the previous period is attributed to purchase order commitments placed prior to the pandemic.

Revenues from Collaboration, Licensing and Services

The following table presents our revenue from collaboration, licensing and services, by segment, for the nine months ended September 30, 2020 and 2019 and the year ended December 31, 2020 and 2019.

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Commercialized products	1	95		163
Vaccine candidates	3,988	(10,552)		(10,516)
Technologies and services	8,986	5,441		7,038
Total revenues from collaboration, licensing and services	**12,974**	**(5,015)**		**(3,315)**

In the nine months ended September 30, 2020, total revenue from collaborations, licensing and services were €13.0 million, an increase of €18.0 million compared to the prior year period in which we recognized negative revenue of €(5.0) million. In the nine months ended September 30, 2020, our revenue from collaborations, licensing and services included €4.0 million related to our Lyme research and development collaboration with Pfizer, which we entered into in April 2020. Technologies and services revenues increased from €5.4 million in the nine months ended September 30, 2019 to €9.0 million in the nine months ended September 30, 2020, primarily resulting from increases in service revenues from our Solna facility and contract manufacturing we perform for third parties. In the nine months ended September 30, 2019, our negative revenue from collaborations, licensing and services was primarily driven by the recognition of 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, 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, 2019 included elsewhere in this prospectus.

During the nine months ended September 30, 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 €1.7 million, or 4.9%, to €37.2 million with a gross margin on product sales of 32.9% for the nine months ended September 30, 2020, as compared to COGS of €35.5 million and gross margin of 62.9% for the nine months ended September 30, 2019. This increase 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 €37.2 million, or 33.5% of our total operating income (expenses), for the nine months ended September 30, 2020, of which €18.3 million related to IXIARO sales, yielding a product gross margin of 40.8%, and of which €11.1 million related to DUKORAL sales, yielding a gross margin of 15.4%. COGS related to the third-party product distribution business was €1.4 million, and COGS related to cost of services was €6.5 million. COGS was €35.5 million, or 42.0% of our total operating income (expenses), for the nine months ended September 30, 2019, of which €21.3 million related to IXIARO sales, yielding a product gross margin of 66.8% and of which €9.1 million related to DUKORAL sales, yielding a gross margin of 53.9%. COGS related to the third-party product distribution business was €1.8 million and COGS related to cost of services was €3.4 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 67.0%. €14.0 million of COGS related to DUKORAL sales, yielding a gross margin of 55.6%. Of the remaining 2019 COGS, €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 €28.5 million, or 122.8%, to €51.8 million for the nine months ended September 30, 2020 from €23.2 million in the nine months ended September 30, 2019. Research and development expenses were 46.5% of our total operating income (expenses) for the nine months ended September 30, 2020, as compared to 27.5% of our total operating income (expenses) for the nine months ended September 30, 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.

Research and development expenses totaled €38.0 million, or 29.9% of our total operating income (expenses), 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 functions.

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	**Nine months ended September 30,**		**Year ended December 31,**	
	2020	**2019**	**2020**	**2019**
	(unaudited)		(unaudited)	
Lyme (VLA15)	(21,959)	(9,011)		(14,783)
Chikungunya (VLA1553)	(18,578)	(8,027)		(14,460)
COVID-19 (VLA2001)	(5,192)	—		—
hmPV	(1,019)	(1,431)		(2,052)
IXIARO	(1,096)	(1,364)		(1,904)
DUKORAL	(1,064)	(1,225)		(2,023)
Other research projects	(2,859)	(2,180)		(2,799)
Total research and development expenses	**(51,767)**	**(23,238)**		**(38,022)**

VLA15. Our research and development expenses related to our Lyme vaccine candidate program increased by €12.9 million, or 143.7%, to €22.0 million in the nine months ended September 30, 2020 from €9.0 million in the prior year period. This increase was primarily driven by the advancement of VLA15 in our Phase 2 clinical trial.

VLA1553. Our research and development expenses related to our chikungunya vaccine candidate program increased by €10.6 million, or 131.4%, to €18.6 million in the nine months ended September 30, 2020 from €8.0 million in the prior year period. This increase was primarily driven by increased expenses related to 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 commercial products and the rest of our development pipeline remained relatively steady in the nine months ended September 30, 2020 compared to the prior year period.

Marketing and Distribution Expenses

Marketing and distribution expenses decreased by €3.3 million, or 19.3%, to €13.8 million in the nine months ended September 30, 2020 from €17.0 million in the nine months ended September 30, 2019. Marketing and distribution expenses comprised 12.4% of our total operating income (expenses) for the nine months ended

September 30, 2020 compared to 20.2% of our total operating income (expenses) for the nine months ended September 30, 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.

Marketing and distribution expenses totaled €24.1 million, or 19.0% of our total operating income (expenses), for the year ended December 31, 2019. These expenses were a result of continued investments in our key markets, the United States and Canada, and included primarily €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 €6.3 million, or 48.5%, to €19.3 million for the nine months ended September 30, 2020 from €13.0 million for the nine months ended September 30, 2020. General and administrative expenses comprised 17.3% of our total operating income (expenses) for the nine months ended September 30, 2020 compared to 15.3% of our total operating income (expenses) for the nine months ended September 30, 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.

General and administrative expenses totaled €18.4 million, or 14.5%, of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily 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 as well as of €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	**Nine months ended September 30,**		**Year ended December 31,**	
	2020	**2019**	**2020**	**2019**
	(unaudited)			
Employee benefit expense other than share-based compensation(1)	(42,647)	(33,422)		(46,219)
Share-based compensation expense	(4,660)	(1,240)		(2,552)
Consulting and other purchased services	(42,325)	(17,782)		(29,840)
Raw materials and consumables used	(7,719)	(6,813)		(9,844)
Depreciation and amortization & impairment	(7,274)	(6,201)		(8,607)
Building and energy costs	(5,784)	(4,853)		(6,995)
License fees and royalties	(2,702)	(5,171)		(7,553)
Supply, office and IT-costs	(2,222)	(2,370)		(3,281)
Cost of services and change in inventory	(2,177)	(1,882)		(5,320)
Advertising costs	(2,130)	(4,515)		(6,801)
Warehousing and distribution costs	(1,378)	(2,146)		(3,013)
Travel and transportation costs	(470)	(1,390)		(1,921)
Other expenses	(586)	(1,022)		(1,399)
Operating expenses	**(122,074)**	**(88,807)**		**(133,345)**

(1) As of September 30, 2020 the position "employee benefit expense other than share-based compensations" includes a provision in the amount of €5.8 million of employer contribution fees, which are payable at the exercise of the IFRS 2 programs (as of September 30, 2019 and December 31, 2019: nil).

Other Income (Expenses)

The table below summarizes the other operating income (expenses) for the nine months ended September 30, 2020 and 2019 and the years ended December 31, 2020 and 2019:

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Research and development tax credit	6,498	3,966		6,314
Grant income	4,609	(48)		1,886
Profit/(loss) on disposal of fixed assets, net	(6)	(13)		(92)
Taxes, duties, fees, charges, other than income tax	(131)	(116)		(146)
Miscellaneous income/(expenses), net	(236)	377		(1,623)
Total other operating income (expenses), net	**10,733**	**4,165**		**6,338**

Other income and expenses increased by €6.6 million, or 157.7%, to €10.7 million for the nine months ended September 30, 2020 from €4.2 million for the nine months ended September 30, 2019. This increase was primarily due to our receipt of the CEPI grants totaling €3.8 million and COVID-19 pandemic related grants of €0.8 million in the 2020 period, as well as higher tax credits resulting from increased qualifying research and development expenses. Research and development tax credits from Austria were €5.7 million and €2.6 million for the nine months ended September 30, 2020 and 2019, respectively. The CIR from France totaled €0.8 million and €1.3 million for the nine months ended September 30, 2020 and 2019, respectively.

Other income and expenses totaled €6.3 million for the year ended December 31, 2019. Research and development tax credits from Austria were €4.4 million and the CIR from France was €1.9 million. Grants primarily consisted of the CEPI grant in the amount of €1.8 million. 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 prospectus for more information about this litigation.

Financial Income (Expense)

The table below summarizes our financial income (expense) for the nine months ended September 30, 2020 and 2019 and the years ended December 31, 2020 and 2019:

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Finance income				
Interest income from other parties	98	168		199
Fair value gains on derivative financial instruments	200	—		—
Foreign exchange gains, net	—	1,731		1,250
	299	**1,900**		**1,449**

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Finance expense				
Interest expenses on loans	(4,596)	(1,073)		(1,588)
Interest expense on refund liabilities	(1,764)	(44)		(89)
Interest expenses on lease liabilities	(673)	(692)		(926)
Other interest expense	(18)	(2)		(30)
Fair value losses on derivative financial instruments	—	(460)		(449)
Foreign exchange losses, net	(4,000)	—		—
	(11,051)	**(2,272)**		**(3,082)**
Finance income/(expenses), net	**(10,753)**	**(372)**		**(1,633)**

Finance expense, net was €10.8 million for the nine months ended September 30, 2020 compared to €0.4 million in the nine months ended September 30, 2019. This increase in finance expense, net was primarily due to adverse exchange rate effects in the nine months ended September 30, 2020 due to the significant increase in USD cash position held as a result of the Pfizer milestone payment and the loan costs attributed to the financing agreement with Deerfield and OrbiMed entered into in February 2020. The increase in finance expense, net was also due to an increase in other interest expenses on non-current refund liabilities and a one-time effect relating to an early repayment (early repayment fee of €0.6 million) of our loan with the European Investment Bank, or EIB, as part of the European Horizon 2020 initiative entered into in July 2016, discussed further below.

Finance expense, net was €1.6 million for the year ended December 31, 2019 and consisted of €2.6 million of interest and similar expenses and €0.4 million of fair value losses on derivative financial instruments, partly offset by net foreign exchange gains of €1.2 million and interest income of €0.2 million.

Income Tax

We recorded €0.9 million of income tax benefit for the nine months ended September 30, 2020 compared to an income tax expense of €0.5 million for the nine months ended September 30, 2019. This change in income tax benefit (expense) was primarily driven by the level of inventory held in the United States and the effect from eliminated inter-company profits.

Profit/(Loss) for the Period

Our loss for the period for the nine months ended September 30, 2020 was €62.3 million, increased from a loss of €2.4 million in the nine months ended September 30, 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.

Liquidity and Capital Resources

Overview

Since our inception, we have financed our operations primarily through the issuance of equity and secured debt. As of September 30, 2020, we had €156.2 million in cash and cash equivalents.

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. As of September 30, 2020, we had borrowings and lease liabilities of €111.3 million, of which €57.2 million were lease liabilities and €54.1 million were other loans, mainly from the financing agreement with Deerfield and OrbiMed. As of December 31, 2019, we had borrowings and lease liabilities of €85.2 million, of which €58.9 million were lease liabilities, €19.8 million were bank borrowings, and €6.6 million were other loans. As of December 31, 2019, €80.9 million of our borrowings and lease liabilities had a maturity of more than one year.

On December 20, 2013, we received a $30 million loan from an investment fund managed by Pharmakon Advisors, referred to herein as the Pharmakon Loan. The loan extended over a five year period and carried an interest rate ranging from 9.5% to 10.5%. On November 18, 2015, the loan was amended to increase the loan by an additional $11 million. Pursuant to the terms of the loan, starting in 2016 through January 2019, we paid a royalty to Pharmakon Advisors ranging from 2.5% to 3.1% on our IXIARO sales during the term of the loan. The interest rate and the royalty payable in connection with the loan were both recognized as finance expenses. The loan was fully repaid in January 2019.

In July 2016, we entered into a €25 million term loan facility with the 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. In the year ended December 31, 2017, two €5 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 million tranche was drawn following the same conditions as the last two tranches of this loan. This loan was fully repaid in the first quarter of 2020.

In February 2020, we entered into an $85 million 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 (unrestricted cash on hand and cash equivalent investments on a consolidated basis) 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, €103.75 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 September 30, 2020, $60.0 million (€54.1 million) was drawn down under our debt financing agreement with Deerfield and OrbiMed.

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

The table below summarizes our cash flows for the nine months ended September 30, 2020 and 2019 and the years ended December 31, 2020 and 2019:

€ in thousands	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Net cash generated from operating activities	77,631	5,043		5,529
Net cash used in investing activities	(8,072)	(7,986)		(10,685)
Net cash generated from/(used in) financing activities	22,424	(6,841)		(7,696)
Net change in cash and cash equivalents	**91,983**	**(9,784)**		**(12,852)**

Operating Activities

Net cash generated from operating activities in the nine months ended September 30, 2020 was €77.6 million compared to €5.0 million in the nine months ended September 30, 2019. The increase was primarily due to the $130.0 million (€116.9 million) upfront payment we received from Pfizer and related to our Lyme research collaboration and license agreement reflected in working capital and non-current assets, partially offset by €62.3 million of operating losses. Increase in inventories and reduction in trade payables further decreased cash by €5.0 million and €2.4 million respectively.

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 in the nine months ended September 30, 2020 was €8.1 million, compared to €8.0 million in the nine months ended September 30, 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.

Net cash used in investing activities was €10.7 million for the year ended December 31, 2019 and was comprised primarily of equipment purchases.

Financing Activities

Net cash generated from financing activities was €22.4 million in the nine months ended September 30, 2020 compared to €6.8 million used in financing activities in the nine months ended September 30, 2019. The increase was primarily due to the impact of borrowing activities. Net cash for the nine months ended September 30, 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 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 September 30, 2020, we had accumulated a net loss of €231.5 million. Our net loss was € million and €1.7 million for the years ended December 31, 2020 and 2019, respectively, and €62.3 million and €2.4 million for the nine months ended September 30, 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 VLA15, 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 the section of this prospectus titled “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, installment payments from our COVID-19 agreement with the UK government, milestone and service payments from our collaboration with Pfizer regarding our Lyme vaccine, our existing liquidity and the proceeds of the global offering. 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 September 30, 2020 will be sufficient to fund our operations through at least the next 12 months from the date of this prospectus.

Contractual Obligations

The following table discloses aggregate information about our material long-term contractual obligations as of December 31, 2019 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	3,850	17,010	11,644	393	32,898
Lease liabilities	3,225	6,422	27,572	30,206	67,424
Contract liabilities and refund liabilities	448	29	7,000	—	7,477
Total	**7,523**	**23,461**	**46,216**	**30,598**	**107,799**

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

Borrowings

As of December 31, 2019, the outstanding amount of bank borrowings and other loans was €26.3 million. It 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).

As of September 30, 2020, the outstanding amount of bank borrowings and other loans was €54.1 million. Of this, €48.2 million related to a 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%. Due to the quarterly interest calculation method, the aggregate annual interest actually paid is an amount equivalent to 10.09%. Part of the loan was used to fully repay the existing loan of €20.0 million with EIB. Other borrowings of €5.9 million related to financing of research and development expenses and to a loan that finances receivables under the CIR which has various conditions (interest rates) and terms (maturities).

Lease Liabilities

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 the lease agreement for premises in Vienna, Austria. We expect these leases will terminate in 2023 and 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).

As of September 30, 2020, the outstanding, discounted amount of lease liabilities was €57.2 million. Of this, €30.9 million 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. €25.1 million related to the lease agreement for premises in Vienna, Austria. We expect this lease will terminate in 2023 and 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).

Refund Liabilities

As of December 31, 2019, the carrying amount of refund liabilities was €6.6 million. This primarily comprises of expected payment to GSK related to the termination of the strategic alliance agreements, signed in June 2019 with payments expected in 2024.

As of September 30, 2020, the carrying amount of refund liabilities was €75.6 million. Of this, €68.1 million related to the collaboration with Pfizer for development of our Lyme disease vaccine, as we are required to contribute 30% of Phase 3 clinical trial costs for this vaccine. €6.2 million related to expected payment to GSK related to the termination of the strategic alliance agreements, signed in June 2019 with payments expected in 2024.

Off-Balance Sheet Arrangements

During the periods presented, we did not and do not currently have any off-balance sheet arrangements as defined under SEC rules, such as relationships with other entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our statements of financial position.

Critical Accounting Policies and Judgments and 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. See Note 5.3 to our consolidated FY 2019 financial statements appearing elsewhere in this prospectus for a description of our significant accounting policies.

Our management applied judgement and estimates on the following critical accounting topics:

Revenue Recognition of our Collaboration, Licensing and Services Agreements

Management's judgement is required to determine the identification and separation of performance obligations (especially when determining whether the license is distinct, which is the case when the customer can benefit from the license without further involvement), the determination of the transaction price (including the judgement of payables to customers), and allocation of the transaction price to the performance obligations on relative standalone selling price. The standalone selling price is sometimes not available or are hard to value intangible assets, so various valuation techniques are used. In addition, management's judgement is required whether revenue from collaborations and licensing is recognized over time or at a point in time.

In June 2019, we terminated the SAA with GSK. Judgements have been applied in the likelihood of reaching future milestones, where payments are dependent.

In April 2020, we entered into a collaboration to co-develop and commercialize our Lyme disease vaccine with Pfizer. This agreement included a $130 million (€116.9 million) upfront payment from Pfizer, which we received in June 2020 and booked in an amount of €116.9 million. While we are obligated to contribute 30% of all development costs through completion of the development program, as of September 30, 2020, €68.1 million have been recognized as (discounted) refund liabilities to reflect the requirement to pay 30% of Pfizer's research and development costs and €43.0 million are treated as contract liabilities and will be realized within the next 12 months. The agreement includes various performance obligations: 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 last quarter of 2020. Judgement and estimates were applied when determining the transaction price (including the likelihood for refund liability) as well as at the allocation of the transaction price to the performance obligations. In the nine months ended September 2020, €4.0 million were recognized as revenue from collaboration, licensing and services. €2.9 million contract costs are included in other assets as of September 30, 2020. In case the refund liability varies from the estimates, the revenue will be adjusted in the period where the estimate is updated.

In September 2020, we announced a collaboration with the UK government for our COVID-19 vaccine candidate, VLA2001. Under the agreement, if our vaccine development is successful, we will provide the UK government with 60 million doses of VLA2001 in the second half of 2021. The UK Government then has options over 40 million additional doses in 2022, which option was exercised in January 2021, and a further 90 million doses, in aggregate, from 2023 to 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion. The UK government is also investing up-front 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 includes three 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 third is an option to sell an additional 90 million doses at the expected market price. During the first nine months of 2020, none of these performance obligations were satisfied, therefore no revenue was recognized in this period. As of September 30, 2020, €100.3 million are included in trade receivables and €100.3 million are included in contract liabilities. Total expenses for research and development for the COVID-19 vaccine were €5.2 million in the first nine months of 2020.

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 need management’s judgment.

Valuation of Intangibles / Impairment tests

Due to the COVID-19 pandemic situation the long range business plans have been updated several times during 2020. Impairment tests for IXIARO as well as for DUKORAL have been performed in the first and second quarters of 2020, respectively. Management estimates are applied on the long range business plan – on the revenue as well as on the expense side and on probabilities of success. While the IXIARO valuation is relatively insensitive to changes in discount rate or future revenues, an impairment for DUKORAL assets would be required at an increase of discount rate of 7 basis points from 8.77% to 8.84%. An additional reduction in revenues of 10.0% would result in an impairment loss of €1.8m in 2020.

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 €110.2 million as of December 31, 2019 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. This is the case for entities where there is no profitable history and/or a negative outlook in the following 5-years period of the long range business plan.

Measurement of Contingencies and Loss Provision

As part of our activities, we may be exposed to contractual commitment risk. Management exercises its judgment to estimate the probability and amount of cash outflows, as well as the information to disclose regarding

contingent liabilities. For the litigation related to the Vivalis-Intercell merger, a provision has been included for potential settlement costs, but not for the maximum amount that could be claimed by the plaintiffs. This could be material if the exchange ratio between Intercell and Valneva shares used in the merger is amended as this could be applied to all outstanding Intercell shareholders. Management considers having to pay the maximum amount that could be claimed by the plaintiffs to be remote.

Share-based Compensation and Related Expected Employer Contribution Costs

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our Management Board and Supervisory Board members and our employees, including stock options (ESOPs), Free Convertible Preferred Shares, Free Ordinary Shares and Equity Warrants (BSAs). In 2017 and 2019, we also established a Phantom Stock Option Program with terms and conditions similar to ESOPs, for employees who are U.S. citizens.

The fair value of such share-based compensation is recognized as an expense for employee services received in exchange for the grant of the options. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted, excluding the impact of any non-market vesting conditions. Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Annually, we revise our estimates of the number of options that are expected to become exercisable. We recognize the impact of the revision of original estimates, if any, in the income statement and make a corresponding adjustment to equity.

While assumptions in measuring fair values on the share-based compensations have been taken into account, management has considered the likelihood of an event of change of control remote, therefore the accelerated vesting was not taken into account. Further information is explained in Note 5.22 of to our consolidated financial statements as of and for the year ended December 31, 2019 included elsewhere in this prospectus.

Leases

For any extension options of lease agreements, management applies judgement whether it is reasonable certain to exercise the options, which was applied for lease arrangement on production sites.

Material Weaknesses

In conjunction with preparing our consolidated financial statements as of and for the year ended December 31, 2019 for this offering, 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 herein, 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 begun to develop a remediation plan to address these material weaknesses and strengthen our controls in these areas. While we are working to remediate the material weaknesses as quickly and efficiently as possible, we cannot at this time provide the expected timeline in connection with implementing our remediation plan and we do not expect the remediation to be complete at the time of completing our audit for the year ending December 31, 2020. These remediation measures may be time-consuming and costly, and might place significant demands on our financial and operational resources. See our risk factor on these material weaknesses in “Risk Factors—There are

material weaknesses in our internal controls over financial reporting and if we are unable to maintain effective 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."

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 5.2 to our consolidated financial statements as of and for the year ended December 31, 2019 appearing elsewhere in this prospectus. We did not have to change our accounting policies or make retrospective adjustments as a result of adopting these standards.

There are no standards that are issued and not yet effective that are expected to have a material impact on our consolidated financial statements.

Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange 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	Nine months ended September 30,		Year ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
EUR/USD +10%	1,174	(2,023)		(3,134)
EUR/USD -10%	895	2,473		3,830
EUR/GBP +10%	(10,839)	(1,165)		(1,122)
EUR/GBP -10%	13,247	1,424		1,371
EUR/SEK +10%	182	400		114
EUR/SEK -10%	(222)	(489)		(140)
EUR/CAD +10%	(463)	(286)		(275)
EUR/CAD -10%	566	350		336

As of September 30, 2020, the positive impact from an increase in EUR/USD is caused by derivative instruments.

As of September 30, 2020, the increase in the Foreign Currency Exchange Risk in GBP is caused by trade receivables denominated in GBP related to the milestone payments expected to be received from the UK Government relating to the COVID-19 vaccine program. The incoming cash is expected to be used for payments to fund manufacturing and research and development and other costs denominated in GBP.

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 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, 2019, the calculated impact on income before tax of a 0.25% shift would be an increase or decrease of less than €0.1 million.

The calculated impact on income before tax of a 0.25% shift would be an increase or decrease of €0.2 million as of September 30, 2020 and less than €0.1 million as of September 30, 2019.

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.

JOBS Act Exemptions and Foreign Private Issuer Status

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in total annual gross revenue, have more than $700.0 million in market value of our ordinary shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these provisions that allow for reduced reporting and other burdens.

We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

Upon consummation of the global offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;

- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and
- Regulation FD, which regulates selective disclosures of material information by issuers.

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 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 North America, where approximately 300,000 Americans 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. To our knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials and we believe that it is differentiated from other clinical stage chikungunya vaccine candidates since VLA1553 is the only candidate that targets long-term protection with a single administration.

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 vaccine candidate for COVID-19 in clinical trials in Europe. We believe that, if approved, our vaccine, as an inactivated virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could offer sustained protection despite mutations of the virus. In September 2020, we entered into a collaboration with the government of the United Kingdom, pursuant to which the government has ordered 60 million doses of VLA2001 for delivery in the second half of 2021 and 40 million doses for delivery in 2022 and has the option to purchase up to 90 million doses between 2023 and 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion.

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.

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 three BioSafety Level 3 research and development 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.

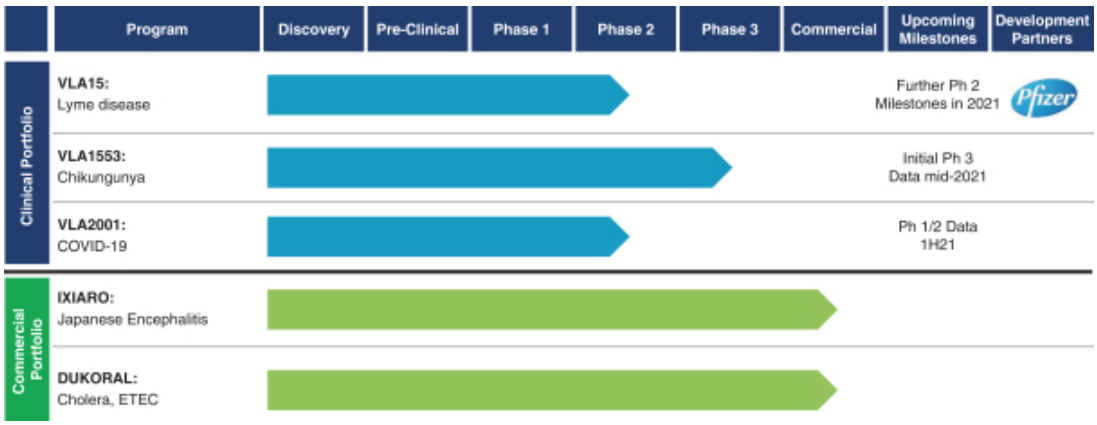
We are a public company listed on Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We have assembled a team of experts with deep scientific, 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.

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:



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 two Phase 2 clinical trials of VLA15 in over 800 healthy adults and 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 anticipated to commence in the first quarter of 2021. The dosing of the first subject in this trial will trigger a milestone payment from Pfizer of $10 million. Together with Pfizer, we expect that our Phase 3 clinical trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the pivotal, placebo-controlled field efficacy trial that we are planning for the 2023 tick season. We expect to report initial data, based on the first tick season of the trial, by the end of 2023. If the results from these clinical trials are positive, we are targeting submitting a biologics license application, or BLA, and marketing authorization application, or MAA, in the second half of 2024. VLA15 has received Fast Track designation from the FDA.
- **VLA1553 –** a vaccine candidate against the chikungunya virus, 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, to our knowledge, VLA1553 is

the only chikungunya vaccine candidate in Phase 3 clinical trials. Additionally, when compared to other chikungunya assets that are being evaluated in clinical trials, we believe that VLA1553 has a number of advantages, including the fact that it is the only candidate designed to require a single administration. Based on the data generated in our Phase 1 clinical trial in which we observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants, which results were sustained after 12 months, as well as our discussions with regulators, VLA1553 has advanced to a Phase 3 clinical trial, in which we have achieved over 80% enrollment as of February 2021 and for which we expect to complete recruitment in the first half of 2021 and report initial data in mid-2021. VLA1553 received Fast Track designation from the FDA and PRIME designation from the European Medicines Agency, or 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, subject to agreement with FDA that this surrogate endpoint is reasonably likely to predict protection from chickungunya 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 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. Our inactivated whole virus vaccine candidate is currently being evaluated in the Phase 2 portion of a fully-enrolled Phase 1/2 clinical trial. Although vaccines against SARS-CoV-2 have already been approved, 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 September 2020, we announced a collaboration with the UK government, which has the option to purchase up to 190 million doses through 2025. We expect to report initial data from our Phase 1/2 clinical trial in April 2021 and to use these data to select the final dose for use in our Phase 2/3 trial. If the results are positive, we expect to initiate a pivotal Phase 2/3 trial which could support an initial regulatory approval in the second half of 2021. We began production of VLA2001 in January 2021 in parallel with clinical development in order to optimize the timeline for potential deliveries of VLA2001.

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 €94.1 million in the year ended December 31, 2019 and €30.8 million in the nine months ended September 30, 2020. Sales in 2020 have been significantly impacted by the COVID-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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options.

- **DUKORAL –** an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and/or heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. We acquired DUKORAL in 2015 and recorded €31.5 million of revenues in the year ended December 31, 2019 and €13.2 million in the nine months ended September 30, 2020. Sales in 2020 have been 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 Strengths

Our vision is to build a leading vaccines company with a portfolio of specialized assets targeting diseases with limited preventive or therapeutic treatment options where our vaccines can contribute unique or differentiated prophylactic solutions. We believe that the following strengths will allow us to continue to deliver on this vision and build on our leading position as a vaccine focused biotechnology company:

- **Highly specialized and targeted approach to development of unique prophylactic vaccines.** We take a specialized approach to developing our vaccine candidates by focusing on disease targets that lack a preventative and effective therapeutic treatment option and where prophylactic vaccines can have a meaningful impact. Our deep understanding and broad range of experience with vaccine technologies allow us to target and focus on diseases according to greatest medical need rather than according to whether a specific technology or mechanism of action can be effective. We also remain focused on diseases where there is limited existing competition from therapeutics or where we believe our vaccines could offer clear benefits and differentiation compared to competitive assets. Once we have identified a target disease, we develop a vaccine candidate with the mechanism of action we believe will be most effective against that particular disease. As a result of this strategy and our ability to mobilize our expertise to achieve rapid product candidate selection and development, we believe that our vaccine candidates are the leading candidates against their disease targets, with VLA15 representing the only vaccine in late clinical development targeting Lyme disease and VLA1553 being the first vaccine candidate targeting the chikungunya virus that has entered into Phase 3 clinical trials.
- **Advanced pipeline of differentiated clinical-stage assets designed to address large target populations.** Our development portfolio is primarily comprised of late stage clinical assets designed to prevent a variety of infectious diseases with high unmet need. Specifically, VLA15 targets Lyme disease, which impacts an estimated 300,000 people in the United States and 200,000 people in Europe each year, with 10-20% of those patients having persistent debilitating symptoms for which there is no current effective treatment. Similarly, VLA1553 targets the chikungunya virus, a mosquito-borne virus for which there is no effective treatment and that often causes sudden, large outbreaks with high infection rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. Our pipeline also includes VLA2001, a vaccine candidate against COVID-19, on which we have entered into a collaboration with the UK government. To our knowledge, this is the only inactivated COVID-19 vaccine in clinical development in Europe or the United States. We expect to report initial data in April 2021 and, if the results are positive, we expect to initiate a pivotal Phase 2/3 trial which could support an initial regulatory approval in the second half of 2021. In keeping with our specialized strategy, we believe our COVID-19 vaccine, if approved, could offer clear benefits compared to other vaccines that obtain initial regulatory approvals, taking into account considerations such as safety, cost, ease of manufacture and distribution and could offer sustained protection despite mutations of the virus.
- **Product development and regulatory expertise with clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization.** In the process of successfully obtaining regulatory approval for IXIARO, and advancing two clinical assets to late-stage trials, we have enrolled thousands of volunteers and patients in global clinical trials and developed the experience and expertise necessary to quickly and efficiently execute our strategic plans from product development through the regulatory approval process and on to commercialization. We believe that our deep

understanding of the regulatory requirements in various countries and our strong connections to key stakeholders in select geographies such as the United States, Europe and Canada strengthen our expertise in product development and set us up for commercial success.

- **Highly developed, nimble and sophisticated manufacturing infrastructure.** We believe that we have the experience, capabilities and resources to produce commercial quantities of viral and bacterial vaccines and the proven ability to scale our operations both in-house and with contract manufacturing organizations, or CMOs. Given the complexity and safety protocols associated with producing a wide variety of vaccines, having the infrastructure necessary to safely and efficiently scale up manufacturing is essential to successful product development and commercialization. We have a robust manufacturing and laboratory platform with facilities across Europe to meet our clinical and commercial needs. Our infrastructure includes BioSafety Level 3 research and production facilities in Livingston (Scotland), Vienna (Austria) and Nantes (France). Our cGMP manufacturing and quality control facilities in Livingston, Solna (Sweden) and Vienna are approved by or registered with many different authorities including, with respect to Livingston and Vienna, the FDA. Furthermore, as part of our deal with the UK government, the UK Government is fully funding the expansion of our Livingston production capabilities.

- **Two commercialized vaccines, specialist sales infrastructure and distribution rights for third-party vaccines which help to fund our clinical development efforts**. We have successfully commercialized two vaccines that are primarily used to protect travelers against diseases that are endemic or prevalent in certain regions. Our portfolio includes IXIARO for the prevention of Japanese encephalitis and DUKORAL for the prevention of cholera and, in some markets, also ETEC. We have a contract, along with a track record of previous contracts, with the U.S. Department of Defense to supply IXIARO, the only vaccine against Japanese encephalitis approved for use in the United States, for U.S. military personnel, who are required to be vaccinated against this disease. We are also leveraging our specialist commercial infrastructure in North America and certain European countries to market and distribute vaccines for third parties. For example, in 2020 we entered into an agreement with Bavarian Nordic to distribute their vaccines against rabies and tick-borne encephalitis in Canada, the United Kingdom, France and Austria. These distribution rights strengthen our commercial capabilities and further promote the Valneva brand. We expect to leverage our commercial infrastructure to support commercialization of our vaccine candidates, if approved.

- **Highly experienced leadership team with track record of success in the vaccine space.** We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Thomas Lingelbach, our President and CEO, has more than 25 years of experience in the vaccine industry, previously serving as CEO of Intercell and leading global vaccine industrial and product development efforts at Novartis and Chiron. Franck Grimaud, our President and Chief Business Officer, has spent 25 years in corporate business development and was CEO and co-founder of Vivalis. Juan Carlos Jaramillo, MD, our Chief Medical Officer, has 20 years of experience in medical affairs, clinical development and global market access at GlaxoSmithKline, Celsion, Grünenthal and Daiichi Sankyo. Frédéric Jacotot, our General Counsel and Corporate Secretary, has 30 years of legal experience in the pharmaceutical industry. David Lawrence, our acting CFO, has more than 30 years of experience serving in executive and board roles in large pharmaceutical, high-growth biotech and tech companies. Perry Celentano, our Interim COO, has an extensive track record in the pharmaceutical and vaccines industry including roles with Merck, Novartis and Dynavax. In total, our senior executive team has more than 100 years of combined experience working at industry leaders and successfully developing vaccine candidates that have had a meaningful impact on the targeted diseases. Over the course of this experience, members of our management team have supported the submission of over 40 INDs and 20 NDAs/BLAs and have contributed to the development of 17 approved products.

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 two Phase 2 clinical trials of VLA15 in Europe and the United States which together enrolled over 800 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. In collaboration 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, anticipated to commence in the first quarter of 2021. 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 an MAA in the second half of 2024.
- **Seek regulatory approval for, and commercialize, VLA1553 as a prophylactic vaccine candidate against chikungunya virus.** In our Phase 1 clinical trials, we observed that VLA1553 led to the development of antibodies to chikungunya in 100% of the 120 healthy participants in this trial. Based on this Phase 1 dataset, we have advanced VLA1553 directly into Phase 3 clinical trials and are currently conducting a pivotal trial in over 4,000 healthy adults. We expect to report results from our Phase 3 clinical trial in mid-2021 and, if the data are positive, we intend to prepare a BLA and MAA to submit to the regulatory agencies for approval. As the first company to initiate a Phase 3 clinical trial of a chikungunya vaccine, we believe we would be 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, we would target product sales as early as 2023.
- **Advance VLA2001 through clinical development for the prevention of COVID-19.** We initiated clinical testing of VLA2001, an inactivated, adjuvanted SARS-CoV-2 virus vaccine, in December 2020. VLA2001 is a vaccine candidate developed from an inactivated virus, which is a type of vaccine that has proven effective against other viruses, including influenza. We are preparing for a potentially pivotal Phase 2/3 clinical trial in approximately 4,000 healthy adults. We expect this trial to commence in the second quarter of 2021 after final data from our ongoing Phase 1/2 trial, if positive. This Phase 2/3 trial can potentially form the basis for an initial regulatory approval. Given the fact that VLA2001 is an inactivated whole virus vaccine, an approach with a well-proven and established profile, we believe our vaccine, if approved, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could offer sustained protection despite mutations of the virus. Further clinical studies will be required to obtain additional or final regulatory approvals. With the support of the UK government, we have already begun to scale our manufacturing facilities and have commenced production to address the projected commercial demand for VLA2001.
- **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, parvovirus B19 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. 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 study for whom a specific antibody develops and becomes detectable in blood
- ***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 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 two Phase 2 clinical trials of VLA15 in over 800 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 "—Material Agreements—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 allow for completion of vaccination in time for the pivotal, placebo controlled field efficacy trial that we are planning for the 2023 tick season. If the results from this Phase 3 trial are positive, we plan to submit a biologics license application, or BLA, and MAA in the second half of 2024 based on efficacy data after the 2023 tick season. 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 300,000 Americans 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 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.

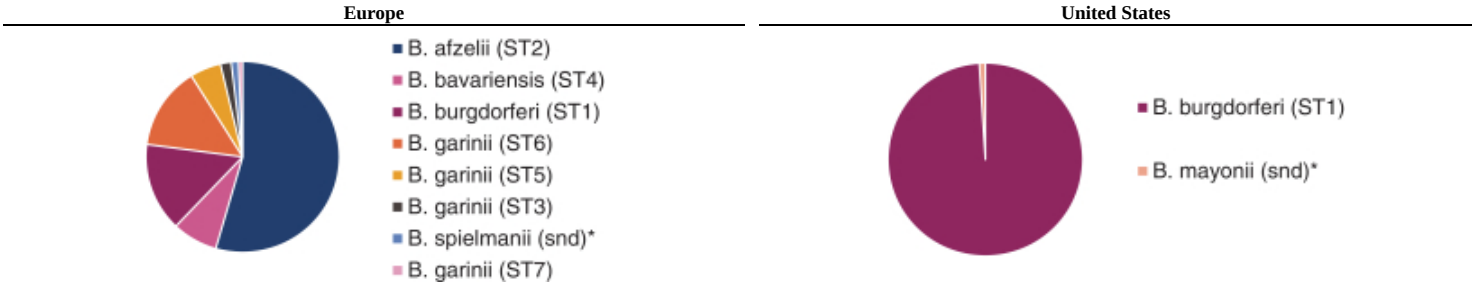
When diagnosed sufficiently early, Lyme disease can be successfully treated with a two-week to four-week course of oral antibiotics. However, given that the disease is often misdiagnosed in its early stages, patients often miss this therapeutic window. Additionally, chronic symptoms can commonly persist 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 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.

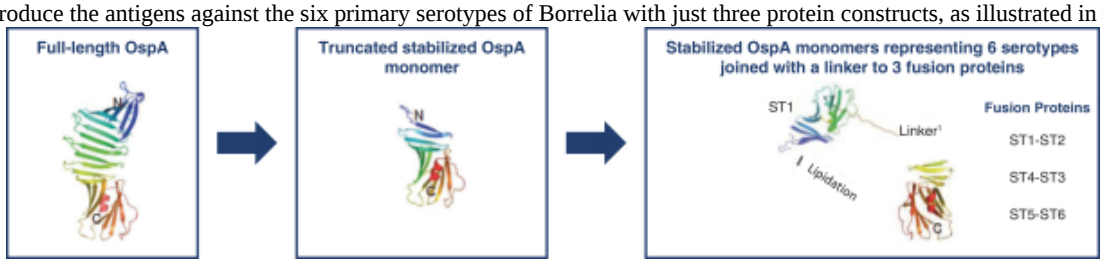
Step 1	Step 2	Step 3	Step 4
Vaccine, when injected, elicits high levels of anti-OspA antibodies	**Tick attaches to vaccinated human and begins feeding on blood (24- to 48-hour attachment needed to transmit *B. burgdorferi*)**	**Anti-OspA antibodies from vaccine enter tick via consumed blood**	**Antibodies 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:



* *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

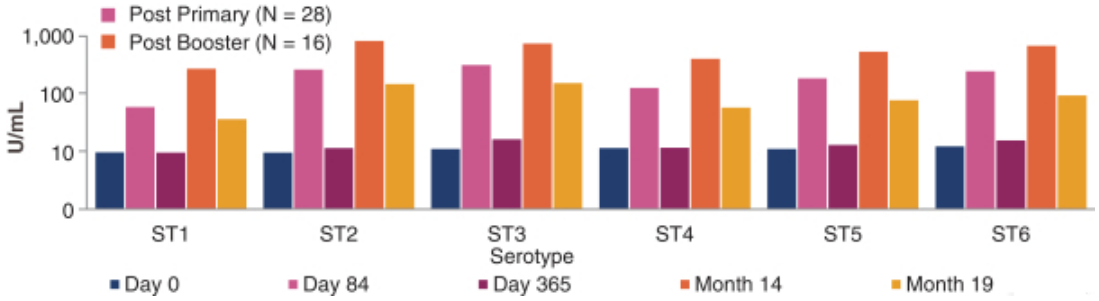
We evaluated VLA15 in a partially randomized, multi-center dose escalation Phase 1 clinical trial conducted in Belgium and the United States in 179 healthy adults below 40 years of age. The first 24 subjects were included in an open-label trial in which they participated in a staggered dose escalation design. The remaining 156 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 at month 19, with an interim analysis at month 14. These single re-vaccinations resulted in a significant immune-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.

lgG Geometric Mean Titres (GMT) by Serotype Over Time



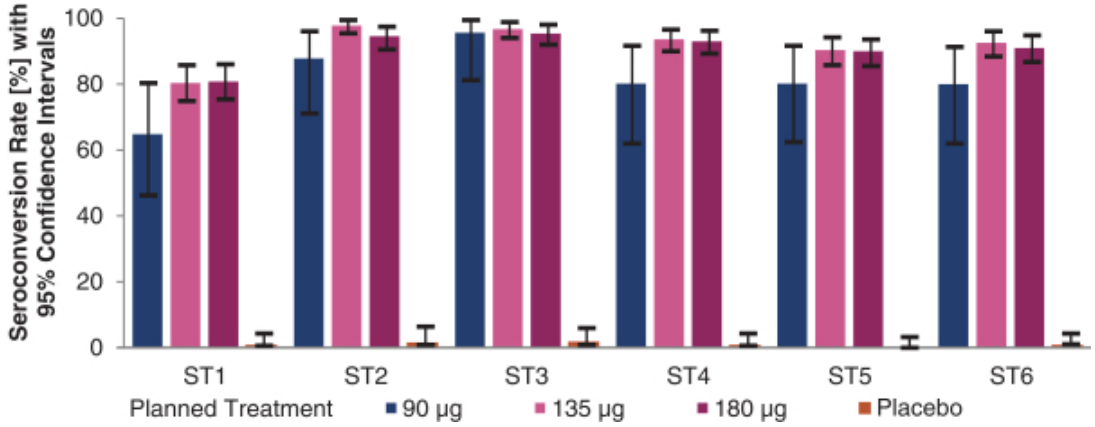
Phase 2 Clinical Trials and Results

We conducted two Phase 2 clinical trials of VLA15 in Europe and the United States which evaluated the safety and efficacy of VLA15 at different dosage levels and schedules. Together, these trials enrolled 818 healthy adults of 18 to 65 years of age. We also plan to commence a third Phase 2 trial in the first quarter of 2021 in conjunction with our collaboration with Pfizer. This trial will incorporate a reduced dosing schedule and include pediatric participants.

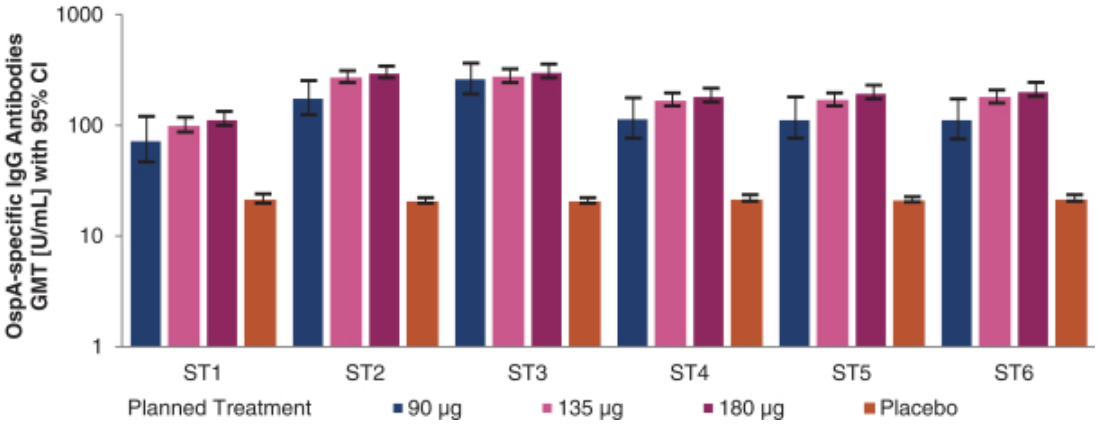
VLA15-201 Trial and Results

Our first Phase 2 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 two 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 geometric mean titers, or GMTs, for IgG against each OspA serotype ST1 to ST6. GMT calculates the average antibody across a cohort of subjects. Secondary endpoints examined SCR, geometric mean fold rise, or GMFR, and occurrence of adverse events.

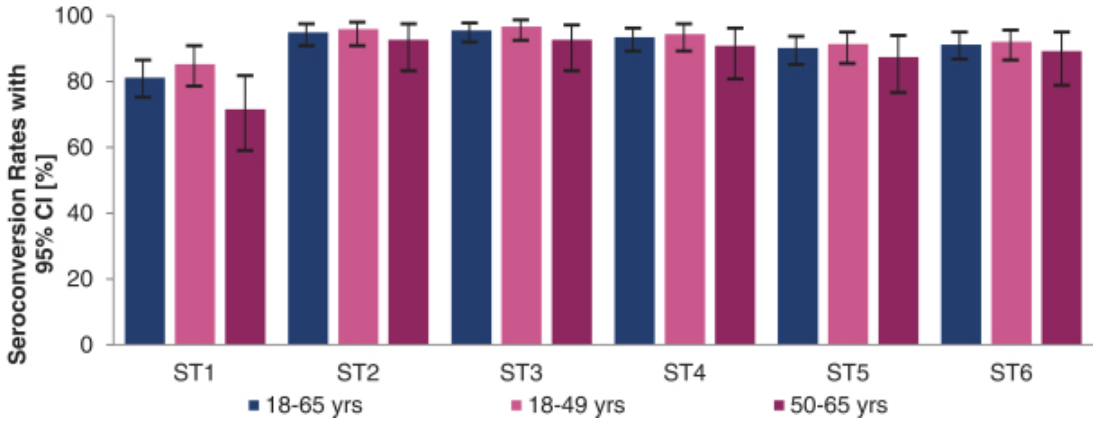
In July 2020, we announced statistically significant results from our Phase 2 clinical trial of VLA15-201 in which we observed VLA15 was immunogenic across all dose groups tested. Compared to results from the Phase 1 clinical trial, the higher doses used in our Phase 2 trial elicited higher antibody responses across all serotypes than those observed after the primary dose in the Phase 1 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 significant differences observed 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 Lyme (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.

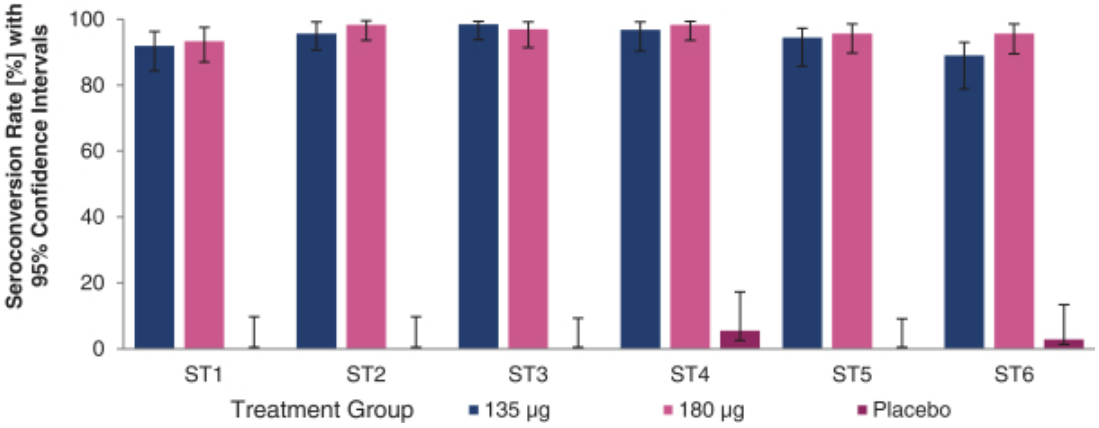


VLA15 was generally well tolerated across all dose and age groups tested. No serious adverse events, or SAEs, related to VLA15 were observed in any treatment group. The most common solicited local adverse events were injection site pain (68.4%) and tenderness (76.6%), whereas the most common solicited systemic adverse events were headache (33.2%), fatigue (31.6%) and muscle pain (myalgia) (41.1%). The 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 Trial and Results

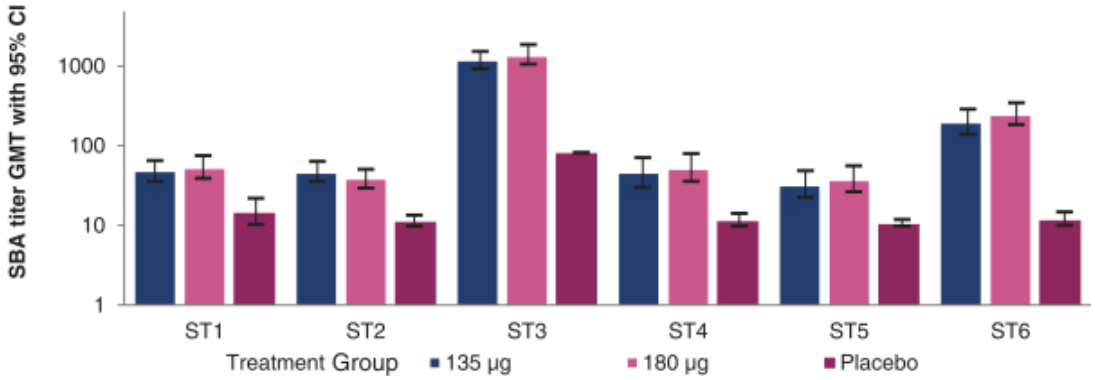
Our second Phase 2 trial, VLA15-202, was a randomized, observer-blind, placebo-controlled multi-center Phase 2 clinical trial conducted in the United States with 246 healthy volunteers aged 18-65. The subjects were randomized 2:2:1 to receive either VLA15 with alum (either 135 µg or 180 µg) or placebo, administered through intramuscular injection at month zero, two and six. The primary endpoint of the trial was GMTs for IgG against each OspA serotype, measured at month 7 to highlight the importance of further increases in OspA-specific IgG titers after the primary immunization series as well as optimized antibody persistence, which are likely necessary to achieve a successful vaccine candidate. Secondary endpoints evaluated SCR, GMFR 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 Lyme (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 third-party 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 LD (135 µg group) was reported as an adverse event of significant interest: erythematous rash, developed approximately two weeks after the first vaccination.

On December 2, 2020, we announced the acceleration of the pediatric development of VLA15. The Phase 2 clinical trial VLA15-221, which we plan to commence in the first quarter of 2021 subject to regulatory approval, will include approximately 600 subjects ranging from 5-65 years old. This will be the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old, and we expect to report initial data from the pediatric population in the second quarter of 2022. The trial will also include a reduced immunization schedule, at months zero and six rather than zero, two, and six, and will investigate a booster dose of VLA15 administered one year following the six-month dose. The dosing of the first subject in this trial will trigger a milestone payment from Pfizer of $10 million.

Phase 3 Trial

We are working closely with Pfizer on our large-scale efficacy trial which will be conducted in the United States and the European Union. We anticipate that this trial will start in the third quarter of 2022, subject to feedback from regulatory authorities. We expect to report initial data, based on the first tick season of the trial, by the end of 2023. We are targeting a BLA/MAA submission based on efficacy data in the second half of 2024.

The planned Phase 3 clinical trial will include adults as well as pediatric patients, adolescents and adults, ages 5 and above, with approximately 16,000 participants in total. There will be a randomized 1:1 ratio of participants receiving the vaccine and placebo, with a single dose of 180µg with alum given at the beginning of the trial and a booster vaccination given 18 months later to certain participants. Efficacy will be assessed six months after the initial dose and patients will be followed for three years to assess persistence. The planned primary endpoint for the Phase 3 clinical trial will be the efficacy of VLA15 in preventing confirmed Lyme disease in the first tick season after the primary series vaccination, with enrollment and primary dosing done from September 2021 through March 2022 and Lyme surveillance to be done from March through November 2023. The secondary endpoint is the efficacy of VLA15 in preventing confirmed Lyme disease in the second tick season after completion of the 18 month booster.

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.

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 are now conducting a pivotal trial in over 4,000 healthy adults. VLA1553 has received Fast Track 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, which is an immune

response that predicts protection against clinical endpoints, subject to agreement with FDA that this surrogate endpoint is reasonably likely to predict protection from chickungunya 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 and rates of infection are observed and compared at various points in time across each of the various trial groups.

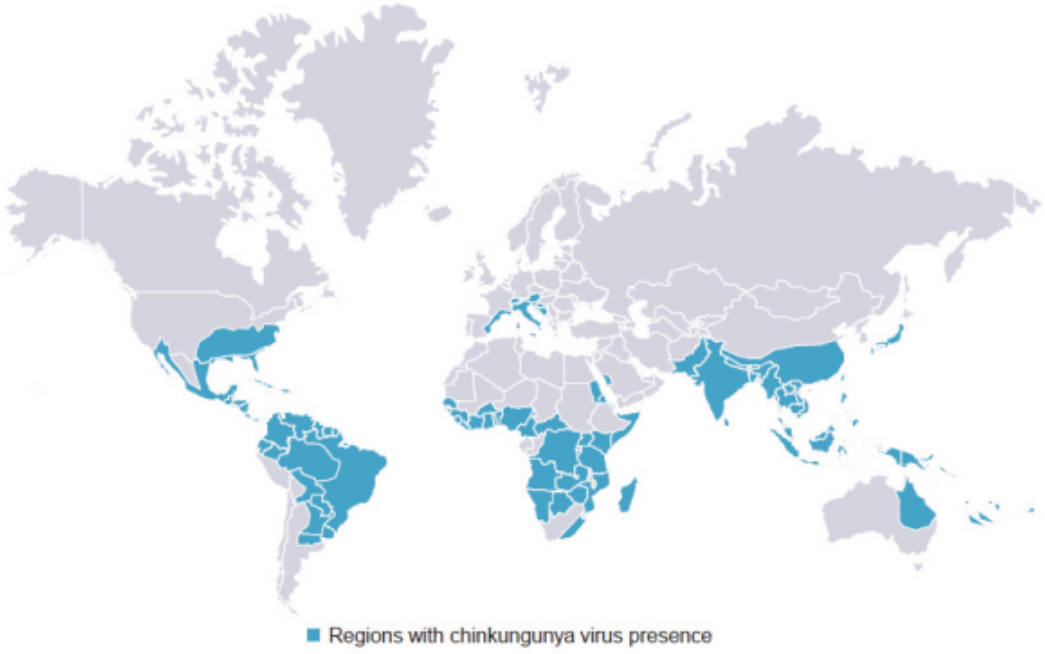
The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a PRV. To our knowledge, VLA1553 is currently the only chikungunya vaccine in Phase 3 clinical testing. We anticipate reporting the initial results from our Phase 3 clinical trial in mid-2021. If approved, we intend to market VLA1553 as a traveler vaccine in North America and Europe. 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 plan to commence an adolescent clinical trial of VLA1553 in 750 healthy volunteers in Brazil in 2021. We have been awarded up to $23.4 million in funding from CEPI in relation to this partnership. See "—Material Agreements—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 where the economic impact is considered to be significant. 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 and 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 two candidates that have reached Phase 2 clinical trials: a measles-vectored vaccine candidate, which is being developed by Merck, and a virus-like particle vaccine candidate developed by

Emergent BioSolutions. Both programs have completed Phase 2 clinical trials but have not publicly announced initiation of Phase 3 clinical trials. Additionally, we believe that both of these vaccine candidates also face limitations relative to VLA1553, including VLA1553 being designed to only require a single administration, while Merck and Emergent BioSolution's assets are likely to require multiple shots to reach necessary 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.

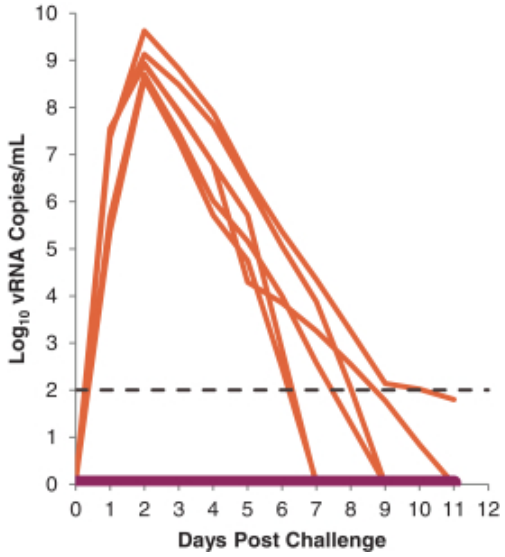
Pre-Clinical Data

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

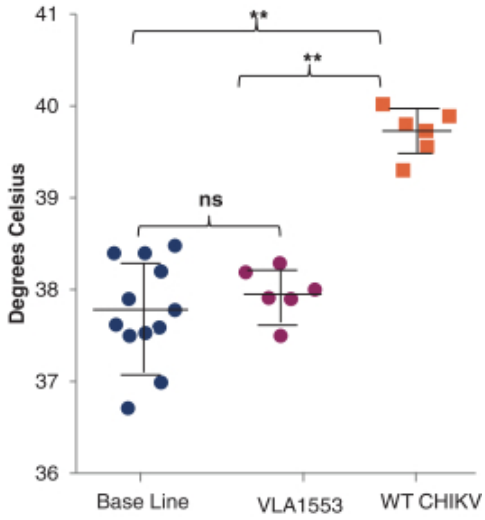
- It was highly immunogenic and induced a strong and long lasting neutralizing antibody response in non-human primates, or NHPs, models after a single administration.
- It was protective in NHPs that received a high-dose of wild-type, or WT, chikungunya virus after vaccination.
- It was not observed 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



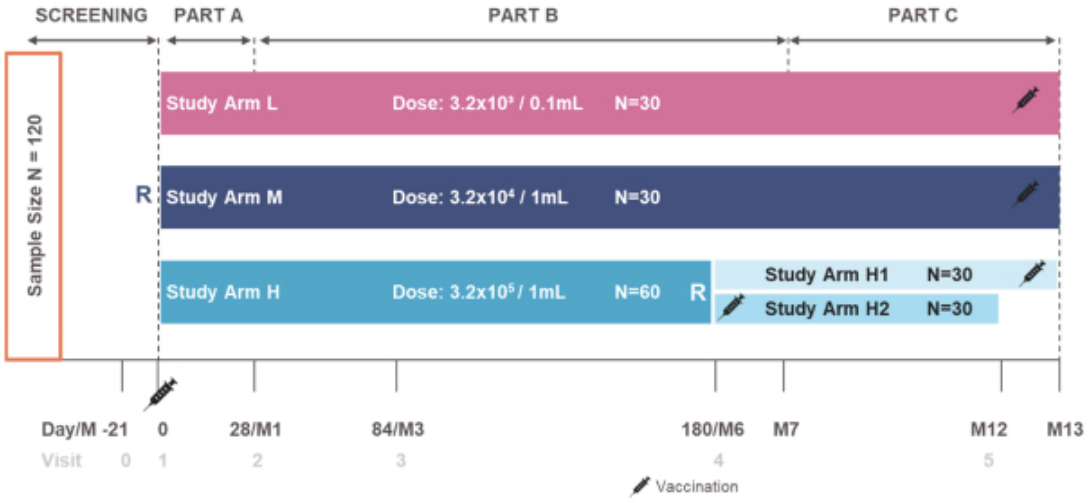
Base Line Immunized Animals Unimmunized Animals

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

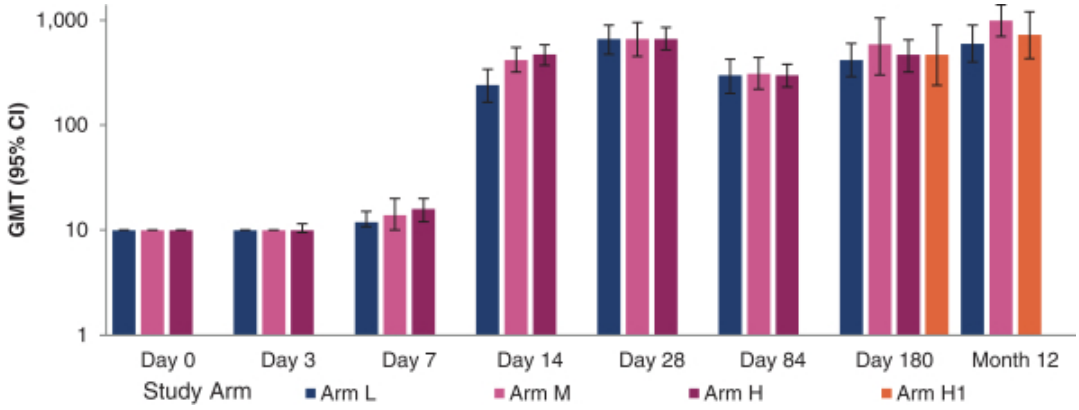
The above left figure shows that whereas unimmunized animals showed a rapid increase in viral load within one day of the challenge, as depicted by the orange lines, there was no detectable viremia in any of the immunized animals, as depicted in the purple line on the x-axis. The dotted line represents 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

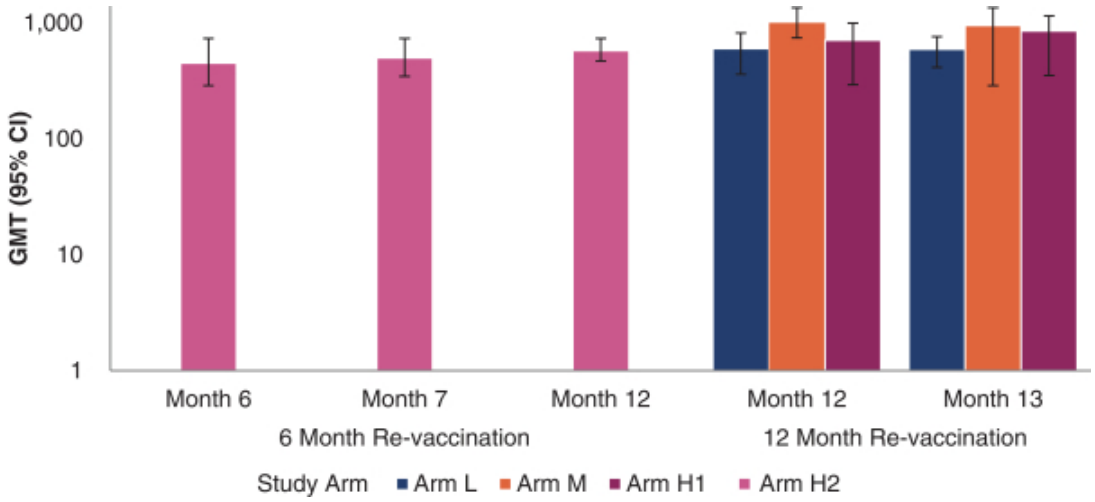
We conducted a single blind, randomized dose-escalation Phase 1 clinical trial of VLA1553 in 120 adults, at multiple centers in the United States, the results of which were published in Lancet in 2020. In this trial we examined three doses of VLA1553: a low dose having a viral titer of 3.2 x 10^3, a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



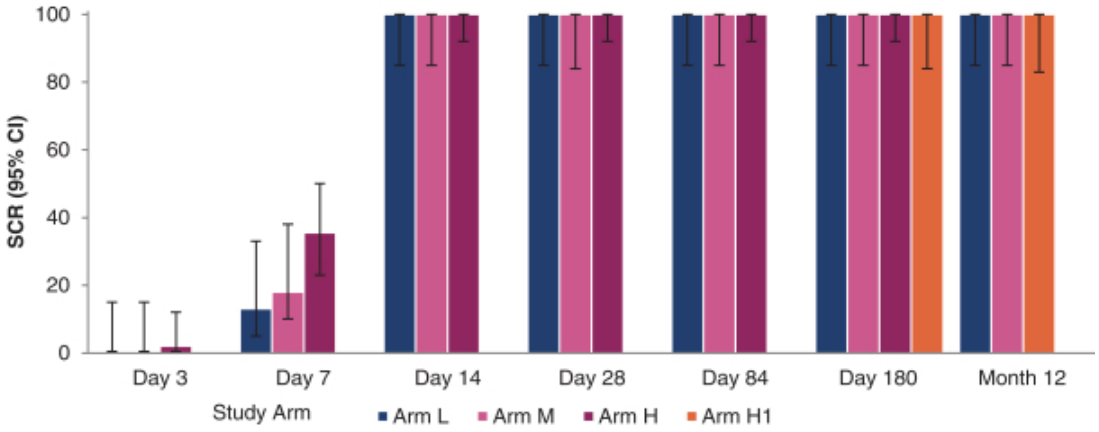
Chikungunya virus neutralizing antibodies were observed in 100% of patients for 12 months at all three of the doses evaluated as can be observed in the figure below. A single vaccination was sufficient to induce sustaining high-titer neutralizing antibodies at twelve months post vaccination.



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.

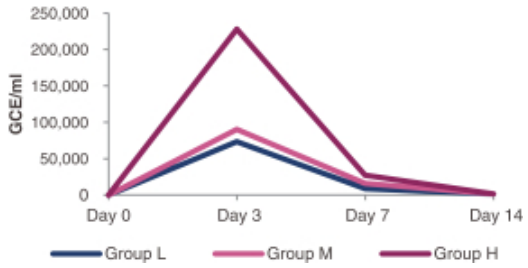


The titer of these neutralizing antibodies was assessed by determining how far the antibodies in the plasma could be diluted and still reduce *in vitro* viral infection by 50%, a commonly used parameter referred to as the neutralization titer or NT_{50}. Seroconversion was defined as having an NT_{50}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

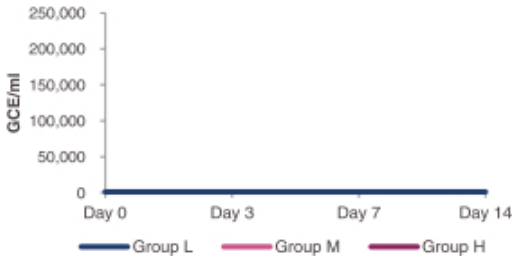


Plasma of the trial volunteers was screened for viremia, which peaked at day three in all groups and was lower in the low-dose and medium-dose groups. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

Viremia after Single Vaccination



Viremia After Re-Vaccination with VLA1553



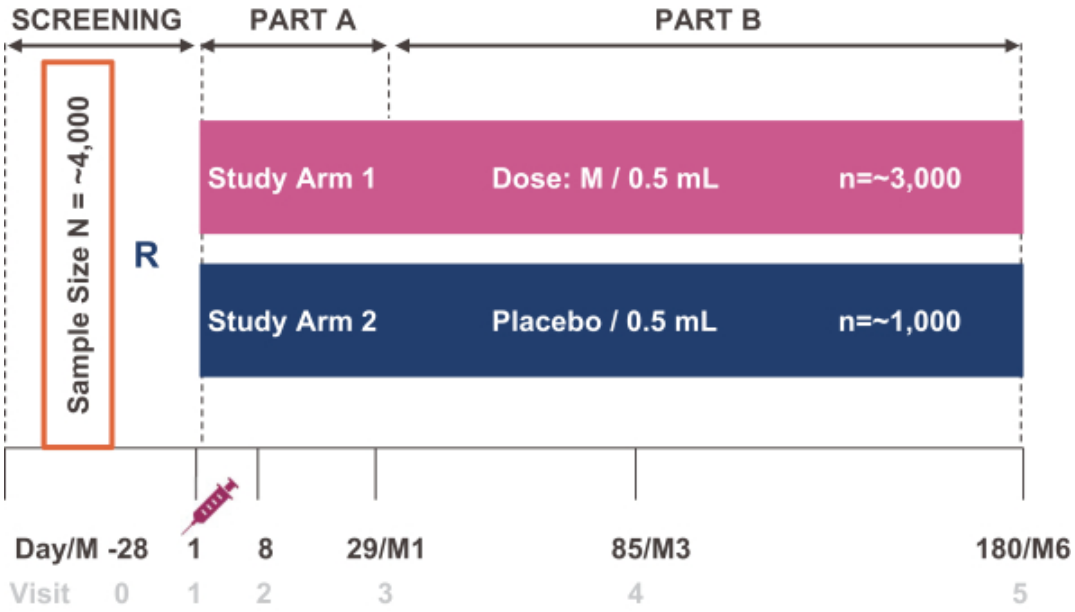
The majority of adverse events across the dose groups were assessed as mild or moderate and were reported after the single vaccination. No adverse event of special interest, meaning adverse events resembling a chikungunya-like infection, and no vaccine-related SAEs were reported. Injection site reactogenicity 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.

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 subject to agreement with the FDA on our proposed surrogate. 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 Trial

In September 2020, we initiated our Phase 3 clinical trial of VLA1553 in 4,060 healthy adults aged 18 or older in the United States. As of February 2021, we have achieved over 80% enrollment in this trial and expect to complete enrollment in the first half of 2021 and we expect to report initial data in mid-2021. In this double-blind, multi-center, randomized Phase 3 clinical trial, participants were randomized 3:1 into two groups to receive either VLA1553 0.5mL or placebo. The primary endpoint is safety and immunogenicity 28 days after a single vaccination with VLA1553. A subset of participants will be tested for sero-protection based on an immunological surrogate under the accelerated approval pathway. Participants will be followed for a total of six months; further long-term follow up is planned. The total duration of the trial is expected to be nine to 12 months and we believe that the outcome, if positive, may provide the basis for regulatory approval. The graphic below shows the design of the Phase 3 clinical trial.

Design of the VLA1553 Phase 3 Trial



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 are taking advantage of the viral production infrastructure which we assembled to manufacture IXIARO to rapidly generate an inactivated SARS-CoV-2 vaccine candidate. We have begun clinical trials of VLA2001, with the objective of achieving first regulatory approval in the second half of 2021 if the clinical trial results are positive. In September 2020, we announced a collaboration with the UK government for VLA2001. Under the agreement, if our vaccine development is successful, we will provide the UK government with 60 million doses of VLA2001 in the second half of 2021. The UK Government then has options over 40 million doses in 2022, which option was exercised in January 2021, and a further 90 million doses, in aggregate, from 2023 to 2025. See "—Material Agreements—UK Supply Agreement" for more details on our partnership with the UK Government.

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, if approved, could potentially offer clear benefits compared to other vaccines that obtain initial regulatory approvals in terms of safety, cost, ease of manufacture and distribution and could also offer sustained protection despite 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 January 6, 2021, more than 87 million people have been infected and COVID-19 has caused more than 1.8 million deaths.

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 and monoclonal antibody therapies. For example, the FDA has granted emergency use authorization to Gilead's

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.

Many biopharmaceutical companies and academic centers have been in a race to develop a prophylactic vaccine by using several platforms including mRNA, adenoviral vectors and recombinant proteins. To date, three 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-generation 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 in the United States and Europe, to develop a vaccine based on an inactivated virus, a technology that has been well-validated in the clinic and commercial market for other viral diseases. We believe that an inactivated SARS-CoV-2 vaccine has potential to show efficacy and safety comparable to other types of vaccines against SARS-CoV-2, as inactivated whole virus vaccines tend to produce broad immune responses that may offer protection against the most frequent mutations of the virus causing minor antigenic changes, known as antigenic drift. Based on this, we believe that VLA2001 could generate an immune response of greater amplitude and duration, which could consequently offer greater protection against COVID-19 disease. When taking safety into account, we believe that VLA2001 may offer advantages compared to vaccines using other technologies. 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 and to have a longer shelf life than current mRNA vaccines.

We have entered into a collaboration with Dynavax Technologies to evaluate the use of their adjuvant CpG 1018, a component of their FDA-approved hepatitis B vaccine, in VLA2001. See "—Material Agreements—Dynavax Supply Agreement" for more information about this collaboration. Clinical trials with hepatitis B vaccination consistently demonstrated more rapid induction of protective antibody titers with CpG 1018 compared to alum in all populations studied, including groups that are harder to immunize such as the elderly and immunocompromised individuals. 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 virus vaccine.

We are increasing the capability of our Biosafety Level 3 laboratory at our sites in Nantes, Vienna and Livingston in order to rapidly advance our development of VLA2001. 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 have 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. In September 2020, we reached an agreement with the UK government to provide up to 190 million doses of VLA2001. As part of this agreement, the UK government is supporting our research efforts and the expansion of our Livingston production facility which, at its current capacity, can produce up to 50 million doses per year. In January 2021, we announced that we are in advanced discussions with the European Commission for the supply of up to 60 million doses of VLA2001.

We commenced in-human clinical studies for VLA2001 in December 2020 and expect to submit a BLA in second half of 2021, subject to the appropriate regulatory authority requirements.

Pre-clinical Trial and Results

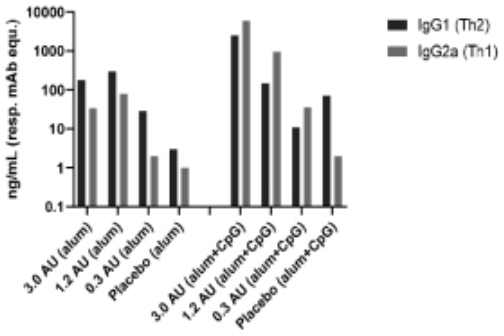
In our pre-clinical experiments, we evaluated the immunogenicity of VLA2001 using female BALB/c-strain mice. We immunized mice two times subcutaneously with a dose of 100 µL VLA2001 vaccine on days 0 and 21. The mice were dosed in three groups, one that received a placebo (buffer with alum adjuvant only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

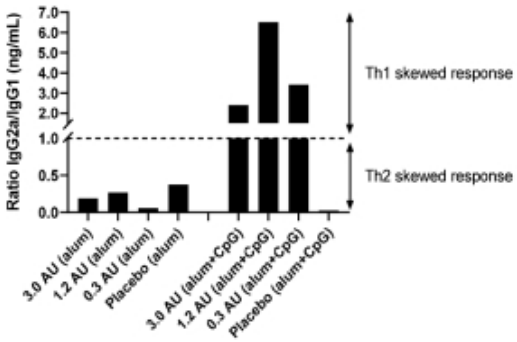
We have also observed that the alum+CpG 1018 adjuvant formulation of VLA2001 consistently induced higher IgG antibody titersin mice than the alum-only formulation. With regards to the functional antibody response, sera from BALB/c mice immunized with VLA2001 plus alum+CpG 1018 showed neutralization titers 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.

Exp4743 Subclass ELISA



Exp4743 Th1/Th2 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.

VLA 2001 Phase 1/2 Study

We initiated 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 150 healthy adults have been recruited. We have commenced the Phase 2 portion of the trial.

The trial design consists of a randomized, dose-escalation, multi-center study with three dose groups (low, medium and high dose) of 50 subjects each.

The study will be conducted in two parts: Part A (Day 1 to Day 36) and Part B (Day 37 to Day 208). Part B will be initiated following an evaluation of initial data from Part A. Part A will be 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. For safety reasons, the first 15 subjects will be included into the study in an open-label, not randomized manner following a staggered dose escalation of VLA2001. Dose escalation will be 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 Data Safety and Monitoring Board, or DSMB, will review the accrued safety data at Day 4 of all 15 sentinel subjects. If the DSMB review is favorable, randomization of the remaining 135 subjects across all sites will be initiated.

The remaining 135 subjects will be enrolled, screened and randomized in a 1:1:1 fashion to the three dose groups in the blinded part of the study. Subjects will be observed for 30 minutes post-vaccination on Day 1. An unscheduled safety telephone call will be performed in case a Grade 3 adverse event or serious adverse event will be reported by the subject via eDiary. All subjects will be followed by eDiary for seven days post vaccination, starting on the day of vaccination. Subjects will return to the study site on Day 8 (visit 2). After approximately 20 subjects per dose group have been randomized and followed up with seven days post first vaccination, the DSMB will review the accrued safety data and continue to review such data periodically up to Day 36 for all randomized subjects. All subjects will receive their second vaccination on Day 22 (visit 3) and will be followed up with on Day 36 (visit 4), 14 days after the second vaccination. The DSMB will review safety and immunogenicity data up to Day 36.

In Part B of the study, all subjects will be further followed up on Day 106 (visit 5) and Day 208 (visit 6), six months after the second vaccination.

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 with the results obtained we will define the appropriate path towards a Phase 2 clinical design. 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 expect first readouts in the second half of 2021. 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.

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.

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 €94.3 million in the year ended December 31, 2019 and €30.8 million in the nine months ended September 30, 2020. Sales in 2020 have been 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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of approximately $46 million for 320,000 doses and approximately $36 million for 250,000 doses, respectively, if DLA exercises those options. 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.

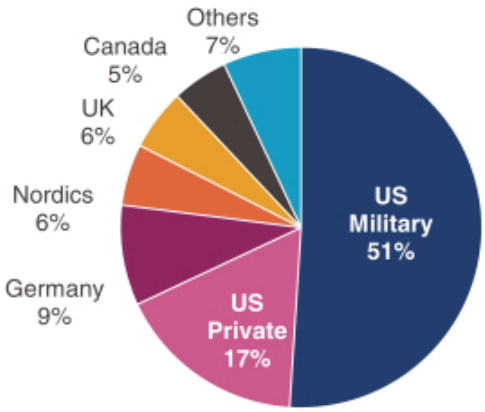
IXIARO Overview

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 7-28 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.

Sales of IXIARO

IXIARO was first approved by the FDA and EMA in 2009, and since then sales for IXIARO have grown to €94.1 million during the year ended December 31, 2019. Over this time, 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 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.



FY2019 product sales analysis €94.1m

Sales in 2020 are expected to continue to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its December 2020 report, the United Nations World Tourism Organization, or UNWTO, predicted that international travel, as measured by international arrivals, would rebound in 2021, based on the assumptions of a gradual reversal of the pandemic, the rollout of a COVID-19 vaccine, significant improvement in traveler confidence and major lifting of travel restrictions by the middle of 2021, as well as a large pent-up demand after months of closed borders and travel bans. Recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels by 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 Europe 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.

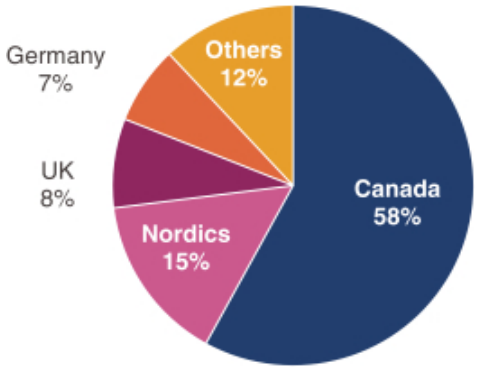
DUKORAL Overview

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 €31.5 million in the year ended December 31, 2019 and €13.2 million in the nine months ended September 30, 2020, of which Canada represented approximately 58% and 52%, 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 2020 and 2021 are expected to continue to be significantly impacted by ongoing COVID-19 travel restrictions.



FY2019 product sales analysis €31.5m

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 commercialise 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 2019 product sales, we manage approximately 85% 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.

In 2019, North America accounted for 73% of worldwide IXIARO sales, comprising 51% generated by the U.S. military, 17% generated by U.S. private, and 5% in Canada.

In 2019, sales of DUKORAL in Canada represented about 58% of worldwide DUKORAL sales.

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 commercialise 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 50,000 square meters, operates under a Manufacturers License from MHRA. The site is qualified to meet required quality standards of several regulatory bodies including FDA, EMA, TGA and Health Canada. We employ currently around 200 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 partnership with the UK government, the Livingston site is currently being expanded to include two additional production units. Upon completion of the expansion, we expect the site will have viral vaccine bulk manufacturing capacity of above 200 million doses per annum. This provides capacity in excess of the UK Government COVID vaccine requirements.

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 EMA, 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. Post-completion, this capacity can be further leveraged for third-party businesses. 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.

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 Pasteur (Australia/some Asian territories) with a live-attenuated, chimeric yellow fever backbone-based vaccine. 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 2019.

The only country where our Japanese encephalitis vaccine currently faces direct competition is Australia, where it splits market share with Sanofi’s live-attenuated chimeric vaccine, 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 75% of DUKORAL sales in 2019, with Canada alone representing over 60%. 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 EMA 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. Lymrix, 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.

COVID19

A number of companies are actively advancing COVID-19 vaccines through the clinic. Pfizer and BioNtech, Moderna Therapeutics and AstraZeneca have received approval for their COVID-19 vaccines from U.S. or European regulatory authorities. Additionally, a number of companies such as CanSino Biologics, Bharat Biotech, Johnson & Johnson, Novavax, Inovio Pharmaceuticals are currently developing vaccine candidates into Phase 2 and Phase 3 clinical stage development.

Material Agreements

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 current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of approximately $46 million for 320,000 doses and approximately $36 million for 250,000 doses, respectively, if DLA exercises those options.

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.

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 are obligated to manufacture and supply SARS-CoV-2 vaccines, referred to as the product, 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. As of December 31, 2020, we have received an aggregate of under the UK Supply Agreement.

We are 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, and priority supply over any other third party orders, 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. As of December 31, 2020, we have received advance payments to fund certain manufacturing-related expenses and for the first installment from product order in connection with the UK Supply Agreement. The UK Authority is obligated 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. With respect to sales to non-UK customers of product manufactured using any facilities used under the UK Supply Agreement, we are obligated to pay the UK Authority a low single-digit royalty on such net sales, subject to a maximum royalty payment.

The UK Supply Agreement shall continue in place until quantities of conforming product equal to the volumes ordered have been delivered to the UK Authority. The UK Authority may terminate the agreement for loss of supply, for lack of safety or efficacy of the vaccine, for convenience, for our insolvency, if we cease or threaten to cease to carry on business, if we undergo a change of control, if we assign the agreement in violation of its terms, if we materially breach our obligation to notify the UK Authority of any occasion of tax non-compliance (or fail to provide details on mitigating factors in connection therewith), if there are material consequences resulting from our material failure to comply with material environmental, social, or labor law, for violation of specified terms of the agreement, if the product presents material safety issues or significantly lacks efficacy, if the product is discontinued or withdrawn from the market in any country for safety, quality, or regulatory reasons, is not renewed or is otherwise rejected, withdrawn or suspended by the applicable licensing authority, or in the event of a uncured loss of supply or material price increase of the product. Either party may terminate the agreement in the event of a prolonged force majeure event or for an uncured breach of the material obligations of the agreement by the other party.

Dynavax Supply Agreement

In September 2020, we 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 Product. 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 has an initial purchase order commitment amount of up to $136.8 million.

The Dynavax Agreement has an initial term through December 31, 2025 and renews automatically thereafter until either party notifies the other upon 12 months' notice of its intention to not renew 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 programme 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. We

have 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 is required to use reasonable commercial efforts to promote, sell and distribute IXIARO in Germany and is 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 are 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 provides that GSK must not manufacture, market, file applications for regulatory approval, distribute, sell or promote, in Germany manufacture, market, file applications for regulatory approval, distribute, sell or promote, in Germany a directly competing product that is a generic substitute for IXIARO.

The GSK Distribution Agreement shall continue until December 31, 2021. Either party may terminate the agreement upon (a) an uncured material breach of the agreement by, insolvency of, or change of control of the other party, or (b) withdrawal of marketing authorization for IXIARO in Germany. GSK may terminate this agreement if we fail to supply IXIARO under a firm purchase order for a specified period of time. In addition, we may terminate the agreement if GSK ceases to carry on business marketing pharmaceutical products in Germany, fails to comply with anti-corruption laws, does not achieve specified minimum purchase quantities, or breaches diligence obligations under that certain distribution agreement between the parties for the distribution of DUKORAL and we terminate such DUKORAL agreement for this same reason.

VaccGen Sublicense Agreement

In April 2003, we (through our predecessor company Intercell Biomedical Ltd.) entered into a sublicense agreement, or the VaccGen Agreement, with VaccGen International, LLC, or VaccGen. We subsequently amended the VaccGen Agreement in October 2003, June 2004, March 2005, October 2005, April 2006, November 2006, December 2006, August 2007, and February 2010. Pursuant to this agreement, we obtained (a) an exclusive, worldwide (except the Caribbean), sublicensable sublicense under a prophylactic vaccine for Japanese encephalitis, the Vaccine, related patents and other intellectual property related to improvements made during the term of the agreement to develop, gain regulatory approval for, manufacture, have manufactured, distribute, use, offer for sale, import, sell, market, and otherwise commercially exploit the Vaccine and (b) an exclusive, worldwide (except for the Caribbean), royalty-free, transferable, sublicensable right and license under VaccGen's interest in certain Vaccine information to use, reproduce, distribute, display, prepare derivative works of and otherwise modify, make, sell, offer to sell, import and otherwise use and exploit such information in connection with the foregoing license.

We are obligated to use commercially reasonable efforts to develop, manufacture, gain regulatory approval for and launch the Vaccine and to maximize net sales of the Vaccine worldwide (except the Caribbean). In connection with the VaccGen Agreement, we paid VaccGen an initial license fee of $350,000, a second license fee of $450,000, and $50,000 upon execution of the August 2007 amendment, pursuant to which the licensed territory was expanded to include the Republic of Korea. Additionally, we paid VaccGen $3.45 million in development and regulatory milestones and are obligated to pay VaccGen mid to high single-digit royalties on net sales of the Vaccine based on the entity making such sale, subject to specified reductions, and, in each case, subject to a minimum royalty payment ranging from mid six figures to low seven figures. Royalties on net sales of the Vaccine in specified countries are payable from January 1, 2010 until fourteen years thereafter or fourteen years from the date of regulatory approval in a specified country, based on the country of sale, marketing, or distribution. Royalties on other net sales of the Vaccine where the sale does not infringe, but for the sublicense granted to us under the VaccGen Agreement, a valid claim of the vaccine patents licensed to VaccGen issued in a country are payable to VaccGen until seven years from the first commercial sale of such Vaccine in such country. Royalties on other net sales of the Vaccine where the sale infringes a valid claim of the vaccine patents licensed to VaccGen issued in a country are payable to VaccGen beginning upon commercialization of such Vaccine and continue until the expiration or final determination of invalidity of the last such valid claim that would be infringed by such sale in such country. A further reduced royalty for a period of seven years from such expiration or final determination of invalidity of the last such valid claim that would be infringed by such sale in such

country is due. We are also obligated to pay VaccGen a low double-digit percentage within a range of ten percentage points of any sublicensing income we receive.

The VaccGen Agreement expires upon the earlier of the expiration of the last royalty or payment obligation or when we no longer develop, market, or sell the Vaccine for at least twelve consecutive months. Either party may terminate the agreement upon an uncured material default of or material breach of any material condition or covenant of the agreement. VaccGen may terminate the agreement for our insolvency, if we do not fund the development plan in accordance with the terms of the agreement or if we acquire a competing vaccine.

Vetter Supply Agreement

In March 2008, we (through our predecessor company Intercell Biomedical Ltd. and Intercell AG) entered into a commercial supply agreement, or the Vetter Agreement, with Vetter Pharma-Fertigung GmbH and Co. KG, or Vetter, pursuant to which Vetter is obligated to produce and supply to us with vaccine-filled syringes for use in connection with Japanese encephalitis throughout the world, excluding Japan. The Vetter Agreement renews automatically until either party notifies the other of its intention to not renew the agreement. Either party may terminate the agreement upon an uncured material default of the agreement by, including insolvency of, the other party.

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 29, 2020, we had a portfolio of over 479 issued patents, including over 84 granted in Germany, France, the United Kingdom, Spain and Italy, over 33 issued in the United States, over 110 pending patent applications, including 25 pending in Europe and 9 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 4 issued U.S. patents (9,884,115, 9,895,437, 9,913,898 and 10,668,146) 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. The appeal procedure could ultimately result in a narrower or broader scope of protection being upheld compared to that maintained by the opposition division. 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 a patent application with claims directed to stable pharmaceutical compositions covering DUKORAL and methods of use thereof, where 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.

VLA15—Borrelia vaccine candidate

In regards to our *Borrelia* vaccine candidate VLA15 which is currently licensed to Pfizer, we own a patent family which includes two issued U.S. patents with claims covering the composition of matter of VLA15, one pending U.S. patent application, one granted European patent (validated in over 35 countries) with claims covering the composition of matter of VLA15, 15 granted foreign patents, and 5 pending foreign patent applications. Patent applications, if issued, and patents in this family are expected to expire in 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 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.

We also own 5 European 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, we own two patent families that include two 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.

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, we own 5 European patent applications with claims relating to the antigen, the adjuvant formulation and processes of preparing VLA2001. 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.

VLA84—Clostridium difficile candidate

In regards to our *C. difficile* candidate VLA84, 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, one pending U.S. patent application, 9 granted foreign patents in such jurisdictions as Australia, China, and Japan, and 4 pending foreign patent applications. This patent family also includes a granted European patent validated in over 35 countries that has been opposed. The European Patent Office maintained our European patent in amended form, which still covers VLA84. We and the opposer each filed an appeal against this decision, and the appeal procedure is currently pending. Patent applications, if issued, and patents in this family are expected to expire in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We also filed an opposition in a European patent owned by a third party that has claims that might cover our *C. difficile* vaccine 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 and is currently pending.

VLA1601—Zika vaccine candidate

In regards to our Zika vaccine candidate VLA1601, we own a patent family with one granted U.S. patent 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.

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 29, 2020 are shown in the table below.

Trademarks	Number of registrations or applications (in case of European Union trademarks, all jurisdictions are counted)
IXIARO®, IXIARO logo	186
JESPECT®	45
DUKORAL®	87
EB66®	63
IC31®	34
Valneva®, Valneva logos	212
SBL trademarks	20

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, 2020, we hold 61 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, 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 priority 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 European Union

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 marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union 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 European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must 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 member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will enter into force in 2020 with a three-year transition period. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide 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 European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union 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 European Union or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

An Orphan Drug Designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a “similar medicinal product.” 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. The market exclusivity period for the authorized therapeutic indication 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 for Orphan Drug Designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either to EMA using the centralized procedure or to competent authorities in European Union Member States using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, 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 evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

International Regulation

In addition to regulations in the United States and Europe, 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 or European Commission approval.

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

U.S. Healthcare Laws and Regulations

Healthcare providers, physicians 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, physicians, 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 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, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives;
- 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.

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, in 2017, the U.S. Congress enacted the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was

repealed by the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case; oral arguments were heard on November 10, 2020 and the Supreme Court's decision is forthcoming. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 absent additional congressional action. 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 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 on September 24, 2020 providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. The Interim Final Rule has not been finalized and is subject to revision and challenge. For example, on December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against the implementation of this interim final rule.

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, particularly in light of the new presidential administration.

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 prospectus.

Facilities

Our corporate headquarters are 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.

At our corporate headquarters in Saint-Herblain, we own approximately 34,208 square feet of laboratory and office space. We currently lease approximately 969 square feet to Vital Meat SAS, a company that is part of Groupe Grimaud, our largest shareholder.

We occupy a facility located in Vienna, Austria where we lease approximately 115,442 square feet of laboratory and office space, of which approximately 4,962 square feet are currently subleased to Haplogen Bioscience GmbH.

We occupy office space in Lyon, France used primarily for sales and marketing activities totaling approximately 3,391 square feet. Valneva France SAS subleases approximately 1,636 square feet of office space to Valneva SE.

We occupy two manufacturing facilities in Solna, Sweden used primarily for manufacturing our products and performing various services. One of the facilities totals approximately 133,300 square feet and includes approximately 53,547 square feet used for industrial operation manufacturing, including production activities, housing laboratories, engineering and offices; approximately 12,863 square feet used as a clinical trial manufacturing unit, including development and manufacture of clinical trial material, laboratories and offices; approximately 16,189 square feet used for supply chain, warehouse and customer service; approximately 12,980 square feet used for quality control, including laboratories and offices; and approximately 22,971 square feet used for commercial operations, quality assurance, administration, legal, IT and other support functions. The other facility totals approximately 43,055 square feet among which approximately 6,783 square feet are used for industrial operation manufacturing, including fill and finish and GMP area, approximately 36,272 square feet Clean Not Classified areas, media production, cool rooms, goods receipt and offices for industrial operations and quality assurance. These facilities are leased through December 31, 2037 and January 2031 respectively.

We occupy office space in Fleet, United Kingdom totaling 775 square feet that is used primarily for sales and marketing activities. This office space is leased through July 31, 2021.

We occupy two neighboring facilities located in Livingston, Scotland, United Kingdom used primarily for the manufacturing of bulk vaccines, warehousing and office space. We own both of these facilities, one of which was part of the Intercell/Vivalis merger and totals approximately 38,180 square feet while the other was added in August 2020 to allow business expansion and is currently being extended from 26,610 square feet to approximately 53,820 square feet.

We also lease four office and warehouse facilities in the immediate vicinity of the main Livingston sites, which will all become redundant once the newer main facility is fully redesigned and expanded. These facilities include an office and warehouse space of approximately 7,793 square feet leased until February 2022, a 6,458 square feet office and warehouse facility leased until 2023, a 2,583 square feet office which is on a one year lease from November 2021, and a 10,763 square feet office and warehouse facility on a two year lease from December 2021.

We occupy an office suite in Kirkland, Québec, Canada totaling approximately 1,464 square feet that is used primarily for sales and marketing activities. This office space is leased through December 31, 2021.

We occupy an office suite in Maryland, United States totaling approximately 3,789 rentable square feet that is used primarily for sales and marketing activities. This office space is leased through August 31, 2022.

Employees and Human Capital

As of December 31, 2020, we had a total of 581 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	212
Valneva Canada Inc.	5
Valneva SAS	4
Valneva Scotland Ltd	132
Valneva SE Lyon	3
Valneva SE Nantes	40
Valneva Sweden AB	164
Valneva UK Ltd	7
Valneva USA, Inc.	14
Total	**581**

Of these employees, 265 (46%) were primarily engaged in manufacturing, 144 (25%) in research and development, 122 (21%) in general and administrative functions and 40 (7%) in commercial operations.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

MANAGEMENT

Corporate Governance

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.

Directors and Officers

The following table sets forth information concerning the members of our Management Board and Supervisory Board as of January 1, 2021.

Name	Age	Position
Management Board Members		
Thomas Lingelbach	58	Chairman of the Management Board, President, Chief Executive Officer
Franck Grimaud	54	President, Chief Business Officer
Juan Carlos Jaramillo	50	Chief Medical Officer
Frédéric Jacotot	56	General Counsel, Corporate Secretary
Supervisory Board Members		
Frédéric Grimaud	56	Chairman of the Supervisory Board
James Sulat	70	Vice Chairman of the Supervisory Board
Anne-Marie Graffin	59	Member of the Supervisory Board
Thomas Casdagli	44	Member of the Supervisory Board
Sharon Tetlow	61	Member of the Supervisory Board
Johanna Willemina Pattenier	61	Member of the Supervisory Board

Two-Tiered Board Structure

We are a European public company with limited liability (*Societas Europaea* or SE), with our headquarters in France. We accordingly are subject to the European legislation on the *Societas Europaea*, namely the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the statute for a European company, or the SE Regulation; and the French laws n° 2005-842 of 26 July 2005, as amended, as well as—insofar as not contrary to the SE Regulation—to the French regulations on limited liability companies. In accordance with these regulations, we have chosen to have a two-tiered structure. Accordingly, our corporate bodies consist of the Management Board (*directoire*), the Supervisory Board (*conseil de surveillance*) and the shareholders' meeting (*assemblée générale des actionnaires*).

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 four-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 currently serves as president of the CMC Board of Hookipa Pharma Inc. Mr. Lingelbach holds an M.S. in Engineering from Technische Hochschule Gießen / THM.

Franck Grimaud has served as our President 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.

Juan Carlos Jaramillo, MD, 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 Directors of Arch Therapeutics, Inc. since 2015 and served 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 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.

Thomas Casdagli has served on our Supervisory Board since December 2019. Mr. Casdagli has been a partner at MVM Partners LLP, a life science investment firm, since 2002 and served as a member of the Board of Directors of Alliance Pharma plc from 2009 to May 2018. Previously, he was a chartered accountant with PricewaterhouseCoopers' Private Equity and Venture Capital practice. Mr. Casdagli holds an MBioch in Molecular and Cellular Biochemistry from Oxford University. We believe Mr. Casdagli's financial and investment expertise, his experience in the pharmaceutical industry and his public company board experience qualifies him to serve on our Supervisory Board.

Sharon Tetlow has served on our Supervisory Board since June 2020. She founded and has served as Managing Partner of Potrero Hill Advisors, which provides strategic and operational financial support to life science companies, since January 2016. Prior to that, she was the Managing Director of Danforth Advisors, a firm that provides service offerings for life sciences companies, from 2013 to January 2016 and served as Chief Financial Officer of Pathwork Diagnostics, Inc., a biotechnology company, from 2011 to 2013. Ms. Tetlow has served as a member of the Board of Directors of Catalyst Biosciences, Inc. since January 2020. 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 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.

Role of the Supervisory Board in Risk Oversight

Our Supervisory Board is primarily responsible for the oversight of our risk management activities and has delegated to the audit and governance committee the responsibility to assist our Supervisory Board in this task. While our Supervisory Board oversees our risk management, our management, through the Management Board is responsible for day-to-day risk management processes. Our Supervisory Board expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Supervisory Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Supervisory Board Committees

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

Subject to available exemptions, the composition and functioning of all of our committees will comply with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq listing rules and SEC rules and regulations.

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

Audit and Governance Committee

Our audit and governance committee assists our Supervisory Board in its oversight of our corporate accounting and financial reporting and oversees the selection of our auditors, their remuneration and independence and keeps the Supervisory Board informed on control systems, key processes and procedures, security and risks. The members of our audit and governance committee are James Sulat, Sharon Tetlow and Frédéric Grimaud. Mr. Sulat is the chair of the committee.

Our Supervisory Board has determined that 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 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 Thomas Casdagli, all of which 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 remuneration 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) remuneration, 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.

Corporate Governance Practices

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 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 the shareholders of the Company, 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 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.

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. Following the completion of this global offering, the Code of Conduct will be 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.

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.

Compensation of Members of the Management and Supervisory Boards

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 our attendance fees for the 12-month period starting on June 1, 2020:

Member Role	Attendance Fee
Supervisory Board Chairman	€ 50,000
Supervisory Board Vice-Chairman and Committee Chairman	€ 45,000
Committee Chairman (other than Vice-Chairman)	€ 35,000
Supervisory Board Member	€ 30,000

In December 2020, the Supervisory Board approved the following changes to annual attendance fees, effective beginning January 1, 2021:

Member Role	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, 2020:

Member	Attendance Fee
Frédéric Grimaud	€ 50,000
James Sulat	€ 30,489
Anne-Marie Graffin	€ 24,647
Thomas Casdagli(1)	—
Sharon Tetlow(2)	€ 13,696
Johanna Willemina Pattenier(2)	€ 13,696
Alexander von Gabain(3)	€ 10,000
Sandra Poole(3)	€ 10,000
Louisa Shaw-Marotto(3)	€ 15,000

(1) Mr. Casdagli waived all attendance fees earned for the year ended December 31, 2020.
(2) Member beginning June 17, 2020.
(3) Member until June 17, 2020.

Compensation of Members of the Management Board—2020

Our Management Board is currently comprised of four members:

- Thomas Lingelbach, Chair of the Board, President & CEO;
- Franck Grimaud, President & CBO;
- Frédéric Jacotot, General Counsel & Corporate Secretary; and
- Juan Carlos Jaramillo, CMO (appointment effective since October 1, 2020).

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, 2020:

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 remuneration	€376,260.53	As per Supervisory Board decision of February 25, 2020, which sets the gross annual salary at €390,920, and taking into account a compensation waiver with respect to Q2 2020.
Annual variable compensation	€234,552	60% of 2020 gross annual salary set by the Supervisory Board of February 25, 2020. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2020, on January 8, 2021.
Fringe benefits :		
– Car rental	Lease fee: €14,520 Insurance: €3,452.20 Other car related expenses (except fuel) : €2,997.06	Maximum €1,210 per month as per Mr. Lingelbach's Management Agreement.
– Death and endowment insurance policy	€12,000	Long-term life insurance policy as a retirement savings product.
– Reimbursement of homework place journeys made by flights, and associated costs	€4,743.92	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	**€648,525.71**	

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 remuneration	€255,431.13	As per Supervisory Board decision of February 25, 2020, which sets the gross annual salary at €265,383, and taking into account a compensation waiver with respect to Q2 2020.
Annual variable compensation	€132,691.50	50% of 2020 gross annual salary set by the Supervisory Board of February 25, 2020. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2020, on January 8, 2021.
Fringe benefits :		
– Car rental	Lease fee: €10,237.56 Insurance: €1,709.98	Maximum €1,210 per month as per Mr. Grimaud's Management Agreement.
– *Garantie Sociale des Chefs et Dirigeants d'Entreprises*	€8,004	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	**€408,074.17**	

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 remuneration	€198,870.78	As per Supervisory Board decision of February 25, 2020, which sets the gross annual salary at €206,619, and taking into account a compensation waiver with respect to Q2 2020.
Annual variable compensation	€103,309.50	50% of 2020 gross annual salary set by the Supervisory Board of February 25, 2020. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2020, on January 8, 2021.
Fringe benefits :		
– *Garantie Sociale des Chefs et Dirigeants d'Entreprises*	€8,077.44	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	**€310,257.72**	

Dr. Juan Carlos Jaramillo – Management Board member, CMO from October 1, 2020

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 remuneration	€71,250	Prorated amount taking into account the starting date of Dr. Jaramillo's office as Management Board member. Annual gross salary set at €285,000 into Dr. Jaramillo's Management Agreement.
Annual variable compensation	€35,625	50% of 2020 gross annual salary set into Dr. Jaramillo's Management Agreement (Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2020, on January 8, 2021). Prorated amount taking into account the starting date of Dr. Jaramillo's office as Management Board member.
Fringe benefits :		
– Car allowance	€13,200	€1,100 per month as per Dr. Jaramillo's Management Agreement.
– Death and endowment insurance policy	€3,000	Long-term life insurance policy as a retirement savings product. Prorated amount taking into account the starting date of Dr. Jaramillo's office as Management Board member (annual premium to be paid by Valneva Austria is set at €12,000 into Dr. Jaramillo's Management Agreement)
– Reimbursement of homework place journeys made by flights, and associated costs	€1,221.32	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	**€124,296.32**	

Mr. David Lawrence – CFO (and Management Board member until September 30, 2020)

Mr. Lawrence's compensation is set in accordance with (a) the provisions of the Management Agreement executed between Mr. Lawrence and Valneva UK Ltd., effective at the end of our Combined General Meeting of June 27, 2019, (b) our Supervisory Board decisions, and (c) the provisions of the Settlement Agreement executed with Valneva UK Ltd. on September 4, 2020 (in the context of Mr. Lawrence's end of employment within Valneva), as applicable. Mr. Lawrence currently serves as our interim CFO pursuant to a consultant services agreement entered into as of January 2021.

Type of compensation	Amount of compensation earned	Description
Fixed remuneration	€265,949.19	As per Supervisory Board decision of February 25, 2020, which sets the gross annual salary at €278,496, and taking into account a compensation waiver with respect to Q2 2020. Amount taking into account an exchange rate from £ to € of 0.88471.
Termination indemnities	€776,197.59	Cash indemnities in the context of Mr. Lawrence's end of employment within Valneva. Amount taking into account an exchange rate from £ to € of 0.88970.
Payment in lieu of accrued but untaken holidays	€33,816.34	Amount taking into account an exchange rate from £ to € of 0.88970.
Fringe benefits :		
– Car allowance	€13,200	€1,100 per month.
– Contribution to UK pension plan	€56,870.35	15% of (i) 2020 gross annual salary (as set by the Supervisory Board of February 25, 2020 and adjusted after the 15% compensation waiver with respect to Q2) and (ii) paid bonus with respect to objectives 2019 (*i.e.* €114,081,42). Amount taking into account an exchange rate from £ to € of 0.88471. Standard pension plan in Mr. Lawrence's country.
Total compensation	**€1,146,033.47**	

Mr. Wolfgang Bender – CMO (and Management Board member until October 31, 2020)

Mr. Bender's compensation is set in accordance with (a) the provisions of the Management Agreements executed between Mr. Bender and Valneva SE, on the one hand, and on the other hand, between Mr. Bender and Valneva Austria GmbH, entered into force, depending on the case, on September 1, 2017, or at the end of our Combined General Meeting of June 27, 2019, (b) the decisions of our Supervisory Board, and (c) the provisions of the Termination Agreements entered into with Valneva SE and Valneva Austria GmbH on August 5, 2020, as applicable.

Type of compensation	Amount of compensation earned	Description
Fixed remuneration	€265,650.20: – €93,434.02 (Valneva SE) – €172,216.18 (Valneva Austria GmbH)	As per Supervisory Board decision of February 25, 2020, which sets the gross annual salary at €117,404 with respect to Valneva SE, and €178,926 with respect to Valneva Austria GmbH, and taking into account a compensation waiver with respect to Q2 2020.
Annual variable compensation	€148,165: – €58,702 (Valneva SE) – €89,463 (Valneva Austria GmbH)	50% of 2020 gross annual salary set by the Supervisory Board of February 25, 2020. Validation by the Supervisory Board of 100% of the objectives set with respect to the year 2020, on January 8, 2021.
Retirement indemnity	€40,000	Cash indemnities in the context of Mr. Bender's end of employment within Valneva.
Fringe benefits :		
– Car allowance	€13,200	€1,100 per month.
– Contribution to German health insurance and pension plan	€5,880.64: – €2,572.78 (Valneva SE) – €3,307.86 (Valneva Austria GmbH)	Maximum €7,200 paid by Valneva SE and maximum €10,800 paid by Valneva Austria GmbH. Reference period: from January to July 2020 inclusive. Standard pension plan in Mr. Bender's country.
– Reimbursement of homework place (Germany-Austria) journeys made by flights, and associated costs	€4,766.03	
Total compensation	**€477,661.87**	

Compensation of Members of the Management Board—2021

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, 2021:

Management Board Member	2021 Base Salary
Thomas Lingelbach	€ 420,000
Franck Grimaud	€ 265,383
Frédéric Jacotot	€ 206,619
Juan Carlos Jaramillo	€ 288,420

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 intend to obtain insurance coverage for liability under the Securities Act. We also intend to enter 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 will 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, Free ordinary shares and BSAs (defined below).

Our Management Board's authority to grant these stock options, BSAs, Free Convertible Preferred Shares 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, Free Convertible Preferred Shares 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, 2020:

Plan name	BSA 27
General Meeting date	June 30, 2016
Grant decision date	December 15, 2017
BSAs issued by the Management Board	87,500
Subscription price per share	€ 2.574
BSAs lapsed as of December 31, 2020	15,625
BSAs exercised as of December 31, 2020	28,125
Outstanding BSAs as of December 31, 2020	43,750
Valneva SE ordinary shares potentially resulting from exercise of the warrants remaining as of December 31, 2020	43,750

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, 2020:

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
Plan name	**ESOP 2013**	**ESOP 2015**	**ESOP 2016**	**ESOP 2017**	**ESOP 2019**
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	2,671,510
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, 2020	0	0	0	0	0
Shares resulting from exercise of stock options	0	0	0	0	0
Outstanding stock options as of December 31, 2020	645,900	533,000	399,250	998,000	2,335,260
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, 2020	710,321	533,000	399,250	998,000	2,335,260
Stock options having lapsed as of December 31, 2020	407,050	179,000	185,000	271,500	336,250

Free Ordinary Shares

Free ordinary shares (*actions ordinaires gratuites*) are employee equity incentive instruments pursuant to which the beneficiaries are granted, for free, the possibility to receive our ordinary shares under certain conditions.

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. In the context of David Lawrence's end of permanent employment within Valneva, it was decided that Mr. Lawrence will retain a portion of his free ordinary shares following his departure.

The following table shows the free ordinary shares outstanding as of December 31, 2020:

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 will 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 will therefore occur upon completion of each vesting period mentioned above, subject to employment and performance conditions.
Free ordinary shares fully vested as of December 31, 2020	0
Free ordinary shares being vested as of December 31, 2020	2,027,848 (including 856,807 by corporate officers)
Free ordinary shares lapsed as of December 31, 2020	164,099
Performance and employment conditions	Concerning non-corporate officers employees, the vesting of each tranche will be contingent upon the beneficiary's performance in the Relevant Year having been rated not lower than "Meets Expectations" (regardless of any qualifying sign), as assessed by his/her supervisor under the Company's employee performance appraisal rules. Concerning corporate officers, the vesting of each tranche will be contingent upon the level of achievement of the Management Board member's collective and individual goals in the Relevant Year (as defined below), as assessed by the Supervisory Board, starting above 60% (60% = no vesting) and increasing in a linear way, so that 80% goal achievement will result in vesting of 50% of the relevant tranche and 100% goal achievement will result in vesting of 100% of the relevant tranche. ***Relevant Year*** means 2021 for the first tranche, 2022 for the second tranche and 2023 for the third tranche. If a vesting period expires before the performance has been assessed for the Relevant Year, the vesting of the relevant tranche will be postponed until all Participants have been assessed. Additionally, each of the beneficiaries must continuously remain a Management Board member, corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting, subject to the retirement

Plan name	Free ordinary share plan 2019-2023
	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.
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 Free Convertible Preferred Shares, or 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 will be limited by decreasing the conversion ratio if the stock price exceeds the target. If the stock price reaches the target price of €8 in 2021, this plan may result, at a maximum and after conversion of the Free Convertible Preferred Shares, in the Chair of the Management Board receiving 346,952 of our ordinary shares, and in the each of the other Management Board members receiving 288,362 of our ordinary shares. In the context of David Lawrence's end of permanent employment within Valneva, it was decided that Mr. Lawrence will retain a portion of his free convertible preferred shares following his departure.

The following table shows the Free Convertible Preferred Shares outstanding as of December 31, 2020:

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 (5,596 to the Chair of the Management Board, 4,651 to the other Management Board members, and 1,157 for each of the other Executive Committee members (now “Management Committee”) and the Manufacturing site Heads (exception: 1,718 FCPS for the Senior Vice-President for whom pre-requisite investment was greater)
Duration of vesting period	4 years as from December 15, 2017, subject to certain employment conditions.
FCPS fully vested as of December 31, 2020	0
Plan name	**Free Convertible Preferred Share program 2017-2021**
FCPS being vested as of December 31, 2020	33,481 (including 14,898 by corporate officers)
FCPS lapsed as of December 31, 2020	536
Conversion of free convertible preferred shares into ordinary shares of the Company	The FCPS will be convertible into Valneva SE ordinary shares 4 years after their initial granting (***Conversion Date***), if the minimum Final Share Price (as hereinafter defined) is met at vesting date. In such a case, the conversion will be realized on the basis of a ratio determined by the Management Board at the time of launching the plan. 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 (e.g. 6.2450 to be rounded to 6.25). No conversion will occur if the Final Share Price is lower than €4.50. If the Final Share Price is higher than €8, the conversion ratio will be such that the beneficiaries’ gross gain will not exceed the gross gain they would have realized if the Final Share Price was €8. Subject to fulfilling these conditions, if the beneficiary does not request conversion of his convertible preferred shares within 3 months from expiry of the 4 years’ period mentioned above, his FCPS will be automatically converted into Valneva SE ordinary shares at the end of that 3 months’ period. The FCPS cannot give rights to more than 2,363,000 ordinary shares of the Company.

Phantom Shares

In 2017 and 2019, we established a Phantom Stock Option Program 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 2029 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, 2019 and 2020, the 2017 and 2019 programs consisted of an aggregate of 244,250 and 241,250 phantom shares, respectively.

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.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since January 1, 2018, we have engaged in the following transactions with members of our Management and Supervisory Boards and holders of more than 5% of our outstanding voting securities, and their respective affiliates, which we refer to as our related parties.

Transactions With Groupe Grimaud and Affiliates

In September 2018, we entered into a Collaboration and Research License Agreement with Groupe Grimaud La Corbière SA, 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, 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 €98.3 thousand excluding tax in 2018, €228.7 thousand excluding tax in 2019 and €193.1 thousand excluding tax in 2020.

Agreement with BliNK

In January 2018, we entered into a Storage Services Agreement with BliNK Biomedical SAS, or BliNK, a French company in which Valneva SE held an equity stake of approximately 48.9% as of December 31, 2020. This agreement was entered into in order to provide BliNK with temporary biological material storage space while it was finalizing its negotiations of storage agreements with third parties. This agreement was terminated effective April 16, 2019. Under this agreement, BliNK made payments to the company totaling €2,893.97 in 2018 and €822.68 in 2019.

Arrangements with the Members of our Management and Supervisory Boards

Management and Supervisory Board Compensation

See “Management—Compensation of Members of the Management and Supervisory Boards” for information regarding compensation of the members of our Supervisory and Management Boards.

Indemnification Agreements

In connection with this global offering, we intend to enter into indemnification agreements with each of our Management Board and Supervisory Board members. See the section of this prospectus titled “Management—Limitations on Liability and Indemnification Matters.”

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transaction with Related Companies

From time to time, in the ordinary course of our business, we may contract for services from companies or institutions in which certain members of our Management Board or Supervisory Board may serve as a director or advisor. The cost and provision of these services are negotiated on an arms-length basis and none of these

Related Person Transaction Policy

We comply with French law regarding approval of transactions with related parties. Prior to the closing of this global offering, we expect that the Supervisory Board will adopt a related person transaction policy that sets forth

our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this global offering. 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 updated Code of Conduct, which we intend to adopt in connection with this global offering, 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.

PRINCIPAL SHAREHOLDERS

The following table and accompanying footnotes sets forth, as of , 2021 and following the completion of the global offering, 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.

To our knowledge, as of , 2021, approximately shares, or % of our ordinary shares, were held of record by residents of the United States.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including free ordinary shares that vest within 60 days of , 2021 and options and warrants that are currently exercisable or exercisable within 60 days of , 2021. Ordinary shares subject to free ordinary shares, options and warrants currently exercisable or exercisable within 60 days of , 2021 are deemed to be outstanding for computing the percentage ownership of the person holding these free ordinary shares, options or warrants 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.

The percentage ownership information shown in the table prior to the global offering is based upon ordinary shares outstanding as of , 2021. The percentage ownership information shown in the table after the global offering is based on ordinary shares outstanding, assuming the sale of ordinary shares (including ordinary shares in the form of ADSs) by us in the global offering and no exercise of the underwriters' option to purchase additional ordinary shares (including ordinary shares in the form of ADSs).

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 Beneficially Owned Before Global Offering	Percentage of Ordinary Shares Beneficially Owned	
		Before Global Offering	After Global Offering
5% Shareholders:			
Bpifrance Participations SA		%	
Fonds MVM (MVM IV LP & MVM GP (No.4) Scottish LP)			
Groupe Grimaud La Corbière SA			
Polar Capital LLP			
Management Board and Supervisory Board members:			
Thomas Lingelbach			
Franck Grimaud			
Juan Carlos Jaramillo			
Frédéric Jacotot			
Frédéric Grimaud			
James Sulat			
Anne-Marie Graffin			
Thomas Casdagli			
Sharon Tetlow			
Johanna Willemina Pattenier			
All members of our Management Board and Supervisory Board as a group			

* Represents beneficial ownership of less than 1%.

DESCRIPTION OF SHARE CAPITAL

General

The following description of our share capital summarizes certain provisions of our bylaws. Such summaries do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of our bylaws, a copy of which has been filed as an exhibit to the Registration Statement of which this prospectus forms a part.

As of December 31, 2020, our outstanding share capital consisted of a total of 90,950,048 ordinary shares with a nominal value of €0.15 per share and 20,514 convertible preferred shares with a nominal value of €0.15 per share.

As of December 31, 2020, the outstanding equity warrants, stock options, Free Convertible Preferred Shares and free ordinary shares could potentially result in the following new ordinary shares:

- 43,750 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*, or BSA), including 3,125 ordinary shares issued upon exercise of equity awards subsequent to December 31, 2020;
- 4,975,831 ordinary shares issuable upon exercise of outstanding stock options (regardless vesting dates), including 790,075 ordinary shares issued upon exercise of stock options subsequent to December 31, 2020;
- 2,027,848 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,075,822 ordinary shares issuable upon full vesting and conversion of outstanding Free Convertible Preferred Shares;

Under French law, our bylaws set forth only our issued and outstanding share capital as of the date of the bylaws. Our fully diluted share capital represents all issued and outstanding ordinary shares, as well as all potential ordinary shares which may be issued upon exercise of outstanding equity warrants and stock options and following the vesting of Free Convertible Preferred Shares and free ordinary shares, as approved by our shareholders and granted by our Management Board.

As of December 31, 2020, our share capital as set forth in our bylaws is €13,645,584.30, representing 90,950,048 ordinary shares with a nominal value of €0.15 per share and 20,514 preferred shares with a nominal value of €0.15 per share. An increase of our share capital may only be approved by an extraordinary meeting of shareholders or as delegated to the Management Board by an extraordinary meeting of shareholders.

Upon closing of the global offering, our outstanding share capital will consist of ordinary shares, nominal value €0.15 per share (or if the underwriters exercise their option to purchase in full) and convertible preferred shares with a nominal value of €0.15 per share.

Reconciliation of the Ordinary Shares Outstanding Prior to This Global Offering

The following table shows the reconciliation of the number of ordinary shares issued and outstanding as of December 31, 2018, 2019 and 2020:

	Ordinary Shares
Ordinary Shares outstanding at December 31, 2018	90,917,048
Number of ordinary shares issued in connection with the exercise of BSA equity warrants	6,250
Ordinary Shares outstanding at December 31, 2019	90,923,298
Number of ordinary shares issued in connection with the exercise of BSA equity warrants	26,750
Ordinary Shares outstanding at December 31, 2020	90,950,048

History of Securities Issuances

From January 1, 2018 through December 31, 2020, the following events have changed the number of our issued and outstanding ordinary shares:

- On October 1, 2018, we issued 13,333,334 ordinary shares, in connection with a private placement whose total cash contributions amounted to €50,000,002.50 (including €2,000,000.10 as nominal value).
- On May 3, 2019, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on April 24, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On November 4, 2019, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on October 25, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On May 15, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on May 12, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On July 29, 2020, we issued 4,875 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on July 27, 2020 carried out by cash contribution of €19,110 (including €731.25 as nominal value).
- On August 31, 2020, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on August 25, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 1, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on November 26, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 10, 2020, we issued 12,500 new ordinary shares to former and current Supervisory Board members, in connection with the exercise of equity warrants on December 4, December 7 and December 9, 2020 carried out by a total cash contribution of €32,175 (including €1,875 as nominal value).

Key Provisions of Our Bylaws and French Law Affecting Our Ordinary 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, a copy of which has been filed as an exhibit to the Registration Statement of which this prospectus forms a part.

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 favour 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 five 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 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 may be removed from office, with or without cause and without notice, by the Supervisory Board or at any General Meeting of shareholders, by a simple majority vote of the shareholders present and voting at the meeting in person or by proxy.

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 our interest, but at least once per quarter. Meetings are called by the Chairman or a member of the Management Board appointed for this purpose.

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.

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. Each member must own at least one of our ordinary shares for the entire term of the appointment. 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 Vice Chairman, who are in charge of convening the Supervisory Board and leading the debates.

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 or one-third of the members of the Supervisory 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, it being specified that in a case of a split-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 day-to-day 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.

Shareholders' Observers

At the General Meeting of shareholders, one or more shareholders' observers may be appointed, at the discretion of the Supervisory Board for a term of office expiring at the shareholders meeting convened to decide on the financial statements for the preceding financial year after the first anniversary date of their appointment. Shareholders' observers may be individuals or companies and are not required to be shareholders.

The observers attend all Supervisory Board meetings, with the right to speak but not to vote. They hold the same information and communication rights than 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. See the section of this prospectus titled "Management—Equity Incentives" for a description of the Convertible Preferred Shares granted to the Company's management and employees.

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. Purchasers of ADSs or ordinary shares in this offering, in the open market following the completion of this offering or in subsequent offerings will be unlikely to meet the requirements to have double voting rights attach to any ordinary shares held by them.

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.

Our current shareholders waived their preferential subscription rights with respect to this global offering at an extraordinary general shareholders' general meeting held on December 22, 2020.

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. The Convertible Preferred Shares are held under registered form.

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 Shares by Non-French Persons

See "Limitations Affecting Shareholders of a French Company."

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.

Temporary measures for annual shareholders meetings and executive and Supervisory Board meetings due to COVID-19 crisis

In 2020, due to the COVID-19 pandemic the French government adopted several ordinances and decrees adapting the rules governing meetings and deliberations of shareholders and governing bodies of legal entities held until April 1, 2021 (notably Decree No. 2020-1310 of October 29, 2020 as amended in particular by Law no. 2020-1379 of November 14, 2020). The ordinances and decrees provide the possibility of holding meetings of executive and supervisory boards remotely for all decisions that previously required a physical meeting. In addition, the ordinances and decrees provide that general meetings of shareholders can be held behind closed doors or by means of a teleconference or audio-visual conference call.

By decision of the Management Board, the general meeting of shareholders may be held behind closed doors (*huis-clos*), i.e., without the shareholders or their proxies (and any other person having the right to attend the meeting such as the statutory auditors and the employee representatives) being physically present. The possibility of holding a meeting behind closed doors requires that, on the date of the meeting announcement, the convening notice or on the date of the meeting, an administrative measure restricting or prohibiting traveling or collective gatherings for health reasons prevents the physical presence at such meeting of its members, even if this measure is ultimately no longer in effect on the date of the meeting. As of the date of this prospectus, measures restricting gatherings are still in force (decree Nº 2020-1310 of October 29, 2020, as amended, prohibits, as general rule, any meeting where barrier measures cannot be implemented and in all places and under all circumstances; in particular, subject to certain exceptions, any meeting involving more than six people simultaneously in places open to the public are prohibited). In this case, shareholders will be able to vote remotely and prior to the general meeting of shareholders by the usual means available to date, i.e., vote by correspondence, blank proxy or Internet voting.

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 ‘‘Limitations Affecting Shareholders of a French Company;’’
- 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 ‘‘Limitations Affecting Shareholders of a French Company;’’
- 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 the section of this prospectus titled "Description of Share Capital–Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares;"
- 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.

Securities Exercisable for Ordinary Shares

Equity Incentives

See the section of this prospectus titled "Management—Equity Incentives" for a description of securities granted by our Management Board to our members of Management Board and of Supervisory Board, employees and consultants.

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.s 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	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
	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.	
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	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
	day or within 15 days) or for successive meetings convened with the same agenda.	
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	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
	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.	
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 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	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
	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.	
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. 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

	France	Delaware
		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

	France	Delaware
		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.
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.

Legal Name; Formation; Registered Office

Our legal name and commercial name is Valneva SE. We were incorporated on March 24, 1999. Our headquarters are 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 +33 228 073 710. 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 part of this prospectus.

Listing

We intend to apply to have our ADSs listed on the Nasdaq Global Market under the symbol "VALN." Our ordinary shares are currently listed on Euronext Paris under the symbol "VLA."

Transfer Agent and Registrar

Upon the completion of this global offering, the depositary for our ADSs will be Citibank, N.A. CACEIS is our transfer agent and registrar for our ordinary shares and currently maintains our share register for our ordinary shares. The share register reflects only record owners of our ordinary shares. Holders of our ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying the ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

LIMITATIONS AFFECTING SHAREHOLDERS OF A FRENCH COMPANY

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 on December 28, 2020 by the Decree n° 2020-1729, has created until December 31, 2021 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

While our current shareholders waived their preferential subscription rights with respect to this global offering at a shareholders' general meeting held on December 22, 2020, in the future our shareholders will have 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 of this prospectus titled "Description of American Depositary Shares" explains in detail the depositary's responsibility in connection with a rights offering. See also "Risk Factors—Risks Related to Ownership of Our Ordinary Shares and the ADSs."

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Citibank, N.A. has agreed to act as the depositary for the ADSs. 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 will appoint Citibank as depositary pursuant to a deposit agreement. A copy of the deposit agreement will be filed 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 at www.sec.gov.

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. 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.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, 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.

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.

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, 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

Upon completion of the offering, the ordinary shares being offered pursuant to the prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary will issue ADSs to the underwriters named in the prospectus.

After the closing of the offer, 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. The voting rights of holders of ordinary shares are described in the sections of this prospectus entitled "Description of Share Capital" and "Limitations Affecting Shareholders of a French Company".

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. Certain depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. 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.

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.*

SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to the global offering, while our ordinary shares have been listed on Euronext Paris since 2013, there has been no public market on a U.S. national securities exchange for our ordinary shares or ADSs and we cannot assure you that a significant public market in the United States for the ordinary shares or ADSs will be sustained after this global offering.

Future sales of ADSs in the U.S. public market after this global offering, and the availability of ADSs for future sale, could adversely affect the market price of the ADSs prevailing from time to time. As described below, a significant number of currently outstanding ordinary shares will not be available for sale shortly after this global offering due to contractual restrictions on transfers of ordinary shares and ADSs. However, sales of substantial amounts of ADSs or ordinary shares, or the perception that these sales could occur, could adversely affect prevailing market prices for the ADSs and could impair our future ability to raise equity capital.

Based on the number of ordinary shares outstanding on December 31, 2020, upon completion of the global offering, ordinary shares (including ordinary shares in the form of ADSs) will be outstanding (or shares if the underwriters exercise in full their option to purchase up to additional ordinary shares, which may be in the form of ADSs), assuming no outstanding warrants or options are exercised and assuming no free ordinary shares become vested. All of the ADSs sold in the offering will be freely tradable without restrictions or further registration under the Securities Act, except for any ADSs sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The ordinary shares held by existing shareholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the United States on the Nasdaq Global Market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or Rule 701 promulgated under the Securities Act.

Rule 144

In general, a person who has beneficially owned restricted ordinary shares for at least six months would be entitled to sell their securities pursuant to Rule 144 under the Securities Act provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (2) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted ordinary shares for at least six months, but who are our affiliates at the time of, or at any time during the 90 days preceding a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1.0% of the number of ordinary shares (including ordinary shares in the form of ADSs) then outstanding, which will equal approximately ordinary shares immediately after the completion of the global offering based on the number of ordinary shares outstanding as of December 31, 2020; and
- the average weekly trading volume of the ADSs on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144. Non-affiliate resales of restricted shares under Rule 144 also are subject to the availability of current public information about us until a period of one year has elapsed since the securities were acquired from the issuer or an affiliate of the issuer.

Rule 701

Rule 701 under the Securities Act permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees or

members of the Supervisory and Management Boards who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares subject also to French law, as described below.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Lock-up Agreements

We, the members of our Management Board and Supervisory Board and certain of our shareholders have agreed that, without the prior written consent of Goldman Sachs & Co. LLC and Jefferies LLC, or, collectively, the Representatives, on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus (i) offer, sell, contract to sell, pledge, grant any option to purchase, lend or otherwise dispose of any ordinary shares or ADSs, or any options or warrants to purchase any ordinary shares or ADSs, or any securities convertible into, exchangeable for or that represent the right to receive ordinary shares or ADSs, (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition (whether by the undersigned or someone other than the undersigned), or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of any ordinary shares or ADSs, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of ordinary shares or ADSs or other securities, in cash or otherwise; or (iii) otherwise publicly announce any intention to engage in or cause any action or activity described in clause (i) above or transaction or arrangement described in clause (ii) above. The restrictions described in this paragraph are subject to certain exceptions. See “Underwriting.”

The Representatives, in their sole discretion, may release the ADSs and other securities subject to the lock-up agreements described above in whole or in part at any time.

We do not currently expect any release of ordinary shares or ADSs subject to lock-up agreements prior to the expiration of the applicable lock-up periods. Upon the expiration of the applicable lock-up periods, substantially all of the ordinary shares and ADSs subject to such lock-up restrictions will become eligible for sale, subject to the limitations described above.

French Law

Under French law, and notably under the General Regulation (*Règlement Général*) issued by the AMF, as well as under Market Abuse Regulation 596/2014 of 16 April 2014, or MAR, any person that holds inside information shall, until such information is made public, refrain from (1) carrying out any transactions relating to securities issued by the company, (2) recommending that another person engage in insider dealing or induce another person to engage in insider dealing, (3) unlawfully disclosing inside information outside of the normal exercise of an employment, a profession or duties. The use of inside information by cancelling or amending an order concerning a financial instrument to which the information relates where the order was placed before the person concerned possessed the inside information, shall also be considered to be insider dealing. These rules apply to all persons who hold inside information as a result of (1) their status as board member, executive officer, manager, employee of the company, third parties acting on behalf of the company and having access to privileged information as party of their professional relations with the company during the preparation or the completion of a particular transaction, such as investor services providers, lawyers or public relations agencies, (2) their holding of securities in the share capital of the company, and/or (3) their access to information because of their employment, profession or duties or their participation in the preparation of a financial transaction.

Under MAR and the General Regulation of the AMF, it is also prohibited for a person to engage or attempt to engage in market manipulation.

Prohibited transactions include all transactions related to securities: stocks, securities convertible, options, warrants, bonds, and in particular, (1) transfer of securities, (2) exercise of options, warrants or any securities giving access to the capital, (3) transfer of free ordinary shares and (4) acquisition of securities.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus delivery requirements of the Securities Act. Accordingly, restricted securities may be sold in offshore transactions in compliance with Regulation S.

MATERIAL UNITED STATES FEDERAL INCOME AND FRENCH TAX CONSIDERATIONS

Material income tax considerations

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 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 is treated as holding and receiving directly its proportionate share of assets and income of such corporation. 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 believe that we a PFIC for our most recently completed taxable year. 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, including this 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 Market, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq Global 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.

In 2011, France introduced a comprehensive set of tax rules applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor's net assets for the purpose of applying the former French wealth tax (replaced by the French real estate wealth tax as from January 1, 2018), for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the former French wealth tax (replaced by the French real estate wealth tax as from January 1, 2018) and for a number of French tax reporting and disclosure obligations. 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 prospectus, 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 ordinary shares or 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) 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 ordinary shares or 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 ordinary shares or 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.

Financial Transactions Tax and Registration Duties

Pursuant to Article 235 *ter* ZD of the FTC, purchases of shares or 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, 2020, our market capitalization did not exceed 1 billion euros, pursuant to BOI-ANNX-000467-23/12/2020.

Moreover, Nasdaq Global Market, on which ADSs will be listed, is not currently acknowledged by the AMF but this may change in the future.

As a consequence, neither the ADSs nor the ordinary shares are currently within the scope of the French tax on financial transactions.

Following this global offering, purchases of our ADSs may be subject to such tax in the future provided that our market capitalization exceeds 1 billion euros in the year preceding the taxation year and that the Nasdaq Global Market is acknowledged by the French AMF.

In the case where Article 235 *ter* ZD of the FTC is not applicable, 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. As ordinary shares of our company are listed on Euronext Paris, which is an organized market within the meaning of the French monetary code, their transfer should be subject to uncapped registration duties at the rate of 0.1% subject to the existence of a written statement (*acte*), and provided that Article 235 *ter* ZD of the FTC is not applicable. Although there is no case law or official guidelines published by the French tax authorities on this point, transfer of ADSs should remain outside of the scope of the aforementioned 0.1% 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 (i) 28% (to be aligned on the standard corporate income tax rate set forth in the first sentence of Article 219-I §2 of the FTC for fiscal years beginning as from January 1, 2020) 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 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 28% (to be aligned on the standard corporate income tax rate set forth in the first sentence of Article 219-I §2 of the FTC 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 ordinary shares or 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 ordinary shares or 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 28% (to be aligned on the standard corporate income tax rate set forth in the first

sentence of Article 219-I §2 of the FTC), 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 ordinary shares or 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 30% (to be aligned on the standard corporate income tax rate set forth in the first sentence of Article 219-I §2 of the FTC) 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 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*).

ENFORCEMENT OF CIVIL LIABILITIES

We are a corporation organized under the laws of France. The majority of our members of the Management Board and Supervisory Board are citizens and residents of countries other than the United States, and the majority of our assets are located outside of the United States. We have appointed an agent for service of process in the United States; however, it may be difficult for investors:

- to obtain jurisdiction over us or our non-U.S. resident members of the Management Board and Supervisory Board in U.S. courts in actions predicated on the civil liability provisions of the U.S. federal securities laws;
- to enforce judgments obtained in such actions against us or our non-U.S. resident members of the Management Board and supervisory;
- to bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us or our non-U.S. resident members of the Management Board and Supervisory Board; and
- to enforce against us or our Management Board in non-U.S. courts, including French courts, judgments of U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws.

Nevertheless, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would be recognized and enforced in France provided that a French judge considers that this judgment meets the French legal requirements concerning the recognition and the enforcement of foreign judgments and is capable of being immediately enforced in the United States. A French court is therefore likely to grant the enforcement of a foreign judgment without a review of the merits of the underlying claim, only if (1) that judgment is enforceable in the jurisdiction of the U.S. court which rendered it, (2) that judgment was rendered by a court having jurisdiction over the dispute (the condition will be met if the dispute is clearly connected to the jurisdiction of the U.S. court and French courts did not have exclusive jurisdiction over the matter), (3) that judgment does not contravene French international public order and public policy, including the right to due process, and (4) the U.S. judgment is not tainted with fraud and is not incompatible with a judgment rendered by a French court in the same matter, or with an earlier judgment rendered by a foreign court in the same matter.

In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so that the victim does not suffer or benefit from the situation. Such system excludes damages such as, but not limited to, punitive and exemplary damages.

As a result, the enforcement, by U.S. investors, of any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities law against us or members of our Management Board and Supervisory Board or certain experts named herein who are residents of France or countries other than the United States would be subject to the above conditions.

Finally, there may be doubt as to whether a French court would impose civil liability on us, the members of our Management Board and Supervisory Board or certain experts named herein in an original action predicated solely upon the U.S. federal securities laws brought in a court of competent jurisdiction in France against us or such members, officers or experts, respectively.

UNDERWRITING

The global offering consists of:

- an offering of a total of ordinary shares in the form of ADSs in the United States, Canada and countries outside Europe; and
- a concurrent offering of a total of ordinary shares in Europe (including France) exclusively offered to "qualified investors" (as this term is defined under EU Regulation n°2017/1129).

We and the underwriters named below have entered into an underwriting agreement with respect to the ordinary shares and ADSs being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of ADSs and/or ordinary shares indicated in the following table. Goldman Sachs & Co. LLC and Jefferies LLC are the representatives of the underwriters.

Underwriters	Number Of Ordinary Shares	Number Of ADSs
Goldman Sachs & Co. LLC		
Jefferies LLC		
Guggenheim Securities, LLC		
Bryan, Garnier & Co		
Total		

The underwriters are committed to take and pay for all of the ADSs and ordinary shares being offered, if any are taken, other than the ADSs and/or ordinary shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional ordinary shares, which may be in the form of ADSs, from us. They may exercise that option once, within 30 days from the date of the underwriting agreement. If any ordinary shares, which may be in the form of ADSs, are purchased pursuant to this option, the underwriters will severally purchase ordinary shares, which may be in the form of ADSs in approximately the same proportion as set forth in the table above.

The address of Goldman Sachs & Co. LLC is 200 West Street, New York, New York 10282, and the address of Jefferies LLC is 520 Madison Avenue, New York, New York 10022.

The following table shows the per ordinary share, per ADS and total underwriting commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ordinary shares, which may be in the form of ADSs.

Paid by the Company

	No Exercise	Full Exercise
Per Ordinary Share	€	€
Per ADS(1)	$	$
Total(1)	$	$

(1) Assumes an exchange rate of $ per euro.

Ordinary shares and ADSs sold by the underwriters to the public will initially be offered at the public offering prices set forth on the cover of this prospectus. After the offering of the ordinary shares and ADSs, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of ordinary shares or ADSs made outside of the United States may be made by affiliates of the underwriters.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ordinary shares, which may be in the form of ADSs, to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make internet distributions on the same basis as other allocations.

We, the members of our Management Board and Supervisory Board and certain of our shareholders have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their ordinary shares or ADSs or securities convertible into or exchangeable ordinary shares or ADSs during the period from the date of this prospectus continuing through the date 90 days after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See “Shares and ADSs Available for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the ADSs. The public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our ordinary shares are listed on Euronext Paris under the symbol “VLA.” We intend to apply for the admission of our ADSs on the Nasdaq Global Market under the symbol “VALN.”

In connection with the offering, the underwriters may purchase and sell our ordinary shares and ADSs in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of ordinary shares or ADSs than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional ordinary shares or ADSs for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional ordinary shares or ADSs or purchasing ordinary shares or ADSs in the open market. In determining the source of ordinary shares or ADSs to cover the covered short position, the underwriters will consider, among other things, the price of ordinary shares or ADSs available for purchase in the open market as compared to the price at which they may purchase additional ordinary shares or ADSs pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional ordinary shares or ADSs for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing ordinary shares or ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares or ADSs made by the underwriters in the open market prior to the completion of the offering. Such stabilization transactions will need to comply with European Union laws and notably Regulation n°596/2014 on market abuse, as amended (the “Market Abuse Regulations”).

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our ordinary shares and ADSs, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the ordinary shares and ADSs. As a result, the price of the ordinary shares and ADSs may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting commissions, will be approximately $. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area, or each a Relevant State, no ordinary shares, or Shares, have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

No ordinary shares, or Shares, have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the Shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the Shares shall require us or any representative to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

France

The ADSs have not been and will not be offered or sold to the public in the Republic of France, and no offering of this prospectus or any marketing materials relating to the ADSs may be made available or distributed in any way that would constitute, directly or indirectly, an offer to the public in the Republic of France (except for public offerings defined in Article L.411-2 1° of the French *Code monétaire et financier*).

The ordinary shares in the form of ADSs may only be offered or sold in France pursuant to article L. 411-2 1° of the French *Code monétaire et financier* to qualified investors (*investisseurs qualifiés*) (as such term is defined in Article 2(e) of the Prospectus Regulation) acting for their own account, and in accordance with articles L. 411-1, L. 411-2 and D. 411-2 to D.411-4, D.744-1 and D. 754-1 and D. 764-1 of the French *Code monétaire et financier*.

Prospective investors are informed that:

- neither this prospectus nor any other offering materials relating to the ordinary shares in the form of ADSs described in this prospectus has been submitted for clearance to the French financial markets authority (*Autorité des marchés financiers*);
- neither this prospectus, nor any offering material relating to the ordinary shares in the form of ADSs has been or will be released, issued, distributed or caused to be released, issued or distributed to the public in France or used in connection with any offer for subscription or sale of the ordinary shares in the form of ADSs to the public in France within the meaning of article L. 411-1 of the French *Code monétaire et financier* (other than public offerings defined in Article L.411-2 1° of the French *Code monétaire et financier*);
- individuals or entities referred to in article L. 411-2 1° of the French *Code monétaire et financier* may participate in the offering, as provided under articles D.411-4, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*; and
- the direct and indirect distribution or sale to the public of the ordinary shares in the form of ADSs acquired by them may only be made in compliance with articles L. 411-1, L. 411-2 1°, L. 412-1 and L. 621-8 to L. 621-8-2 of the French *Code monétaire et financier*.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this offering memorandum (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance", or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of

whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

EXPENSES RELATING TO THE GLOBAL OFFERING

The following table sets forth the costs and expenses payable in connection with the sale of ordinary shares and ADSs in the global offering. All amounts are estimated except the SEC registration fee, the Nasdaq initial listing fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee. Except as otherwise noted, all the expenses below will be paid by us.

Expense	Amount
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq initial listing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing expenses	*
Miscellaneous fees and expenses	*
Total	$ *

* To be completed by amendment.

LEGAL MATTERS

Cooley LLP, Boston, Massachusetts, is representing us in connection with this global offering. The validity of the ordinary shares and certain other matters of French law will be passed upon for us by Hogan Lovells Paris LLP, Paris, France. Legal counsel to the underwriters in connection with this global offering are Goodwin Procter LLP, Boston, Massachusetts, and Gide Loyrette Nouel A.A.R.P.I, Paris, France.

EXPERTS

The consolidated financial statements of Valneva SE as of and for the year ended December 31, 2019 included in this prospectus have been audited by Deloitte & Associés and PricewaterhouseCoopers Audit, independent registered public accounting firms, as stated in their report appearing herein (which report expresses a qualified opinion on the consolidated financial statements as the consolidated financial statements are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the IASB. Such report includes an explanatory paragraph referring to the adoption of IFRS 16 Leases). Such consolidated financial statements are included in reliance upon the report of such firms given upon their authority as experts in accounting and auditing.

The offices of Deloitte & Associés are located at19 boulevard Alfred Daney, 33041 Bordeaux Cedex, France.

The offices of PricewaterhouseCoopers Audit are located at 63, rue de Villiers, 92208 Neuilly-sur-Seine Cedex, France.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a Registration Statement on Form F-1 under the Securities Act with respect to the ordinary shares and ADSs offered in this prospectus. A related registration statement on Form F-6 will be filed with the SEC to register the ADSs. This prospectus, which forms a part of the Registration Statement, does not contain all of the information included in the Registration Statement. Certain information is omitted and you should refer to the Registration Statement and its exhibits for that information. With respect to references made in this prospectus to any contract or other document of Valneva SE, such references are not necessarily complete and you should refer to the exhibits attached to the Registration Statement for copies of the actual contract or document.

Upon completion of this global offering, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, periodic reports and other information, with the SEC.

We are allowed four months after the end of our fiscal year to file our annual report with the SEC, and we are not required to disclose certain detailed information regarding executive compensation that is required from U.S. domestic issuers. Also, as a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing the furnishing of proxy statements to shareholders, and the members of our Supervisory Board and Management Board and our principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required of U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount, or at the same time, as information is received from, or provided by, other U.S. domestic reporting companies. We are only liable for violations of the rules and regulations of the SEC that apply to us as a foreign private issuer.

The SEC maintains a website at www.sec.gov that contains reports and information statements and other information regarding registrants like us that file electronically with the SEC. You also can inspect our registration statement, as well as any other information we file with or furnish to the SEC, on this website. This reference to the SEC’s website is an inactive textual reference only and is not a hyperlink.

We expect to make our annual reports and other information filed with or furnished to the SEC available, free of charge, through our website at www.valneva.com as soon as reasonably practicable after those reports and other information are filed with or furnished to the SEC. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Management Board and Shareholders of Valneva SE

Qualified Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Valneva SE ("the Company") as of December 31, 2019, and the related consolidated statement of income (loss) and comprehensive income (loss), consolidated statement of cash flows and consolidated statement of changes in equity for the year ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, except for the effects of the matter discussed in the following paragraph, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year then ended in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

As discussed in Note 5.2 to the consolidated financial statements, the accompanying consolidated financial statements are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the IASB.

Change in Accounting Principle

As discussed in Note 5.2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Qualified 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Deloitte & Associés

/s/ PricewaterhouseCoopers Audit
/s/ Cédric Mazille

Bordeaux and Neuilly-sur-Seine, France
January 15, 2021

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

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

Consolidated Statement of Income (Loss)

€ in thousand (except per share amounts)	Note	Year ended December 31, 2019
Product sales	5.4/5.5	129,511
Revenues from collaboration, licensing and services	5.1/5.4/5.5	(3,315)
Revenues		**126,196**
Cost of goods and services	5.4/5.6	(52,781)
Research and development expenses	5.4/5.6	(38,022)
Marketing and distribution expenses	5.4/5.6	(24,145)
General and administrative expenses	5.4/5.6	(18,398)
Other income and expenses, net	5.8	6,338
OPERATING PROFIT/(LOSS)		**(811)**
Finance income	5.9	1,449
Finance expenses	5.9	(3,082)
Result from investments in associates	5.15	1,574
PROFIT/(LOSS) BEFORE INCOME TAX		**(870)**
Income tax	5.10	(874)
PROFIT/(LOSS) FOR THE PERIOD		**(1,744)**
Earnings/(Losses) per share		
for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share	5.11	
— **basic**		**(0.02)**
— **diluted**		**(0.02)**

The accompanying notes form an integral part of these financial statements

Consolidated Statement of Comprehensive Income (Loss)

€ in thousand	Note	Year ended December 31, 2019
Profit/(Loss) for the period		**(1,744)**
Other comprehensive income/(loss)		
Items that may be reclassified to profit or loss		
Currency translation differences	5.21	656
Items that will not be reclassified to profit or loss		
Defined benefit plan actuarial gains/(losses)	5.21	(13)
Other comprehensive income/(loss) for the year, net of tax		**644**
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(1,100)**

The accompanying notes form an integral part of these financial statements

2. CONSOLIDATED BALANCE SHEET

€ in thousand	Note	At December 31, 2019
ASSETS		
Non-current assets		**135,561**
Intangible assets	5.12	41,813
Right of use assets	5.13	49,334
Property, plant and equipment	5.14	20,003
Equity-accounted investees	5.15	2,263
Other non-current assets	5.19	17,161
Deferred tax assets	5.10	4,988
Current assets		**129,162**
Inventories	5.17	25,772
Trade receivables	5.18	24,030
Other current assets	5.19	14,921
Cash and cash equivalents	5.20	64,439
TOTAL ASSETS		**264,723**
EQUITY		
Capital and reserves attributable to the Company's equity holders		**135,153**
Share capital	5.21	13,642
Share premium	5.21	244,912
Other reserves	5.21	45,756
Retained earnings/(Accumulated deficit)	5.21	(167,412)
Profit/(loss) for the period		(1,744)
LIABILITIES		
Non-current liabilities		**88,269**
Borrowings	5.23	24,317
Lease liabilities	5.13/5.26	56,592
Contract liabilities	5.5	732
Refund liabilities	5.5	6,105
Provisions	5.27	426
Other liabilities	5.28	97
Current liabilities		**41,300**
Borrowings	5.25	1,999
Trade payables and accruals	5.26	16,567
Income tax liability		2,458
Tax and Employee-related liabilities	5.27	10,624
Lease liabilities	5.13/5.26	2,308
Contract liabilities	5.5	694
Refund liabilities	5.5	448
Provisions	5.27	2,315
Other liabilities	5.28	3,886
TOTAL LIABILITIES		**129,569**
TOTAL EQUITY AND LIABILITIES		**264,723**

The accompanying notes form an integral part of these financial statements

3. CONSOLIDATED STATEMENT OF CASH FLOWS

€ in thousand	Note	Year ended December 31, 2019
Cash flows from operating activities		
Profit/(Loss) for the year		(1,744)
Adjustments for non-cash transactions	5.29	12,704
Changes in non-current operating assets and liabilities	5.29	3,597
Changes in working capital	5.29	(6,682)
Cash generated from operations	5.29	**7,875**
Income tax paid	5.10	(2,346)
Net cash generated from operating activities		**5,529**
Cash flows from investing activities		
Purchases of property, plant and equipment	5.14	(10,502)
Proceeds from sale of property, plant and equipment	5.14	—
Purchases of intangible assets	5.12	(382)
Interest received		199
Net cash used in investing activities		**(10,685)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of costs of equity transactions	5.22	(2,484)
Disposal/(Purchase) of treasury shares	5.22	21
Proceeds from borrowings, net of transaction costs	5.23	11,781
Repayment of borrowings	5.23	(11,684)
Payment of lease liabilities	5.13/5.26	(2,709)
Interest paid		(2,621)
Net cash generated from/(used in) financing activities		**(7,696)**
Net change in cash and cash equivalents		**(12,852)**
Cash and cash equivalents at beginning of the year		77,084
Exchange gains/(losses) on cash		207
Cash and cash equivalents at end of the year	5.20	**64,439**

The accompanying notes form an integral part of these financial statements

4. CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

€ in thousand *(except number of shares)*	Note	*Number of Shares*	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
Balance as of 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	5.2	—	—	—	(9,474)	—	—	(9,474)
Balance as of 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:	5.22							
— value of services		—	—	—	2,504	—	—	2,504
— exercises		*25,975*	4	12	—	—	—	16
Treasury shares	5.22	—	—	—	21	—	—	21
		25,975	4	12	3,169	3,264	(5,008)	1,441
Balance as of December 31, 2019		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**

The accompanying notes form an integral part of these financial statements

5. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

5.1 General information

Valneva SE ("the Company") together with its subsidiaries ("Group" or "Valneva") is a specialty vaccine company focused on prevention against diseases with major unmet needs.

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*. The Group has various vaccines in development including a unique vaccine against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the United States with approximately 500 employees.

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Accounting treatment	Interest held at December 31, 2019
BliNK Biomedical SAS[1]	FR	Equity method	48.9%
Vaccines Holdings Sweden AB	SE	Consolidation	100%
Valneva Austria GmbH	AT	Consolidation	100%
Valneva Canada Inc.	CA	Consolidation	100%
Valneva France SAS	FR	Consolidation	100%
Valneva Scotland Ltd.	UK	Consolidation	100%
Valneva Sweden AB	SE	Consolidation	100%
Valneva UK Ltd.	UK	Consolidation	100%
Valneva USA, Inc.	US	Consolidation	100%

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

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

The Valneva SE site in Saint-Herblain (Nantes, France) includes general and administrative functions and 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 Canada Inc. (Montreal, Quebec) performs marketing and sales activities in Canada in relation to the IXIARO, DUKORAL and VIVOTIF vaccines.

Valneva France SAS (Lyon, France) was founded in February 2019 and will perform marketing and sales activities in France in relation to IXIARO and DUKORAL from 2020 onwards.

Valneva Scotland Ltd. (Livingston, United Kingdom) is primarily involved in the production of Valneva's Japanese encephalitis vaccine, IXIARO.

Valneva Sweden AB (Solna, Sweden) manufactures the DUKORAL vaccine and distributes it, as well as third-party vaccines, in the Nordic countries. In addition Valneva Sweden AB provides R&D services.

1 see Note 5.15

Valneva UK Ltd. (based nearby London, United Kingdom) commercialises DUKORAL and IXIARO in the United Kingdom, as well as MOSKITO GUARD products.

Valneva USA, Inc. focuses on marketing and sales of Valneva's Japanese encephalitis vaccine to the US military and the US private market.

SIGNIFICANT EVENTS OF THE PERIOD

Significant agreements signed in the period

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 an additional 80,000 doses were delivered in April 2020, bringing the total value of the contract to $70 million.

In June 2019, Valneva and GSK announced mutual agreement to end 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 will pay up to a further €7.0 million when milestones of marketing approvals of its Lyme vaccine are fulfilled. As a result, Valneva is fully in control of its main research and development assets, including its Lyme vaccine candidate (VLA15). A negative effect of net €10.7 million was included in Valneva's revenues from collaboration and licensing reflecting both the current and future payment obligations. See Note 5.5.

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.

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.

Basis of preparation

These 2019 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"), except they are not presented in accordance with International Accounting Standard 1, Presentation of Financial Statements, as they do not include comparative information, which constitutes a departure from IFRS as issued by the 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 judgment in applying the Group's accounting policies. The areas involving a higher degree of judgment 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 and authorized for issuance by the Supervisory Board on January 15, 2021.

Impact of new, revised or amended Standards and Interpretations

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

Standard — Interpretation — Amendment		Effective Date	Effects
IFRS 16	Leases	January 1, 2019	See below
IFRIC Interpretation 23	Uncertainty over Income Tax Treatments	January 1, 2019	None
Amendments to IFRS 9	Prepayment Features with Negative Compensation	January 1, 2019	None
Amendments to IAS 28	Long-term Interests in Associates and Joint Ventures	January 1, 2019	None
Annual Improvements to IFRS Standards 2015-2017 Cycle		January 1, 2019	None
Amendments to IAS 19	Plan Amendment, Curtailment or Settlement	January 1, 2019	None

IFRS 16 Leases

From January 1, 2019, IFRS 16 (Leases) has to be applied. It replaces IAS 17 *Leases*, IFRIC 4 *Determining whether an arrangement contains a Lease*, SIC 15 *Operating Leases Incentives* and SIC 27 *Evaluation the Substance of Transactions Involving the Legal Form of a Lease*. For the lessee it results in the removal of the distinction between operating and finance lease, hence most of the leases have to be recognized on the balance sheet.

At the commencement date of a lease, a lessee recognizes a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees are required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees are also required to remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognize the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

In November 2019, the IFRS Interpretations Committee (IC) concluded that the enforceable period of a lease under IFRS 16 Leases reflects broader economics, not just legal rights and termination cash payments. Lessees consider the enforceable period when they are determining the lease term, and therefore which payments to include in the lease liability.

Lessor accounting under IFRS 16 is substantially unchanged from accounting under IAS 17. Lessors continue to classify all leases using the same classification principle as in IAS 17 and distinguish between two types of leases: operating and finance leases.

Valneva chose to apply the modified retrospective approach from the mandatory adoption date of January 1, 2019. Hence, the cumulative effect of initially applying IFRS 16 is recognized in opening equity at the date of initial application with no restatement of prior year figures required. Valneva chose not to apply IFRS 16 to leases of intangible assets according to IFRS 16.4.

For all leases previously classified as operating leases, Valneva measured right-of-use assets as its carrying amount as if IFRS 16 had always been applied since commencement date.

Furthermore, the following practical expedients have been used:

- Using a single discount rate to a portfolio of leases with similar characteristics;
- Applying the recognition exemption for leases ending within 12 months from the date of initial application 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;
- Excluding initial direct costs from the measurement of the right of use asset; and
- Using hindsight, such as in determining the lease term if the contract contains options to extend or terminate the lease.

To identify the IFRS 16 impact areas for Valneva, leasing contracts were identified and analyzed using a lease analysis tool. After the valuation of the contracts and the input of the data into the calculation tool, the postings of the first-time adoption of IFRS 16 were calculated as of January 1, 2019. For the main lease liability relating to a real-estate property in Solna, Sweden an interest rate of 2.49% and a remaining lease term of 19 years have been determined. The premises in Solna are currently leased, but a new lease agreement which will be effective in January 2021 was signed in 2018. This new agreement is seen as a modification to the existing contract and is therefore already taken into consideration at transition.

The effect of adopting IFRS 16 on the opening balance as at January 1, 2019 is as follows:

€ in thousand	Balance as of January 1, 2019 before IFRS 16 adoption	IFRS 16 Adoption	Balance as of January 1, 2019
ASSETS			
Right-of-use-assets	**—**	**50,937**	**50,937**
thereof reclassification from PPE	—	26,414	26,414
Property, plant and equipment	**37,997**	**(26,414)**	**11,583**
EQUITY			
Retained earnings and other reserves	**(171,435)**	**(9,474)**	**(180,909)**
LIABILITIES			
Lease liabilities	**26,662**	**33,997**	**60,659**

In the course of the first-time adoption of IFRS 16, a reclassification from previously accounted for IAS 17 assets from property, plant and equipment to right-of-use assets amounting to €26.4 million was made.

In addition, Valneva recognized right-of-use assets previously accounted for as operating lease expenses amounting to €24.5 million as well as the corresponding lease liability (€34.0 million). The difference amounting to €9.5 million has been recognized in retained earnings and other reserves.

Out of €50.9 million right-of-use-assets, €26.4 million relate to real-estate properties in Austria and €23.6 million relate to real-estate properties in Sweden.

The lease liabilities as at January 1, 2019 are reconciled to the operating lease commitments as followed:

€ in thousand	
Operating lease commitments as at January 1, 2019	**43,509**
Incremental borrowing rates as at January 1, 2019	0.07% - 3.39%
Discounted operating lease commitments at January 1, 2019	**34,154**
Commitments relating to short-term leases	(158)
Commitments relating to leases previously classified as finance leases	26,662
Lease liabilities as at January 1, 2019	**60,659**

(b) ***New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2019, 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 of January 1, 2019:

- IFRS 17 — Insurance contracts;
- Amendments to IFRS 3 — Definition of a Business;
- Amendments to IAS 1 and IAS 8 — Definition of Material;
- Amendments to References to the Conceptual Framework in IFRS Standards.

These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

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.

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;
- income and expenses for each income statement are 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.

Financial risks management

(a) ***Financial risks factors***

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.

(b) ***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.

With all other variables held constant, the impact from changes in exchange rates on the pre-tax result would be as follows:

€ in thousand	Year ended December 31, 2019
EUR/USD +10%	(3,134)
EUR/USD -10%	3,830
EUR/GBP +10%	(1,122)
EUR/GBP -10%	1,371
EUR/SEK +10%	114
EUR/SEK -10%	(140)
EUR/CAD +10%	(275)
EUR/CAD -10%	336

Interest rate risks

The Group is exposed to market risks in connection with hedging both of its liquid assets and of its medium and long-term indebtedness and borrowings subject to variable interest rates.

Borrowings issued at variable rate expose the Group to cash flow interest rate risks, which are offset by cash and financial assets held at variable rate. During 2019, the Group's investments at variable rate, as well as the borrowings at variable rate, were denominated in €, SEK, $, CAD and in GBP.

The Group analyzes its interest rate exposure on a dynamic basis. Based on this analysis, the Group 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 the balance sheet date, the calculated impact on income before tax of a 0.25% shift would be an increase or decrease of €64 thousand.

(c) ***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. The credit quality of financial assets is described in Note 5.16.

(d) ***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 believe that the existing cash and cash equivalents as of December 31, 2019 will be sufficient to fund the operations for at least the next 12 months from the authorization for issuance date of these consolidated financial statements.

The table below analyzes the Group's financial liabilities into relevant maturity groupings based on the remaining period from the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

Balance as of January 1, 2019 before IFRS 16 adoption € 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 (excluding finance lease liabilities)[2]	17,395	5,762	11,028	—	—	—	34,185
Finance lease liabilities	978	1,955	24,208	—	—	—	27,141
Trade payables and accruals	13,325	—	—	—	—	—	13,325
Tax and employee-related liabilities[3]	5,672	—	—	—	—	—	5,672
Contract liabilities, other liabilities and provisions[4]	45	200	25	—	—	—	270
	37,414	**7,918**	**35,261**	**—**	**—**	**—**	**80,593**

At December 31, 2019 € 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	3,850	17,010	11,644	393	—	—	32,898
Lease liabilities	3,225	6,422	27,572	10,811	11,850	7,545	67,424
Contract liabilities and refund liabilities	448	29	7,000	—	—	—	7,477
Trade payables and accruals	16,567	—	—	—	—	—	16,567
Tax and employee-related liabilities[3]	6,570	—	—	—	—	—	6,570
Other liabilities	222	47	—	—	—	—	269
	30,882	**23,507**	**46,216**	**11,203**	**11,850**	**7,545**	**131,204**

The fair values as well as the book values of the Group's borrowings are disclosed in Note 5.23. To manage liquidity risk, the Group holds sufficient cash, cash equivalents and short-term deposit balances.

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.

2 The categories in this disclosure are determined by IFRS 9. Finance leases are mostly outside the scope of IFRS 9 but they remain within the scope of IFRS 7. Therefore, finance leases have been shown separately.

3 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.

4 Deferred income, contract liabilities and provisions are excluded from the other liabilities and provisions balance, as this analysis is required only for financial instruments.

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.

Fair value estimation

The carrying value less impairment provision of trade receivables and payables are assumed to approximate their fair values due to the relatively short maturity of the respective instruments.

5.3 Critical accounting estimates and judgements

In preparing these consolidated financial statements, management has made judgements and estimates that affect the application of the Group’s accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognised prospectively.

Estimates and judgments are continuously evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Judgements

Information about judgements made in applying accounting policies that have the most significant effects on the amounts recognized in the financial statements is included in the following notes:

- Note 5.5: Revenue recognition of collaboration, license and service agreements: Management’s judgement is required to determine the identification and separation of performance obligations (especially when determining whether the license is distinct, which is the case, when the customer can benefit from the license without further involvement), the determination of the transaction price (including the judgement of payables to customers), and allocation of the transaction price to the performance obligations on relative standalone selling price. The standalone selling price is sometimes not available or are hard to value intangible assets, so various valuation techniques are used. In addition Management’s judgement is required whether revenue from collaborations and licensing is recognized over time or at a point in time;
- Note 5.8 and 5.28: Other income: The Group receives funding from the Coalition for Epidemic Preparedness Innovations (CEPI), which include 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. CEPI is a partly private partly by government funded NGO. 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 and of the various components need Management’s judgment.
- Note 5.2: Lease term: whether the Group is reasonably certain to exercise extension options

Assumptions and estimation uncertainties

The Management makes these estimates and assessments continuously based on its past experience and various other factors considered reasonable that form the basis of these assessments.

Information about assumptions and estimation uncertainties at December 31, 2019 that have a significant risk of resulting in a material adjustment to the carrying amounts of assets and liabilities in the next financial year is included in the following notes:

- Note 5.5: Revenue recognition of product sales: estimate of expected returns

- Note 5.5: Revenue recognition of collaboration, license and service agreements: likelihoods for refund liabilities; for revenues spread in accordance to the actual costs compared to the budget;
- Note 5.8 and 5.28: 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 and liabilities: availability of future taxable profit against which deductible temporary differences and tax losses carried forward can be utilized;
- Note 5.12: Intangibles: Amortization period of development expenditures and acquired technologies
- Note 5.12: Impairment test of intangible and tangible assets: key assumptions underlying recoverable amounts, including probability of success for R&D projects;
- Note 5.22: Share-based payments and related expected employer contribution costs: determination of accelerated vesting in the event of a change of control (as considered remotely); and
- Note 5.30: Recognition and measurement of provisions and contingencies: key assumptions about the likelihood and magnitude of an outflow of resources.

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 recognises 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 5.22: share-based payment arrangements; and
- Note 5.16 financial instruments.

5.4 Segment information

Operating segments are reported in a manner consistent with the internal reporting, provided to the chief operating decision maker. The Group identified the Management Board as "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. However, 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 the Group's vaccines IXIARO, DUKORAL, as well as third-party products)
- "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)
- "Technologies and services" (services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements)

As of January 1, 2020 the Group changed its internal reporting process and amended the following allocation rule: general and administrative costs previously reported under Corporate Overhead have been fully allocated to the three operational segments based on estimated level of activities supporting the 3 segments. 56.0% of previously unallocated general and administrative costs were allocated to Commercialized products, 36.5% to Vaccine candidates and 7.5% to technologies and services using a combination of revenues and FTEs as the basis to allocate costs to the segments. Marketing and distribution costs previously reported under Corporate Overhead have been fully allocated to the Commercialized products. This change was done to reflect the way Valneva's chief decision makers (CODM) monitor the performance of the segments. The operating profit (loss) is the measure that is reported to the CODM.

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

Income statement by segment

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

€ in thousand	Commercialized vaccines	Vaccine candidates	Technologies and services	Corporate overhead	Total
Product sales	129,511	—	—	—	129,511
Revenues from collaboration, licensing and services	163	(10,516)	7,038	—	(3,315)
Revenues	129,674	(10,516)[6]	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	(22,989)	(895)	(261)	—	(24,145)
General and administrative expenses	(10,599)	(6,150)	(1,650)	—	(18,398)
Other income and expenses, net	7	7,709	484	(1,861)	6,338
Operating profit/(loss)	**44,376**	**(42,717)**	**(609)**	**(1,861)**	**(811)**

Geographical segments

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

6 For more information see Note 5.1.

Product sales per geographical segment

€ in thousand	Year ended at December 31, 2019
United States	63,700
Canada	24,396
Nordics	11,027
Germany	10,345
United Kingdom	8,594
Austria	2,668
Other Europe	4,961
Rest of World	3,819
Product sales	**129,511**

Non-current operating assets per geographical segment

€ in thousand	At December 31, 2019
United States	149
Canada	68
Nordics	29,334
United Kingdom	11,117
Austria	65,554
Other Europe	4,928
Non-current operating assets	**111,150**

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 located 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.

Information about major customers

Product sales to the largest customer amounted to €46.7 million. Collaboration and licensing revenue from the two largest customers amounted to €4.1 million and €0.8 million, respectively. There are no further customers with a contribution exceeding 10% of the annual revenue.

5.5 Revenues from contracts with customers

IFRS 15 provide accounting requirements for all revenues arising from contracts with customers.

The core principle is that an entity will recognise revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer. The principles in IFRS 15 are applied using the following five steps:

1. Identify the contract(s) with a customer;
2. Identify the performance obligations in the contract;
3. Determine the transaction price;
4. Allocate the transaction price to the performance obligations in the contract;
5. Recognise revenue when (or as) the entity satisfies a performance obligation.

Within the Valneva Group the following revenue streams were identified:

a. Revenue from Product Sales

b. Revenue from Licensing & Services

Product sales

The Group's product sales contracts, normally concluded with distributors and with the U.S. government department of Defense (DoD), 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 deferred and shown as refund liabilities in the consolidated balance sheet.

In some cases, Valneva sells the products through distributors. When more than one party is involved in providing/distributing goods or services, the standard requires an entity to determine whether itself and its distributors 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. Depending on the contractual arrangement the transfer of control could be the point in time when Valneva delivers the product to the distributor, or the point in time when the distributor sells the products to its customer. Indicators that control is transferred to the customer when the distributor makes the sale (distributor acting as an agent), could be, that the price to be paid to Valneva is not fixed as long as the distributor has not completed his sale, if the distributor has extensive rights to return or if the distributor does not have the power to establish price for the sales to its customers.

Revenues from licensing and services

The Group generates revenues from licensing and service agreements for its product candidates and proprietary technologies. The contracts in place often include several different promised services such as research licenses, commercial licenses and further research and development (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.

IFRS 15 provides application guidance specific to the recognition of revenue from licenses of intellectual property. This application guidance provided on licenses is only applicable to licenses that are distinct or if the license is the primary or dominant component (i.e., the predominant item) of the combined performance obligation. To conclude that a license is distinct, the license must be both capable of being distinct and distinct in the context of the contract.

According to the revenue recognition standard some licenses will provide a right of access to the entity's intellectual property throughout the license period; this results in revenue being recognized over time. A license may also be a right to use the entity's intellectual property as it exists at the point in time at which the license is granted, resulting in revenue being recognized at a point in time. The Group's license contracts in place provide right-to-use licenses.

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 of the grant of the licenses. For any variable consideration revenue is recognized at the point in time when the variable constraint is removed. Additionally,

the new standard requires the recognition of revenue for sales-based or usage-based royalties (or sales milestone payments) on licenses at the later of when the subsequent sale or usage occurs and the performance obligation is (partially) satisfied.

For the research and development services and for performance obligations that combine licenses that are not distinct and other services it needs to be analyzed whether one of following criteria met:

- the customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs;
- the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced;
- the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date.

In this case, the revenue for these services is recognized over time in relation to the status of research, otherwise the revenue is recognized at a point in time. 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.

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.

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 vaccines	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**

Valneva's total revenues for 2019 include a negative revenue of €10.7 million related to the June 2019 mutual termination of its Strategic Alliance Agreement ("SAA"), with its customer GlaxoSmithKline Biologicals SA, or GSK (see Note 5.1), 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)**

Disaggregated revenue information

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 vaccines	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**

Geographical markets

Year ended December 31, 2019 € in thousand	Commercialized vaccines	Vaccine candidates	Technologies and services	Total
United States	63,700	162	130	63,992
Canada	24,396	—	—	24,396
Nordics	11,027	—	5	11,032
Germany	10,345	—	150	10,495
United Kingdom	8,596	—	15	8,610
Austria	2,668	—	4,136	6,803
Switzerland	167	(10,714)	—	(10,547)
Other Europe	4,794	36	440	5,270
Other markets	3,980	—	893	4,873
Revenues from contracts with customers	**129,674**	**(10,516)**	**5,768**	**124,926**

Sales channels for product sales

Commercialized products are sold via the following sales channels:

€ in thousand	At December 31 2019
Direct product sales	110,386
Sales through distributors	19,125
Total product sales	**129,511**

Receivables from contracts with customers

Trade receivables include €24,034 thousand receivables from contracts with customers.

Liabilities from contracts with customers

A contract liability has to be recognized, when the customer already provided the consideration (payment) 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" and non-refundable upfront fees.

Development of contract liabilities:

€ in thousand	2019
Balance as of January 1	4,735
Revenue recognition	(462)
Other releases	(4,274)
Addition	1,426
Balance at December 31	1,426
Less non-current portion	(732)
Current portion	694

Other releases refer to the offset of contract liabilities with termination costs of the SAA with GS. See Notes 5.1 and 5.4.

As at December 31, 2019, the aggregate amount of the transaction price, that is partially or fully unsatisfied, is € 7.1 million and it is expected to be recognized by January 2022.

Refund liabilities mainly includes the variable portion of the settlement fee from termination of the SAA with GSK. See Notes 5.1 and 5.4. Additionally deferrals relating to variable considerations like retrospective rebates and discounts are included.

Development of refund liabilities:

€ in thousand	2019
Balance as of January 1	0
Addition	6,553
Balance at December 31	6,553
Less non-current portion	(6,105)
Current portion	448

5.6 Expenses by nature

The consolidated income statement line items cost of goods and services, research and development expenses, marketing and distribution expenses as well as general and administrative expenses include the following items by nature of cost:

€ in thousand	Notes	Year ended December 31, 2019
Employee benefit expense other than share-based compensation	5.7	46,219
Share-based compensation expense	5.7	2,552
Consulting and other purchased services		29,840
Raw materials and consumables used		9,844
Depreciation and amortization and impairment	5.12/5.13/5.14	8,607
License fees and royalties		7,553
Building and energy costs		6,995
Advertising costs		6,801
Cost of services and change in inventory		5,320
Supply, office and IT-costs		3,281
Warehousing and distribution costs		3,013
Travel and transportation costs		1,921
Other expenses		1,399
Operating expenses		**133,345**

Principal Accountant Fees and Services:

€ in thousand	Year ended December 31, 2019		
	PwC Audit	Deloitte & Associés	Total
Audit Fees	213	228	441
Audit-related Fees	16	—	16
Tax Fees	—	—	—
Other Fees	9	3	12
TOTAL	**238**	**231**	**469**

5.7 Employee benefit expense

Employee benefit expenses include the following:

€ in thousand	Year ended December 31, 2019
Salaries	34,128
Social security contributions	10,621
Share-based compensation expense	2,552
Training and education	672
Other employee benefits	798
Total Employee benefit expense	**48,771**

During the year 2019, the Group had an average of 508 employees.

5.8 Other income/(expenses), net

Grants

Grants from governmental agencies and non-governmental organizations are recognized at their fair value 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 repayed are recognized as borrowings.

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-does, 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. CEPI money is treated under IAS 20 and presented as other income. In 2019 €1.8 million of grant income related to CEPI. For more information, see Notes 5.1 and 5.28.

Research and development tax credits

Research and development tax credits granted by tax authorities are accounted for as grants under IAS 20. In 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/(expenses), net include the following:

€ in thousand	Year ended December 31, 2019
Research and development tax credit	6,314
Grant income	1,886
Profit/(loss) on disposal of fixed assets, net	(92)
Taxes, duties, fees, charges, other than income tax	(146)
Miscellaneous income/(expenses), net	(1,623)
Other income/(expenses), net	**6,338**

Miscellaneous income/(expenses) for year 2019 included €2.1 million expense relating to major litigations (for more detailed information, see Note 5.27), and €0.6 million income mainly relating to a reimbursement of energy taxes and income from insurance claims.

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, 2019
Finance income	
Interest income from other parties	199
Foreign exchange gains, net	1,250
	1,449
Finance expense	
Interest expense on loans	(1,588)
Interest expense on refund liabilities	(89)
Interest epenses on lease liabilities	(926)
Other interest expense	(30)
Fair value losses on derivative financial instruments	(449)
Foreign exchange losses, net	—
	(3,082)
Finance income/(expenses), net	**(1,633)**

The net finance result amounted to minus €1.6 million for the year 2019. This decrease in net finance expenses was mainly due to a positive exchange rate effects in 2019 and reduced interest expense due to the decrease in borrowings.

The Group benefits from government assistance through arranging borrowing facilities that would have otherwise not been available to the Group. This assistance includes guarantees for the amount of €6.2 million. The corresponding borrowings are related to financing of Research and Development expenses, and CIR (R&D tax credit in France).

5.10 Income tax

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 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.

Income tax

Income tax is comprised of current and deferred tax.

€ in thousand	**Year ended December 31, 2019**
Current tax	
Current income tax charge	(2,849)
Adjustments in respect of current income tax of previous year	(258)
Deferred tax	
Relating to origination and reversal of temporary differences	2,233
Income tax income/(expense)	**(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, 2019**
Profit/(Loss) before tax	(870)
Tax calculated at domestic tax rates applicable to profits in the respective countries	(1,431)
Income not subject to tax (mainly R&D tax credit)	1,727
Expenses not deductible for tax purposes	(169)
Deferred tax asset not recognized	(7,405)
Utilization of previously unrecognized tax losses	5,480
Income tax credit	105
Effect of change in applicable tax rate	(1,708)
Exchange differences	62
Income tax of prior years	(256)
Minimum income tax	(142)
Income tax	**(874)**

Despite the Group is loss making, there are profitable jurisdictions.

Deferred tax

As of December 31, 2019 the deferred tax assets of €110.2 million 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. 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 of December 31, 2019 the Group has tax losses carried forward of €457 million, of which €176.5 million are related to Valneva SE, €278.7 million are related to Valneva Austria GmbH, €0.6 million are related to Valneva USA, Inc., €1.2 million are related to Valneva Scotland, Ltd. and zero are related to Valneva Sweden AB.

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 offset amounts are as follows:

€ in thousand	At December 31, 2019
Deferred tax assets	
Deferred tax asset to be recovered after more than 12 months	8,995
Deferred tax asset to be recovered within 12 months	5,413
Total deferred tax assets	**14,408**
Deferred tax liabilities	
Deferred tax liability to be recovered after more than 12 months	(9,264)
Deferred tax liability to be recovered within 12 months	(157)
Total deferred tax liability	**(9,421)**
Deferred tax, net	**4,988**

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

€ in thousand	2019
Beginning of year	2,689
Exchange differences	66
Other adjustments due to tax changes	—
Income statement charge	2,233
End of year	**4,988**

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

€ in thousand	At December 31, 2019
Deferred tax asset from	
Tax losses carried forward	114,148
Fixed assets	2,270
Inventory	3,399
Borrowings and accrued interest	1,332
Provision	1,570
Other items	1,903
Non-recognition of deferred tax assets	(110,215)
Total deferred tax assets	**14,408**
Deferred tax liability from	
Fixed assets	(246)
Intangible assets	(8,931)
Other items	(243)
Total deferred tax liability	**(9,421)**
Deferred tax, net	**4,988**

The corporate income tax rate in the United Kingdom will be 17% starting from April 1, 2020 (substantively enacted).

The corporate income tax rate in France will be gradually reduced over the next years to 25%. A 28% rate will apply for the first €500 thousand of profit in 2020 (with the remaining profits subject to a 31% rate in 2020). The rate will be reduced to 26.5% in 2021 and 25% from 2022 onward on the full amount of taxable profits.

The corporate income tax rate (federal and state tax together) in US is 25.67%.

The deferred tax assets and liabilities presented above as at December 31, 2019 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 5.21 and 5.22.

	Year ended December 31, 2019
Net profit (loss) from continuing operations attributable to equity holders of the Company (€ in thousand)	(1,744)
Weighted average number of outstanding shares	91,744,268
Basic earnings (losses) from continuing operations per share (€ per share)	**(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, 2019
Net profit (loss) from continuing operations attributable to equity holders of the Company (€ in thousand)	(1,744)
Weighted average number of outstanding shares for diluted earnings (losses) per share[8]	91,744,268
Diluted earnings/(losses) from continuing operations per share (€ per share)	**(0.02)**

5.12 Intangible assets

Assets that have an indefinite useful life, such as acquired research and development technology and projects and capitalized development projects not ready for use are not subject to amortization and are tested annually for impairment. Furthermore, assets that have an indefinite useful life and assets that are subject to depreciation and amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. 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.

(a) 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 have been incurred.

(b) 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 current acquired research and development technology and projects are amortized over periods of 24 years, which is based on the patent life and technological replacement of a newer vaccine generation.

8 Potentially dilutive securities (195,515 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

(c) Development costs

Research expenses are recognized as expenses when incurred. Development expenses incurred on clinical projects (related to the design and testing of new or significantly improved products) are recognized as intangible assets when the following criteria have been fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and to utilize or sell it;
- there is an ability to utilize or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial, and/or other resources to complete the development and to utilize or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as expenses when they are incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its useful life, generally 10-15 years.

€ in thousand	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
January 1, 2019					
Cost	5,642	83,120	9,789	—	98,551
Accumulated amortization and impairment	(3,597)	(42,332)	(7,731)	—	(53,660)
Net book value	**2,045**	**40,788**	**2,058**	**—**	**44,891**
December 31, 2019					
Opening net book value	2,045	40,788	2,058	—	44,891
Exchange rate differences	7	116	15	—	138
Additions	205	42	88	48	383
Disposals	—	—	(11)	—	(11)
Amortization charge	(629)	(2,687)	(197)	—	(3,512)
Impairment charge	—	(75)	—	—	(75)
Closing net book value	**1,629**	**38,183**	**1,953**	**48**	**41,813**
December 31, 2019					
Cost	5,873	83,294	10,047	48	99,263
Accumulated amortization and impairment	(4,244)	(45,111)	(8,095)	—	(57,450)
Net book value	**1,629**	**38,183**	**1,953**	**48**	**41,813**

Acquired R&D technology and projects

Acquired R&D technology and projects assets with a definite useful life which are not amortized yet comprise primarily the Borrelia vaccine candidate (VLA15) amounting to €3.3 million and the Zika vaccine candidate (VLA1601) amounting to €0 thousand, which was impaired to zero in 2019.

Significant intangible assets with definite useful life comprise primarily the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €78.2 million and a book value amounting to €36.2 million. The accumulated depreciation amounts to €42 million. The remaining life of the IXIARO intangible is 13 years as of December 31, 2019.

Impairment testing

The book values of capitalized in-process research and development projects have been assessed annually for impairment testing purposes using the risk-adjusted discounted cash flow method. Lyme VLA15 is currently the only active research and development program for which a book value is carried on the balance sheet. Management reviews the business performance based on in-process research and development projects. The recoverable amount of this project has been determined based on value-in-use calculations.

The calculations use post tax risk-adjusted cash flow projections based on the Group's long-range business model including probability-of-success assumptions derived from industry specific statistics on success rates of vaccines in the different development phases (risk-adjustment) and a discount rate of 10.43%.

The discount rate of 10.43% is based on 0.34% risk-free rate, 8.96% market risk premium, -0.12% country risk premium, 0.25% currency risk, a beta of 1.19, and a peer group related equity-capital ratio.

The long range business model covers a period of 16 years as well as an estimate on the perpetual annual growth rate beyond this horizon and therefore accounts for all project related cash flows from the development stage over the market entry until the market phase-out (project life cycle) of the relevant projects. These business models are updated on a regular basis and relevant changes in estimations done.

An impairment charge amounting to €0.1 million has been recognized following the decision of Emergent BioSolutions Inc. to not make use of their opt-in right post successful finalization of the Phase 1 clinical trial.

Sensitivity to changes in assumptions

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

- discount rate
- probability of project success
- reduction of expected revenues/royalties.

The net present value calculation uses a discount rate of 10.43%. An increase in the discount rate of 1,071 basis points from 10.43% to 21.14% would trigger an impairment loss. Furthermore, an increase in the discount rate of one percentage point would result in no impairment loss.

The result of the acquired research and development projects (see Note 5.12) is inherently uncertain and the Group may experience delays or failures in clinical trials. A failure to demonstrate safety and efficacy in clinical product development of the acquired Research and Development project would result in an impairment loss. The net present value calculation uses a probability of success rate of 24.4% for acquired products in the stage of research and development. The weighted risk is applied on expected revenues, COGS and Sales and Marketing expenses. Expected Phase 3 research and development costs to develop the program to licensure have been included using a probability to be incurred of 42.7%.

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 revenues of 10% would result in no additional impairment loss in 2019.

5.13 Leases

The Group leases various premises, equipment and vehicles. Rental contracts are typically made for fixed periods of few months to five years. The rental contracts for the premises in Sweden (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.

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 payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used. This is the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

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.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets (below €5 thousand) are recognised 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.

Development of right-of-use assets and lease liabilties

€ in thousand	Right-of-use assets				
	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total	Lease liabilities
Balance as of January 1, 2019 before IFRS 16 adoption	**—**	**—**	**—**	**—**	26,662
Reclass (IAS17)	26,414	—	—	**26,414**	—
IFRS 16 Adoption	24,095	80	347	**24,523**	33,997
Balance as of January 1, 2019	**50,510**	**80**	**347**	**50,937**	**60,659**
Additions	738	—	64	**802**	802
Amortization	(2,389)	(22)	(132)	**(2,543)**	—
Revaluation due to variable payments	61	—	(33)	**27**	27
Termination of contracts	—	—	(13)	**(13)**	(12)
Lease payments	—	—	—	**—**	(3,681)
Interest expenses	—	—	—	**—**	926
Exchange rate differences	120	—	2	**(123)**	179
December 31, 2019	**49,039**	**58**	**236**	**49,334**	**58,901**

More details on lease liabilities can be seen in Notes 5.13 and 5.26.

Other amounts recognized in the consolidated income statement

€ in thousand	Year ended December 31, 2019
Expense relating to short-term leases (included in other income and expenses)	146
Expense relating to leases of low-value assets that are not shown above as short-term leases (included in other income and expenses)	3

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 are incurred.

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	2 - 15 years
+ Furniture, fittings and office equipment	4 - 10 years
+ Hardware	3 - 5 years

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
January 1, 2019						
Cost	52,381	18,333	1,906	1,742	650	75,012
Accumulated depreciation and impairment	(20,374)	(13,771)	(1,496)	(1,374)	—	(37,015)
Net book value	**32,007**	**4,562**	**410**	**368**	**650**	**37,997**
December 31, 2019						
Opening net book value as of January 1, 2019	32,007	4,562	410	368	650	37,997
IFRS 16 Adoption	(26,414)	—	—	—	—	(26,414)
Opening net book value	**5,593**	**4,562**	**410**	**368**	**650**	**11,583**
Exchange rate differences	201	99	10	11	(34)	285
Additions	4,328	2,696	484	28	3,176	10,711
Disposals	(65)	(8)	(1)	(7)	—	(81)
Depreciation charge	(808)	(1,411)	(197)	(86)	—	(2,502)
Reversal of impairment charge	—	7	—	—	—	7
Closing net book value	**9,248**	**5,944**	**707**	**313**	**3,791**	**20,003**
December 31, 2019						
Cost	22,044	21,137	2,432	1,762	3,791	51,167
Accumulated depreciation and impairment	(12,795)	(15,193)	(1,726)	(1,449)	—	(31,163)
Net book value	**9,248**	**5,944**	**707**	**313**	**3,791**	**20,003**

Depreciation and amortization expenses of €591 thousand were charged to cost of goods and services, €1.1 million were charged to research and development expenses, €98 thousand were charged to marketing and distribution expenses and €314 thousand were charged to general and administrative expenses. The increased in depreciation and amortization expenses in 2019 relates to first adoption of IFRS 16 and the amortization of right-of-use assets.

No operating property leases are included in the income statement.

At January 1, 2019, property, plant and equipment contained the following amounts where the Group was a lessee under a finance lease agreement for the office and research laboratory building in Vienna, including a waiver of termination right for 15 years as well as a purchase option:

€ in thousand	Buildings and leasehold improvements	Total
January 1, 2019		
Cost	34,795	34,795
Accumulated depreciation	(8,381)	(8,381)
Net book value	**26,414**	**26,414**

Due to the first time adoption of IFRS 16 in 2019, the assets from finance lease have been reclassified to right-of-use assets. See Notes 5.2 and 5.13.

5.15 Equity-accounted investees

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 that has an impact on the estimated future cash flows from the net investment that 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 at December 31, 2019
BliNK Biomedical SAS	FR	Equity method	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 intends to retain 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 is consolidated at equity according to IAS 28.16.

The Company recorded a profit of €1.6 million related to its share of equity in BliNK. The total equity of BliNK amounts to €4.6 million as of December 31, 2019.

Summarized financial information for material associate

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	At December 31, 2019
BliNK Biomedical SAS	
Non-current assets	3
Current assets	6,370
Non-current liabilities	1,371
Current liabilities	217
Revenue	3,281
Profit/(loss) from continuing operations	1,629
Total comprehensive income	1,629

Reconciliation to the carrying amount

€ in thousand	At December 31, 2019
Net assets of associate	4,627
Proportion of the Company's ownership interest in BliNK Biomedical SAS	48.9%
Balance as of December 31,	**2,263**

5.16 Financial instruments

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value at each balance sheet date.

The valuation techniques utilized for measuring the fair values of assets and liabilities are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect management's market assumptions.

The fair value of instruments that are quoted in active markets are determined using the quoted prices where they represent those at which regularly and recently occurring transactions take place. Furthermore the Group uses valuation techniques to establish the fair value of instruments where prices, quoted in active markets, are not available.

Financial instruments by category

December 31, 2019 € in thousand	Assets at fair value through profit and loss	Assets at amortized cost	Total
Assets as per balance sheet			
Trade receivables	—	24,030	24,030
Other assets	—	11,737	11,737
Cash and cash equivalents	—	64,439	64,439
Assets		**100,206**	**100,206**

	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
Liabilities as per balance sheet			
Borrowings	—	26,316	26,316
Lease liabilities	—	58,901	58,901
Trade payables and accruals	—	16,567	16,567
Tax and employee-related liabilities[9]	—	6,570	6,570
Contract liabilities, other liabilities and provisions[10]	—	220	220
Liabilities	—	**108,574**	**108,574**

Fair value measurements

The following table provides an analysis of financial instruments that are measured subsequent to initial recognition at fair value, grouped into Levels 1 to 3 based on the degree to which the fair value is observable.

- level 1 fair value measurements are those derived from quoted prices (unadjusted) in active markets for identical assets or liabilities;
- level 2 fair value measurements are those derived from inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices); and
- level 3 fair value measurements are those derived from valuation techniques that include inputs for the asset or liability that are not based on observable market data (unobservable inputs).

January 1, 2019 € in thousand	Level 2	Total
Other assets		
Derivatives not designated as hedging instruments	177	177
Other assets	**177**	**177**
Contract liabilities, other liabilities and provisions		
Derivatives not designated as hedging instruments	—	—
Contract liabilities, other liabilities and provisions	**—**	**—**

At December 31, 2019 the Group did not have assets and liabilities measured though profit and loss.

In 2019, the Group entered into various foreign currency option 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.

At January 1, 2019 the Group had the following open foreign currency options:

January 1, 2019	Underlying currency amount	Duration	Fair Value (€ in thousand)
Foreign currency option	$ 4.8 million	89 days	—
Foreign currency option	CAD 5.0 million	113 days	177

9 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.

10 Deferred income, contract liabilites and provisions are excluded from the other liabilities and provisions balance, as this analysis is required only for financial instruments.

At December 31, 2019 the Group did not have open foreign currency options.

Credit quality of financial assets

The credit quality of financial assets that are neither past due nor impaired can be assessed by reference to external credit ratings (if available) or to historical information about counterparty default rates as follows:

€ in thousand	At December 31, 2019
Trade receivables	
Receivables from governmental institutions (AAA-country)	37
Receivables from governmental institutions (AA-country)	8,825
A	5,519
Counterparties without external credit rating	9,650
Trade receivables	**24,030**
Other assets	
A	11,430
Counterparties without external credit rating or rating below A	310
Other assets	**11,740**
Cash and cash equivalents	
AA	2,755
A	56,703
Counterparties without external credit rating or rating below A	4,981
Cash and cash equivalents	**64,439**

The receivables from governmental institutions relate to organsations in countries with AAA or AA-ratings.

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.

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 for trade receivables had to be established at the time there were indications of significant increases in credit risk for each trade receivables before they became past due. Accordingly, at the end of each reporting period, trade receivables were adjusted through a loss allowance in accordance with the 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. Although a certain portion of trade receivables is overdue, the analysis of the historical data showed on

December 31, 2019 that losses incurred are immaterial, taking further into account the limited number of customers as well as credit checks mentioned in Note 5.2. Therefore, loss allowance has been considered immaterial as of December 31, 2019.

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. At December 31, 2019, the expected credit loss was calculated using the cumulative expected default rate based on the counterparties' ratings. Since the result was immaterial, no loss allowance has been recorded.

5.17 Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out (FIFO) method, specifically the first-expiry first-out (FEFO) method. 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. It excludes borrowing costs. Provisions for faulty products are included in the value of inventories.

€ in thousand	**At December 31, 2019**
Raw materials	4,191
Work in progress	14,395
Finished goods	9,046
	27,632
Less: write-down	(1,860)
Inventory	**25,772**

The cost of inventories is recognized as an expense and is included in the position "Cost of goods and services" amounted to €34.6 million, of which €2.8 million related to faulty products, which were written off.

5.18 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	At December 31, 2019
Trade receivables	24,030
Less: provision for impairment of receivables	—
Trade receivables, net	**24,030**

During the year 2019, no material impairment losses have been recognized. The amount of trade receivables past due in 2019 amounted to €2 million. The fair values of trade receivables equal their book values.

5.19 Other assets

Other assets include the following:

€ in thousand	At December 31, 2019
Deposits and advances	19,039
R&D tax credit receivables	5,853
Tax receivables and consumables and supplies on stock	4,974
Prepaid expenses	1,798
Non-current financial assets	367
Current financial assets	—
Miscellaneous current assets	51
	32,081
Less non-current portion	(17,161)
Current portion	**14,921**

The fair values of other assets equal their book values.

5.20 Cash and cash equivalents

Cash includes cash-at-bank, cash in hand, and deposits held at call with banks. Cash equivalents include short-term bank deposits and medium-term notes 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.

As of December 31, 2019, cash and cash equivalents do not include an amount for which there are restrictions on remittances.

€ in thousand	At December 31, 2019
Cash in hand	10
Cash at bank	39,429
Short-term bank deposits (maximum maturity of 3 months)	25,000
Restricted cash	—
Cash and cash equivalents	**64,439**

5.21 Equity

Ordinary shares are classified as equity.

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.

Conditional and authorized capital

On December 31, 2019, the Company had 19,082,251 shares of conditional capital in connection with (see Note 5.22):

- the possible exercise of existing stock options;
- the possible exercise of existing equity warrants (BSAs);
- the possible conversion of existing preferred shares;
- the possible final grant and conversion of existing convertible preferred shares;

Pursuant to resolution No. 36 of the General Meeting held on June 27, 2019, the nominal amount of increases in the Company's share capital which can be carried out by the Company, immediately or in the future, may not under any circumstances exceed a maximum overall amount of €4.5 million or the equivalent value in a foreign currency, to which amount will be added, if applicable, the supplementary nominal amount of shares or securities to be issued for the purposes of any adjustments to be made in accordance with applicable legislative or regulatory provisions and, if applicable, with contractual stipulations providing for other forms of adjustment, in order to preserve the rights of the holders of securities giving access, immediately or in the future, to the share capital of the Company.

Other reserves

€ in thousand	Other regulated reserves[11]	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance as of January 1, 2019 before IFRS 16 adoption	**52,820**	**(5,479)**	**(1,133)**	**5,852**	**—**	**52,060**
Changes in Accounting Policy – Initial Application of IFRS 16	—	—	—	—	(9,474)	(9,474)
Balance as of January 1, 2019	**52,820**	**(5,479)**	**(1,133)**	**5,852**	**(9,474)**	**42,587**
Currency translation differences	—	656	—	—	—	656
Defined benefit plan actuarial losses	—	(13)	—	—	—	(13)
Share-based compensation expense:						
- value of services	—	—	—	2,504	—	2,504
Purchase/sale of treasury shares	—	—	21	—	—	21
Balance at December 31, 2019	**52,820**	**(4,836)**	**(1,112)**	**8,357**	**(9,474)**	**45,756**

11 Regulated non-distributable reserve relating to the merger with Intercell AG

In order to avoid a capital-locking effect at the merger with Intercell AG, the non-distributable reserve has been endowed with an amount corresponding to the difference between the transferring company prior to the completion of the merger and the restricted capital of the absorbing company immediately after the completion of the merger.

The Company has not received nor paid a dividend to its shareholders in the years ended December 31, 2019.

5.22 Share-based payments

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, 2019
Stock option plans	1,177
Free convertible preferred share plans	1,198
Free ordinary shares program	130
Equity warrants	—
Phantom shares	74
Total expenses arising from share-based payments	**2,578**

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.

Stock options are generally granted to employees and until 2015 also to Management Board Members.

Part of the stock options granted in the year 2010 can be exercised as long as certain objectives conditioned to entity stock market performances have been achieved.

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.

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 and was considered remotely, therefore 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:

	2019		
	Number of options	Number of shares available	Average exercise price in € per share
Outstanding at January 1	2,859,850	2,927,662	3.14
Granted	2,569,510	2,569,510	3.05
Adjusted	—	—	—
Forfeited	(182,250)	(184,074)	3.03
Exercised	—	—	—
Outstanding at year end	**5,247,110**	**5,313,098**	**3.06**
Exercisable at year end	1,941,475	2,007,463	

No stock options have been exercised in 2019.

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

Expiry date	Exercise price in € per share	Number of options at December 31, 2019
2020	4.72	7,000
2023	2.92	654,600
2025	3.92	543,750
2026	2.71	418,750
2027	2.85	1,053,500
2029	3.05	2,569,510
		5,247,110

In 2019, 2,569,510 stock options were granted. The weighted average grant date fair value of options granted during the year of 2019 was €0.87. The fair value of the granted options was determined using the Black Scholes valuation model.

Free ordinary shares

In accordance with the powers and authorizations granted by the Company's shareholders meeting held in 2019, the Company's Management Board granted free ordinary shares for the benefit of Management Board and Management Committee members, on December 19, 2019. The purpose of this free ordinary share plan 2019-2023 is to provide a long-term incentive program for the Company's senior management.

The number of free ordinary shares so granted was as follows:

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

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

	Number of free ordinary shares 2019
Outstanding at January 1	—
Granted	2,191,947
Forfeited	—
Definitively granted	—
Outstanding at year end	**2,191,947**

Subject to vesting conditions (including performance and presence conditions), the free ordinary 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 ordinary shares will be rounded down for the first two tranches and rounded up for the third tranche.

The first tranche will vest in the participants two years after December 19, 2019, the second tranche will vest three years after December 19, 2019 and the third tranche will vest four years after December 19, 2019.

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

The plan further provides for accelerated vesting of the free ordinary shares in the event of a Change of Control (as defined in the applicable terms & conditions) occurring no earlier than December 19, 2021. As this was considered remotly at the grant date (judgement by the 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 amount 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 ordinary 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 ordinary 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 ordinary 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 ordinary shares of each tranche until termination of their office as Management Board member or corporate officer.

Equity warrants

In 2015, and 2017 the Company granted equity warrants to members of the Supervisory Board. The warrants granted in 2015 (BSA 25) are exercisable in four equal portions after 2, 17, 31 and 45 months. 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 2015 plan (BSA 25) amounts to €3.92 per share. 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 2019
Outstanding at January 1	164,000
Granted	—
Exercised	(6,250)
Forfeited	(53,875)
Outstanding at year end	**103,875**

Free convertible preferred share plan

On June 25, 2015, the General Meeting of the Company decided to create convertible preferred shares for the benefit of the Management Board members, but also for the benefit of key employees. Consequently, on July 28, 2015, the Management Board implemented the free convertible preferred share ("FCPS") plan 2015-2019, a long-term incentive program for the Company's executive management.

The granted payable convertible preferred shares ("SPS") were as follows:

	Number of payable SPS subscribed for by the beneficiaries	Subscription amount (in euros)
Management Board	744	119,784
Other Executive Committee members	330	53,130
	1,074	**172,914**

Following the subscription of SPS the Management Board conditionally granted the program beneficiaries a number of FCPS corresponding to a ratio of 25 FCPS to 1 SPS, as follows:

	Number of free convertible preferred shares granted to the beneficiaries
Management Board	18,600
Other Executive Committee members	8,250
	26,850

SPS and FCPS will be convertible into the Company's ordinary shares four years after their issuance (with respect to the SPS) or their initial granting (with respect to the FCPS), if the conversion conditions are met.

Due to the share price performance this plan lapsed without exercises in 2019.

***

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 of the above-mentioned four-year period (the "**Conversion Date**"), the Management Board will determine 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**" will be the 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 (*e.g.* 6.2450 to be rounded to 6.25).

No conversion will occur if the Final Share Price is lower than €4.50. If the Final Share Price is higher than €8.00, the conversion ratio will be such that the beneficiaries' gross gain will not exceed the gross gain they would have realized if the Final Share Price was €8.00.

The FCPS cannot give rights to more than 2,363,000 ordinary shares of the Company in the aggregate.

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
	34,017

Changes in the SPS and FCPS are as follows (information for both FCPS plan 2015 and FCPS plan 2017):

	Number of SPS 2019	Number of FCPS 2019
Outstanding at January 1	789	53,742
Granted	—	—
Expired	(789)	(18,617)
Outstanding at year end	**—**	**34,017**

The fair value of FCPS 2015 was determined using the Black Scholes model, whereas the fair value of FCPS 2017 was determined using the Monte Carlo valuation model.

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.

The carrying amount of the liability relating to the phantom shares at December 31, 2019 was €74 thousand. No phantom share were forfeited at December 31, 2019.

Phantom shares outstanding at the end of the period have the following expiry dates and exercise prices:

Expiry date	Exercise price in € per share	Number of options at December 31, 2019
2023	2.919(1)	10,098
2025	3.92	14,000
2026	2.71	9,000
2027	2.85	143,000
2029	3.05	179,750
		355,848

(1) Adjusted in accordance with French law requirements.

In 2019, 179,750 new phantom shares were granted. The fair values of the granted options were determined on the balance sheet date December 31, 2019 using the Black Scholes valuation model. The significant inputs into the models were:

	2019
Expected volatility (%)	34.67
Expected vesting period (term in years)	0.25 –6.42
Risk-free interest rate (%)	(0.67) – (0.41)

5.23 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 yearend include the following:

€ in thousand	At December 31, 2019
Non-current	
Bank borrowings	19,759
Other loans	4,558
Finance lease Liabilities	—
	24,317
Current	
Bank borrowings	—
Other loans	1,999
Finance lease Liabilities	—
	1,999
Borrowings	**26,316**

The other loans included the CEPI loan in amount of €393 thousand. For more detailed information see Note 5.8.

The maturity of non-current borrowings is as follows:

€ in thousand	At December 31, 2019
Between 1 and 2 years	2,055
Between 2 and 3 years	11,552
Between 3 and 4 years	317
Between 4 and 5 years	10,000
Over 5 years	393
Non-current borrowings	**24,317**
Current borrowings	1,999
Total borrowings	**26,316**

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

€ in thousand	At December 31, 2019
EUR	25,923
USD	393
Total borrowings	**26,316**

Bank borrowings and other loans secured

As at December 31, 2019, €26.3 million of the outstanding bank borrowings and other loans are guaranteed, secured or pledged. These bank 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).

As at December 31, 2019, the fair value of guaranteed other loans without taking the interest subsidy into consideration, based on an estimated arms' length interest rate of 3.20%, is €6.3 million (carrying amounts is €6.6 million).

In July 2016, the Company entered into a loan agreement with the European Investment Bank by which the Company was granted a €25 million term loan facility as part of the European Horizon 2020 initiative. Subject to fulfillment of certain conditions precedent, the loan may be drawn in one or several tranches within a 24-month period from signing, which was extended to a 36-month period from signing. Each tranche is repayable at the end of a five-year period starting from the drawing date. The loan is secured by collateral over the Company's material subsidiaries, mainly ranking behind securities linked to Valneva's existing indebtedness. Furthermore, the loan agreement contains covenants, including a positive Group EBITDA and a minimum cash balance of €3 million at all times. The Group does not expect these limitations to impact its ability to meet the cash obligations. In the year ended December 31, 2017, two €5 million tranches respectively were drawn under the loan facility that was granted with no commitment fee and subject to variable interest on amounts drawn. In July 2019, a €10 million tranche was drawn following the same conditions as the last two tranches of this loan.

At December 31, 2019 the loan is included in the balance sheet item “Borrowings” as follows:

€ in thousand	2019
Balance at January 1	**9,797**
Proceeds of issue	10,000
Transaction costs	(40)
Accrued interests	1,323
Payment of interest and loan	(1,322)
Balance at December 31	**19,759**
Less: non-current portion	19,759
Current portion	**—**

Other loans

On December 20, 2013, the Group received a $30 million financing from an investment fund managed by Pharmakon Advisors for Valneva Austria GmbH. The loan extended over a five year period and carried an interest rate ranging from 9.5% to 10.5%. On November 18, 2015 the loan was increased by an additional financing of $11 million. From 2016 onwards, the Group was paying a royalty to Pharmakon Advisors ranging from 2.5% to 3.1% on its IXIARO sales during the term of the loan. The interest rate and the royalty payable in connection with the loan were both recognized as finance expenses. The finance expenses were calculated using the effective interest method and were therefore recognized pro rata to the outstanding principal in each accounting period until the loan was fully amortized. The foreign currency valuation was done at each balance sheet date and resulting exchange gains or losses were shown as finance income/expenses. The asset-based loan was guaranteed by the Company and secured by a security interest on the incoming funds from the Group’s sales of IXIARO and on the shares of the Group’s Austrian and Scottish subsidiaries, which hold the key IXIARO assets. The loan agreement included customary covenants for the Group’s Austrian subsidiary, including limitations on indebtedness and new business activities as well as limitations for payments of dividends and other disbursements to the Company. The Company did not expect these limitations to impact its ability to meet the cash obligation. The loan was fully repaid as of January 2, 2019. At January 1, 2019, the book values of the assets pledged amounted to €253 million.

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

€ in thousand	2019
Balance at January 1	**14,546**
Accrued interest and royalty expense	—
Payment of interest, royalties and loan	(14,546)
Foreign exchange valuation	—
Balance at December 31	**—**
Less: non-current portion	—
Current portion	**—**

5.24 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	At December 31, 2019
Trade payables	8,868
Accrued expenses	7,699
	16,567
Less non-current portion	—
Current portion	**16,567**

5.25 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	At December 31, 2019
Employee-related liabilities	6,570
Social security and other taxes	4,054
	10,624
Less non-current portion	—
Current portion	**10,624**

5.26 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 Notes 5.2 and 5.13.

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

€ in thousand	At December 31, 2019
Between 1 and 2 years	2,372
Between 2 and 3 years	2,341
Between 3 and 4 years	24,618
Between 4 and 5 years	1,510
Between 5 and 10 years	8,258
Between 10 and 15 years	10,248
Over 15 years	7,245
Non-current lease liabilities	**56,592**
Current lease liabilities	2,308
Total Lease liabilities	**58,901**

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

€ in thousand	At December 31, 2019
EUR	26,617
SEK	31,943
Other	340
Total lease liabilities	**58,901**

5.27 Provisions

Provisions for employee commitments

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

	At December 31, 2019
Discount rate	0.70%
Salary increase rate	2.00%
Turnover rate	0%-33.24%
Social security rate	43.00%-47.00%
Average remaining lifespan of employees (in years)	22

Changes in defined benefit obligation

Present value of obligation development:

€ in thousand	2019
Balance at January 1	**333**
Current service cost	59
Actuarial losses/(gains)	13
Balance at December 31	**404**

Other provisions

€ in thousand	At December 31, 2019
Non-current	22
Current	2,315
Other Provisions	**2,337**

	2019
Balance at January 1	**288**
Charged to the income statement:	
Additional provision	2,217
Reversed provision	—
Used provisions	(167)
Exchange differences	—
Balance at December 31	**2,337**

The position comprises in 2019 an amount of €2.1 million from a provision for expected legal and settlement costs under a court proceeding relating to the Intercell AG/Vivalis SA merger (see Note 5.8). Furthermore, a provision for restructuring costs of €0.2 million in 2019 for the site in France is included.

5.28 Other liabilities

€ in thousand	At December 31, 2019
Deferred income	3,715
Other financial liabilities	269
Miscellaneous liabilities	—
Other liabilities	**3,983**
Less non-current portion	(97)
Current portion	**3,886**

Deferred income mainly includes conditional advances from government grants and a grant from CEPI. See Note 5.8.

5.29 Cash flow information

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 at December 31, 2019
Profit/(Loss) for the year		(1,744)
Adjustments for		
• Depreciation and amortization	5.12/5.13/5.14	8,532
• Write-off / impairment fixed assets/intangibles	5.12/5.13/5.14	75
• Share-based compensation expense	5.22	2,552
• Income tax expense	5.10	874
• Dividends received from associated companies	5.15	433
• (Profit)/loss from disposal of fixed assets	5.8	92
• Share of (profit)/loss from associates	5.15	(1,574)
• Fair value (gains)/losses on derivative financial instruments		178
• Other non-cash income/expense		(892)
• Interest income	5.9	(199)
• Interest expense	5.9	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		79
• Long term contract liabilities		(2,321)
• Long term refund liabilities		6,016
• Other non-current liabilities and provisions		(178)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
• Inventory		(2,415)
• Trade and other receivables		(17,278)
• Contract liabilities		(989)
• Refund liabilities		448
• Trade and other payables and provisions		13,552
Cash generated from operations		**7,875**

The following table shows the adjustments to reconcile profit/loss from the disposal of fixed assets to proceeds from the disposal of fixed assets:

€ in thousand	At December 31, 2019
Net book value	92
Profit/(loss) on disposal of fixed assets	(92)
Proceeds from disposal of fixed assets	—

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 at January 1, 2019	**9,918**	**21,019**	**30,937**
Financing cash flows	9,880	(14,367)	(4,487)
Foreign exchange movements	—	(1)	(1)
Other changes	(39)	(94)	(133)
Balance at December 31, 2019	**19,759**	**6,557**	**26,316**

5.30 Commitments and contingencies

Capital commitments

There were no capital expenditure contracted for at December 31, 2019.

Operating lease commitments

From 1 January 2019, the Group has recognised right-of-use assets for these leases, except for short term and low-value leases. See Notes 5.2 and 5.13 for further information.

Future aggregate minimum lease commitments under non-cancelable operating leases are as follows:

€ in thousand	At January 1, 2019
No later than 1 year	2,132
Later than 1 year and not later than 5 years	8,365
Later than 5 years	33,012
Operating lease commitments	**43,509**

Other commitments and guarantees

The other commitments consisted of:

€ in thousand	At December 31, 2019
Loans and grants	1,209
Royalties	11,331
Other commitments	**12,540**

There are no guarantees and pledges as of December 31, 2019.

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 the exchange ratio between Intercell and Valneva shares used in the merger. The Company is discussing potential settlement agreements. The Company therefore included €2.1 million of settlement costs and additional costs in connection with such potential settlement in “other expenses”, see Notes 5.27/5.8.

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 at the end of 2020 or the beginning of 2021. 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.

5.31 Related-party transactions

Purchases of services

Services provided by companies of Groupe Grimaud La Corbière SA are considered related party transactions and included the provision of services and miscellaneous items to the Company. These services were rendered by Group Grimaud La Corbière in connection with operating activities (interest rate swap allocation agreement) or with regulated activities (guarantees).

€ in thousand	Year ended December 31, 2019
Purchases of services:	
Operating activities	—
Purchases of services	**—**

Rendering of services

Services provided by Valneva to Groupe Grimaud La Corbière SA 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, 2019
Provision of services:	
Operating activities	236
Provision of services	**236**

Key management compensation

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

€ in thousand	Year ended December 31, 2019
Salaries and other short-term employee benefits	2,449
Other long-term benefits	15
Share-based compensation expense	1,174
Key management compensation	**3,638**

Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounted to €269 thousand. In the years 2015 and 2017 the Company granted equity warrants to members of the Supervisory Board. For more information, see Note 5.22.

5.32 Events after the reporting period

In January 30, 2020 the World Health Organization (WHO) declared a Public Health Emergency of International Concern because of the new corona disease COVID-19. The Company has reviewed the impact of COVID-19 and has provided several business updates during 2020. The Group has been and could continue to be materially adversely affected by the current COVID-19 pandemic, in regions where Valneva have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. COVID-19 has adversely impacted sales of travel vaccines to the general public, with travel to endemic areas significantly reduced compared to 2019. DUKORAL and IXIARO are aimed at diseases that largely threaten travelers to particular regions. As a result, sales of these vaccines have decreased significantly, adversely impacting the company's financial results. The Group expects Sales in 2020 to continue to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its December 2020 report, the United Nations World Tourism Organization, or UNWTO, predicted that international travel, as measured by international arrivals, would rebound in 2021, based on the assumptions of a gradual reversal of the pandemic, the rollout of a COVID-19 vaccine, significant improvement in traveler confidence and major lifting of travel restrictions by the middle of 2021, as well as a large pent-up demand after months of closed borders and travel bans. Recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels by mid-2023 to end of 2024. If international travel does not resume as quickly or as much as planned, our revenues will continue to be severely affected, and Valneva 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. Valneva continues to closely monitor how the pandemic and related response measures are affecting our business. At the end of September 2020, Valneva reported cash and cash equivalents of €156.2 million. Valneva is also well placed to take further cost management measures if required and has implemented a cost reduction of non-mission critical projects and expenses.

In February 2020, Valneva Austria GmbH signed a debt financing agreement with US Healthcare Funds Deerfield and OrbiMed for an amount of up to $85.0 million. Amortization payments will start in 3 years, while the loan will mature in 6 years. 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 of September 30, 2020, $60.0 million (€54.1 million) had been drawn down in two tranches. The interest rate is 9.95% on a quarterly basis (equivalent to 10.09% on an annual basis). The loan is secured substantially by 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 (unrestricted cash on hand and cash equivalent investments on a consolidated basis) 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, €103.75 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). The Group does not expect these limitations to affect its ability to meet its cash obligations.

In April 2020, a new collaboration to co-develop and commercialize Lyme disease vaccine was signed with Pfizer Inc (NYSE: PFE). This agreement with customer (IFRS15) included a $130 million (€116.9 million) upfront payment, which has been received in June 2020. Valneva will refund 30% of all development costs through completion of the development program. 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 will be recognized at a point in time when Pfizer can benefit and use the license without further involvement of Valneva, which occurred in the last quarter of 2020.

In April 2020, Valneva and Dynavax announced a collaboration to advance vaccine development for COVID-19. Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAV-B vaccine, to support the development of Valneva's COVID-19 vaccine candidate, while Valneva is leveraging its technical and platform capabilities to develop an inactivated, whole virus vaccine candidate against the current COVID-19 threat. In addition, Valneva and Dynavax reached agreement in principle with the UK government to provide up to 190 million doses of its SARS-CoV-2 vaccine candidate. This agreement was signed in 2020. In September 2020, Valneva and Dynavax announced a commercial partnership for the supply of Dynavax's CpG 1018 adjuvant for use in Valneva's SARS-CoV-2 vaccine candidate, VLA2001. The Dynavax Agreement has a purchase order commitment amount of up to $136.8 million.

In June 2020, Valneva and Bavarian Nordic A/S (OMX: BAVA) announced a marketing and distribution partnership for the marketing and distribution of their commercial products. Valneva will commercialize Bavarian Nordic's marketed vaccines leveraging its commercial infrastructure in Canada, UK, France and Austria. Valneva will also take responsibility for Belgium and the Netherlands. The partnership includes vaccines that protect against rabies, Japanese encephalitis, tick-borne encephalitis and cholera.

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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options.

In September 2020, Valneva announced a vaccine partnership with the UK government for its inactivated COVID-19 vaccine, VLA2001. Under the agreement, if vaccine development is successful, Valneva will provide the UK government with 60 million doses in the second half of 2021 (€470 million of expected revenues). UK Government then has options over 40 million doses in 2022 and a further 90 million doses, in aggregate, across 2023 to 2025. Revenue from these options could amount to almost GBP 820 million (€900 million). Valneva's inactivated SARS-CoV-2 vaccine is expected to have a two dose regimen. The payment schedule is in line with our development activities. The UK Government is obligated 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. According to IFRS 15 this agreement includes two performance obligations: Firstly the delivery of 60 million doses, secondly an option to sell further 40 million doses at a lower price than the expected market price and furthermore an option to sell further 90 million doses at the expected market price. To date, none of these performance obligations were satisfied, therefore no revenue was recognized in this period.

In December 2020, an amendment with the UK Government was signed, to extend the option period for the additional 40 million doses from December 31, 2020 to January 31, 2021.

In January 2021, Valneva announced that the Company is in advanced discussions with the European Commission for the supply of up to 60 million doses of its inactivated COVID-19 vaccine, VLA2001.

Brexit

The Group is of the opinion that Brexit may increase its costs and adversely affect some of the main risks to which the Company is exposed, e.g. by increasing risks related to currency exchange fluctuations, manufacturing &

supply, customs duties and tax. The flow of goods between Great Britain and Europe may also be affected. Future performance of the business may also be impacted, as the manufacturing of bulk material for the IXIARO product is conducted in the United Kingdom. The manufacturing for the bulk material for Valneva's SARS-CoV-2 vaccine candidate (see below for details on agreement with UK Government) will be also conducted in the United Kingdom, while filling and packaging of this vaccine will take place in the EU. Furthermore, Valneva has commercial operations in the UK, distributing its own vaccines and some third party products in the local market. Valneva UK Ltd reported a revenue of €1.8 million in the nine months ended September 30, 2020. Valneva has prepared for a "Hard Brexit", notably by setting up safety stocks on both sides of the border, thus minimizing the impact of border crossing problems following Brexit and by reviewing its product release processes for IXIARO. An agreement on Brexit was reached mid-December between the UK Government and the EU. Full details are now being analyzed but will likely result in a setting that is more positive than a hard Brexit scenario.

UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF SEPTEMBER 30, 2020 AND FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)

€ in thousand (except per share amounts)	Note	Nine months ended September 30, 2020	2019
Product sales	4	45,874	86,409
Revenues from collaboration, licensing and services	4	12,974	(5,015)
Revenues		**58,848**	**81,394**
Cost of goods and services	5	(37,249)	(35,517)
Research and development expenses	5	(51,767)	(23,238)
Marketing and distribution expenses	5	(13,772)	(17,064)
General and administrative expenses	5	(19,285)	(12,988)
Other income and expenses, net	6	10,733	4,165
OPERATING PROFIT/(LOSS)		**(52,493)**	**(3,247)**
Finance income	7	299	1,900
Finance expenses	7	(11,051)	(2,272)
Result from investments in associates		(16)	1,695
PROFIT/(LOSS) BEFORE INCOME TAX		**(63,262)**	**(1,924)**
Income tax		928	(510)
PROFIT/(LOSS) FOR THE PERIOD		**(62,334)**	**(2,434)**
Earnings/(Losses) per share for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share			
■ **basic**		**(0.69)**	**(0.03)**
■ **diluted**		**(0.69)**	**(0.03)**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

€ in thousand	Note	Nine months ended September 30, 2020	2019
Profit/(Loss) for the period		**(62,334)**	**(2,434)**
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss		**530**	**(855)**
Currency translation differences	16	530	(855)
Items that will not be reclassified to profit or loss		—	—
Other comprehensive income/(loss) for the period, net of tax		**530**	**(855)**
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(61,805)**	**(3,289)**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

€ in thousand	Note	September 30, 2020	December 31, 2019
ASSETS			
Non-current assets		**138,912**	**135,561**
Intangible assets	8	39,556	41,813
Right of use assets	9	47,482	49,334
Property, plant and equipment	10	24,246	20,003
Equity-accounted investees		2,246	2,263
Other non-current assets	14	19,386	17,161
Deferred tax assets		5,996	4,988
Current assets		**311,273**	**129,162**
Inventories	12	28,394	25,772
Trade receivables	13	109,203	24,030
Other current assets	14	17,497	14,921
Cash and cash equivalents	15	156,178	64,439
TOTAL ASSETS		**450,185**	**264,723**
EQUITY			
Capital and reserves attributable to the Company's equity holders		**76,728**	**135,153**
Share capital		13,643	13,642
Share premium		244,946	244,912
Other reserves		49,629	45,756
Retained earnings/(Accumulated deficit)	16	(169,156)	(167,412)
Profit/(loss) for the period		(62,334)	(1,744)
LIABILITIES			
Non-current liabilities		**171,521**	**88,269**
Borrowings	17	46,503	24,317
Lease liabilities		54,716	56,592
Contract liabilities	18	223	732
Refund liabilities	19	65,260	6,105
Provisions		1,573	426
Other liabilities	20	3,245	97
Current liabilities		**201,936**	**41,300**
Borrowings	17	7,597	1,999
Trade payables and accruals		13,968	16,567
Income tax liability		2,600	2,458
Tax and employee-related liabilities		10,846	10,624
Lease liabilities		2,452	2,308
Contract liabilities	18	146,609	694
Refund liabilities	19	10,304	448
Provisions		2,632	2,315
Other liabilities	20	4,928	3,886
TOTAL LIABILITIES		**373,457**	**129,569**
TOTAL EQUITY AND LIABILITIES		**450,185**	**264,723**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Nine months ended September 30, 2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES			
Profit/(Loss) for the period		(62,334)	(2,434)
Adjustments for non-cash transactions	22	26,255	6,755
Changes in non-current operating assets and liabilities	22	57,450	4,318
Changes in working capital	22	56,539	(2,631)
Cash generated from operations	**22**	**77,909**	**6,008**
Income tax paid		(278)	(965)
Net cash generated from operating activities		**77,631**	**5,043**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(7,648)	(7,982)
Purchases of intangible assets		(536)	(173)
Proceeds from sale of intangible assets		24	—
Interest received		87	168
Net cash used in investing activities		**(8,072)**	**(7,986)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions		35	(2,500)
Disposal/(Purchase) of treasury shares		264	(21)
Proceeds from borrowings, net of transaction costs	17	48,773	11,382
Repayment of borrowings	17	(21,557)	(11,654)
Payment of lease liabilities		(1,633)	(2,740)
Interest paid		(3,459)	(1,309)
Net cash generated from/(used in) financing activities		**22,424**	**(6,841)**
Net change in cash and cash equivalents		**91,983**	(9,784)
Cash and cash equivalents at beginning of the period		64,439	77,084
Exchange gains/(losses) on cash		(286)	87
Restricted cash	15	43	—
Cash and cash equivalents at end of the period	15	**156,178**	**67,387**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand (except number of shares)	Note	Number of Shares	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
Balance as of January 1, 2019		**90,917,837**	**13,638**	**244,900**	**42,587**	**(170,676)**	**3,264**	**133,712**
Total comprehensive loss		—	—	—	(855)	—	(2,434)	(3,289)
Income appropriation		—	—	—	—	3,264	(3,264)	—
Share-based compensation expense:	16							
- value of services		—	—	—	1,218	—	—	1,218
- exercises		22,850	3	5	—	—	—	8
Treasury shares	16	—	—	—	(21)	—	—	(21)
		22,850	3	5	342	3,264	(5,698)	(2,084)
Balance as of September 30, 2019		**90,940,687**	**13,641**	**244,905**	**42,928**	**(167,412)**	**(2,434)**	**131,628**
Balance as of January 1, 2020		**90,943,812**	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Total comprehensive loss		—	—	—	530	—	(62,334)	(61,805)
Income appropriation		—	—	—	—	(1,744)	1,744	—
Share-based compensation expense:	16							
- value of services		—	—	—	3,079	—	—	3,079
- exercises		11,125	2	34	—	—	—	35
Treasury shares	16	—	—	—	264	—	—	(264)
		11,125	2	34	3,873	(1,744)	(60,590)	(58,426)
Balance as of September 30, 2020		**90,954,937**	**13,643**	**244,946**	**49,629**	**(169,156)**	**(62,334)**	**76,728**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statement.

SELECTED NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of preparation and significant events

The unaudited interim condensed consolidated financial statements of Valneva SE ("the Company") together with its subsidiaries ("Group" or "Valneva") as of September 30, 2020 and for the nine months ended September 30, 2020 and September 30, 2019, have been prepared in accordance with IAS 34 Interim Financial Reporting as issued by the International Accounting Standards Board ("IASB") authorizing the presentation of selected explanatory notes. In consequence, these consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2019 available included in this Registration Statement.

The unaudited interim condensed consolidated financial statements of the Company were approved by the Management Board and authorized for issuance by the Supervisory Board on January 15, 2021.

The accounting policies adopted in the preparation of the unaudited interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2019.

Standards, amendments to existing standards and interpretations published by the IASB whose application has been mandatory since January 1, 2020

Amendments to IFRS 9, IAS 39 and IFRS 7 related to interest rate benchmark reform and IFRS 3 related to business combinations have been published by the IASB whose application has been mandatory since January 1, 2020. These amendments had no impact on the Company's financial statements.

Standards, amendments to existing standards and interpretations published by the IASB whose application is not yet mandatory

No standards, amendments to existing standards or interpretations had been published but were not yet applicable as of September 30, 2020, that may have significant impact on the Company's financial statements.

No standards or interpretations were early adopted, if they are not mandatorily applicable in 2020.

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.

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 to the general public, with travel to endemic areas significantly reduced compared to 2019. DUKORAL and IXIARO are aimed at diseases that largely threaten travelers to particular regions. As a result, sales of these vaccines have decreased significantly, adversely impacting the company's financial results. The Group expects sales in Q4 2020 and in 2021 to continue to be impacted due to the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its December 2020 report, the United Nations World Tourism Organization, or UNWTO, predicted that international travel, as measured by international arrivals, would rebound in 2021, based on the assumptions of a gradual reversal of the pandemic, the rollout of a COVID-19 vaccine, significant

improvement in traveler confidence and major lifting of travel restrictions by the middle of 2021, as well as a large pent-up demand after months of closed borders and travel bans. Recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels by mid-2023 to end of 2024. If international travel does not resume as quickly or as much as planned, the company's revenues will continue to be severely affected, and Valneva may not be able to complete the development of its 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. Valneva continues to closely monitor how the pandemic and related response measures are affecting the company's business. At the end of September 2020, Valneva reported cash and cash equivalents of €156.2 million. Valneva is also well placed to take further cost management measures if required and has implemented a cost reduction of non-mission critical projects and expenses. Although it is difficult to predict future liquidity requirements, the Group believes that the existing cash and cash equivalents as of September 30, 2020 will be sufficient to fund the operations for at least the next 12 months from the authorization for issuance date of these interim condensed consolidated financial statements. For details on contractual obligations see Note 21.

Impact from COVID-19 is described in following notes as of September 30, 2020:

Impact from COVID-19	**Note**	
COVID-19 R&D program	1	Agreement with the UK government to provide up to 190 million doses of its SARS-CoV-2 vaccine candidate - €5.2 million expenses for research and development included in first nine months of 2020, €100.3 million included in trade receivables and in contract liabilities, respectively as of September 30, 2020.
Revenues from contracts with customers	4	Decline of revenues of Commercialized products for non-military market from Q2 2020 onward and therefore reduced Cash-inflows.
Impairment testing	8.2	Impairment test on intangible assets performed after triggering events – no impairment as of September 30, 2020
Inventories	12	€5.3 million of the write-down included in income statement due to lower sales expectations and limited shelf life of the finished goods; stop of manufacturing of IXIARO and DUKORAL in Q3 2020: idle capacity costs not capitalized
Trade receivables	13	Update of expected credit loss assessed - only minor impact in Group´s figures
Expenses		In Q3 2020 a cost reduction of non-mission critical projects and expenses was introduced.

Significant agreements signed in the period since January 1, 2019

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 announced mutual agreement to end 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 will 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). A negative effect of net €10.7 million was included in Valneva's revenues from collaboration and licensing reflecting both the current and future payment obligations (see Note 4).

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 6 and Note 20.

In February 2020, the Group signed a debt financing agreement with US Healthcare Funds Deerfield and OrbiMed. The transaction amount is up to $85 million. Amortization payments will start in 3 years, while the loan will mature in 6 years. The intended use of proceeds was to repay existing borrowings from the European Investment Bank (EIB) and allow the Group to continue to advance its leading Lyme and chikungunya development programs in the short term.

In April 2020, a new collaboration to co-develop and commercialize Lyme disease vaccine was signed with Pfizer Inc (NYSE: PFE). This agreement with customer (IFRS15) included a $130 million (€116.9 million) upfront payment, which has been received in June 2020. Valneva will refund 30% of all development costs through completion of the development program. Therefore, as of September 30, 2020 €68.1 million have been recognized as (discounted) refund liabilities. €43.0 million are treated as contract liabilities and will be realized within the next 12 months. 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 will be recognized at a point in time when Pfizer can benefit and use the license without further involvement of Valneva, which occurred in the last quarter of 2020. In the nine months ended September 2020, €4.0 million were recognized as Revenues from collaboration, licensing and services. €2.9 million contract costs are included in other assets as of September 30, 2020. For more details see Notes 4, 18 and 19.

In June 2020, Valneva and Bavarian Nordic A/S (OMX: BAVA) announced a marketing and distribution partnership for the marketing and distribution of their commercial products. Valneva will commercialize Bavarian Nordic's marketed vaccines leveraging its commercial infrastructure in Canada, UK, France and Austria. Valneva will also take responsibility for Belgium and the Netherlands. The partnership includes vaccines that protect against rabies, Japanese encephalitis, tick-borne encephalitis and cholera. There is no financial impact on the consolidated financial statements as of September 30, 2020.

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. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options.

In September 2020, Valneva announced a vaccine partnership with the UK government for its inactivated COVID-19 vaccine, VLA2001. Under the agreement, if the vaccine development is successful, Valneva will provide the UK government with 60 million doses of VLA2001 in the second half of 2021. The UK Government then has options over 40 million additional doses in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion. The UK government is also investing up-front in the scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the collaboration. The UK Government is obligated 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. According to IFRS 15, this agreement includes 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 furthermore an option to sell an additional 90 million doses at the expected market price. During the first nine months of 2020, none of these performance obligations were satisfied, therefore no revenue was recognized in this period. As of September 30, 2020, €100.3 million are included in trade receivables and €100.3 million are included in contract liabilities. Total expenses for research and development for the COVID-19 vaccine were €5.2 million in first nine months of 2020.

In April 2020, Valneva and Dynavax announced a collaboration to an advance vaccine development for COVID-19. Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAV-B vaccine, to support the development of Valneva's COVID-19 vaccine candidate, while Valneva is leveraging its technical and platform capabilities to develop an inactivated, whole virus vaccine candidate against the current COVID-19 threat. In September 2020, Valneva and Dynavax announced a commercial partnership for the supply of Dynavax's CpG 1018 adjuvant for use in Valneva's SARS-CoV-2 vaccine candidate, VLA2001. No deliveries or payments took place between Dynavax and Valneva in the nine month ended September 30, 2020. The Dynavax Agreement has a purchase order commitment amount of up to $136.8 million.

Valneva's share price development in 2020

The Company's share price fluctuated during 2020 and increased especially in Q3 2020 compared to December 31, 2019. Consequently, the fair value of phantom shares and the provision for employer contribution to be paid at exercise increased materially.

2. Group structure

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	September 30, 2020	December 31, 2019
BliNK Biomedical SAS	FR	Equity method	48.9%	48.9%
Vaccines Holdings Sweden AB	SE	Full	100%	100%
Valneva Austria GmbH	AT	Full	100%	100%
Valneva Canada Inc.	CA	Full	100%	100%
Valneva France SAS	FR	Full	100%	100%
Valneva Scotland Ltd.	UK	Full	100%	100%
Valneva Sweden AB	SE	Full	100%	100%
Valneva UK Ltd.	UK	Full	100%	100%
Valneva USA, Inc.	US	Full	100%	100%

3. Segment reporting

The individual segments consist of following:

- "Commercialized products" (marketed vaccines, currently the Group's vaccines IXIARO, DUKORAL as well as third-party products)
- "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)
- "Technologies and services" (services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements)

As of January 1, 2020 the Group changed its internal reporting process and amended the following allocation rule: general and administrative costs previously reported under Corporate Overhead have been fully allocated to the three operational segments based on estimated level of activities supporting the 3 segments. 56.0% of previously unallocated general and administrative costs were allocated to Commercialized products, 36.5% to Vaccine candidates and 7.5% to technologies and services using a combination of revenues and FTEs as the basis to allocate costs to the segments. Marketing and distribution costs previously reported under Corporate Overhead have been fully allocated to the Commercialized products. This change was done to reflect the way Valneva's chief decision makers (CODM) monitor the performance of the segments. The operating profit (loss) is the measure that is reported to the CODM.

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

Income statement by segment for the nine months ended September 30, 2019:

€ in thousand	Commercialized products	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	86,409	—	—	—	86,409
Revenues from collaboration, licensing and services	95	(10,552)	5,441	—	(5,015)
Revenues	**86,505**	**(10,552)**	**5,441**	**—**	**81,394**
Cost of goods and services	(32,172)	—	(3,344)	—	(35,517)
Research and development expenses	(2,589)	(19,700)	(949)	—	(23,238)
Marketing and distribution expenses	(16,164)	(709)	(191)	—	(17,064)
General and administrative expenses	(7,613)	(4,246)	(1,130)	—	(12,988)
Other income and expenses, net	7	3,585	326	248	4,165
Operating profit/(loss)	**27,973**	**(31,621)**	**153**	**248**	**(3,247)**

Income statement by segment for the nine months ended September 30, 2020:

€ in thousand	Commercialized products	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	45,874	—	—	—	45,874
Revenues from collaboration, licensing and services	1	3,988	8,986	—	12,974
Revenues	**45,875**	**3,988**	**8,986**	**—**	**58,848**
Cost of goods and services	(30,775)	—	(6,474)	—	(37,249)
Research and development expenses	(2,160)	(49,070)	(537)	—	(51,767)
Marketing and distribution expenses	(13,260)	(451)	(62)	—	(13,772)
General and administrative expenses	(11,740)	(6,136)	(1,410)	—	(19,285)
Other income and expenses, net	76	10,138	118	401	10,733
Operating profit/(loss)	**(11,983)**	**(41,531)**	**620**	**401**	**(52,493)**

Product sales per geographical segment

€ in thousand	Nine months ended September 30, 2020	2019
United States	18,503	43,089
Canada	8,619	15,864
Nordics	3,093	7,627
Germany	7,042	5,652
United Kingdom	1,758	6,351
Austria	1,348	1,732
Other Europe	2,244	4,112
Rest of World	3,267	1,982
Product sales	**45,874**	**86,409**

4. Revenues from contracts with customers

Revenues as presented in the Unaudited Interim Condensed Consolidated Statements of Income (Loss) and in the Segment Reporting (see Note 3) include both revenues from contracts with customers and other revenues, which are out of scope from IFRS 15:

Nine months ended September 30, 2019 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	86,505	(10,552)	4,462	80,415
Other revenues	—	—	979	979
Revenues	**86,505**	**(10,552)**	**5,441**	**81,394**

Nine months ended September 30, 2020 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	45,875	3,988	8,251	58,113
Other revenues	—	—	735	735
Revenues	**45,875**	**3,988**	**8,986**	**58,848**

Commercialized products revenues were affected by the worldwide reduction in travelling due to the COVID-19 pandemic. While the sales of Commercialized products were not significantly impacted in the first quarter, sales in the second and third quarter have been impacted.

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

€ in thousand	September 30, 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 revenue from the new collaboration agreement with Pfizer (€4.0 million in first nine months 2020) is recognized within the segment Vaccine candidates in 2020.

Disaggregated revenue information

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

Type of goods or service

Nine months ended September 30, 2019 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
IXIARO	64,296	—	—	64,296
DUKORAL	19,782	—	—	19,782
Third party products	2,427	—	—	2,427
Others	—	(10,552)	4,462	(6,089)
Revenues from contracts with customers	**86,505**	**(10,552)**	**4,462**	**80,415**

Nine months ended September 30, 2020 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
IXIARO	30,824	—	—	30,824
DUKORAL	13,172	—	—	13,172
Third party products	1,878	—	—	1,878
Others	—	3,988	8,251	12,238
Revenues from contracts with customers	**45,875**	**3,988**	**8,251**	**58,113**

Geographical markets

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

Nine months ended September 30, 2019 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
United States	43,089	162	130	43,381
Canada	15,864	—	—	15,864
Germany	5,652	—	150	5,802
Austria	1,732	—	2,944	4,676
Nordics	7,627	—	5	7,632
United Kingdom	6,352	—	15	6,367
Other Europe	4,112	(10,714)	345	(6,256)
Rest of World	2,076	—	874	2,950
Revenues from contracts with customers	**86,505**	**(10,552)**	**4,462**	**80,415**

Nine months ended September 30, 2020 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
United States	18,503	3,988	9	22,500
Canada	8,619	—	—	8,619
Germany	7,042	—	200	7,242
Austria	1,348	—	5,241	6,589
Nordics	3,093	—	5	3,098
United Kingdom	1,759	—	736	2,495
Other Europe	2,244	—	1,296	3,540
Rest of World	3,267	—	765	4,031
Revenues from contracts with customers	**45,875**	**3,988**	**8,251**	**58,113**

Sales channels for product sales

Commercialized products are sold via the following sales channels:

€ in thousand	Nine months ended September 30, 2020	2019
Direct product sales	33,997	74,665
Sales through distributors	11,878	11,840
Total product sales	**45,875**	**86,505**

In general, revenues have fluctuated in the past and the Company expects that they will continue to do so over different reporting periods in the future.

5. Operating expenses

The unaudited consolidated income statement line items cost of goods and services, research and development expenses, marketing and distribution expenses as well as general and administrative expenses include the following items by nature of cost:

€ in thousand	Nine months ended September 30, 2020	2019
Employee benefit expense other than share-based compensation[1]	(42,647)	(33,422)
Share-based compensation expense	(4,660)	(1,240)
Consulting and other purchased services	(42,325)	(17,782)
Raw materials and consumables used	(7,719)	(6,813)
Depreciation and amortization & impairment	(7,274)	(6,201)
Building and energy costs	(5,784)	(4,853)
License fees and royalties	(2,702)	(5,171)
Supply, office and IT-costs	(2,222)	(2,370)
Cost of services and change in inventory	(2,177)	(1,882)
Advertising costs	(2,130)	(4,515)
Warehousing and distribution costs	(1,378)	(2,146)
Travel and transportation costs	(470)	(1,390)
Other expenses	(586)	(1,022)
Operating expenses	**(122,074)**	**(88,807)**

1 For the nine months ended September 30, 2020, “Employee benefit other than share-based compensation” includes a provision in the amount of €5.8 million of employer contribution fees, which are payable at the exercise of the IFRS 2 programs (as of September 30, 2019: nil).

6. Other income/(expenses), net

Other income/(expenses), net include the following:

€ in thousand	Nine months ended September 30, 2020	2019
Research and development tax credit	6,498	3,966
Grant income	4,609	(48)
Profit/(loss) on disposal of fixed assets, net	(6)	(13)
Taxes, duties, fees, charges, other than income tax	(131)	(116)
Miscellaneous income/(expenses), net	(236)	377
Other income/(expenses), net	**10,733**	**4,165**

In July 2019 the Group signed a funding agreement with CEPI. Under this funding agreement, Valneva is eligible to 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 World Health Organization, or WHO, prequalification to facilitate broader access in lower and middle income countries. To satisfy the CEPI obligation, Valneva has entered into a binding termsheet with Instituto Butantan, where Valneva will transfer the 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. Valneva is obligated to repay up to $7.0 million to CEPI when certain commercial milestones are reached. The funds received from CEPI are treated under IAS 20 and presented as other income within the operating income. As of September 30, 2020, Valneva recognized €3.8 million of grant income related to CEPI (September 30, 2019: zero), and €0.8 million grants from government authorities related to the current COVID-19 pandemic situation.

7. Finance income/(expenses), net

€ in thousand	Nine months ended September 30, 2020	2019
Finance income		
Interest income from other parties	98	168
Fair value gains on derivative financial instruments	200	—
Foreign exchange gains, net	—	1,731
	299	**1,900**
Finance expense		
Interest expense on loans	(4,596)	(1,073)
Interest expense on refund liabilities	(1,764)	(44)
Interest expense on lease liabilities	(673)	(692)
Other interest expense	(18)	(2)
Fair value losses on derivative financial instruments	—	(460)
Foreign exchange losses, net	(4,000)	—
	(11,051)	**(2,272)**
Finance income/(expense), net	**(10,753)**	**(372)**

For more details regarding interest expense on loans see Note 17.

8. Intangible assets

8.1 Acquired research and development technology and projects

Acquired research and development technology and projects assets with a definite useful life which are not amortized yet are comprised solely of the Lyme disease vaccine candidate (VLA15) amounting to €3.3 million (December 31, 2019: €3.3 million).

Significant intangible assets with definite useful life are comprised primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €78.2 million and a net book value amounting to €33.9 million (December 31, 2019: €36.2 million). Other intangible assets with a definite useful life are comprised primarily of the IC31® technology amounting to €0.5 million (December 31, 2019: €0.5 million) and the EB66® technology amounting to €0.1 million (December 31, 2019: €0.2 million).

8.2 Impairment testing

The book values of capitalized in-process research and development projects have been assessed annually for impairment testing purposes using the risk-adjusted discounted cash flow method. The Lyme disease program VLA15 is currently the only active research and development program for which a book value is carried on the balance sheet (€3.3 million as of September 30, 2020). As the announcement regarding Valneva's collaboration with Pfizer on April 30, 2020 has not been identified as a downside triggering event, no impairment testing has been performed as of September 30, 2020.

Impairment tests, have been performed on the intangible assets related to Valneva's JEV vaccine IXIARO during the first half of 2020.

Given the expected decrease in IXIARO annual product sales in 2020 due to the Covid-19 crisis and travel restrictions a triggering event was identified and an impairment test has been performed. As a basis, the long range business model including product specific financial plans covering a period of 15 years is used. Business plan assumptions have been revised to reflect reductions in expected sales and assuming a recovery of IXIARO sales to pre-COVID levels by 2023.

The calculation uses post tax risk-adjusted cash flow projections and a discount rate of 7.73%.

The discount rate of 7.73% is based on 0.01% risk-free rate, 8.55% market risk premium, minus 0.27% country risk premium, 0.18% currency risk, a levered beta of 1.01, and a peer group related equity-capital ratio.

Due to a reduction in expected product sales caused by the Covid-19 pandemic and travel restrictions, a triggering event also has been identified for DUKORAL. Consequently, an impairment test has been performed by June 30, 2020. While there are no material intangible assets held for DUKORAL the carrying value of Fixed and right of use Assets as well as Working Capital (net book value of € 32.5 million as of June 30, 2020) was tested according to the same methodology.

Similar to IXIARO the company's long range business model including assumptions on market size / market share, product sales and resulting profitability over a 5½-year period as well as a Terminal Value for the period beyond 5½ years has been used as a basis to calculate the value in use. For DUKORAL sales recovery to pre-COVID levels is expected to be slower and also, driven by the expected entry of a competitor product in some European markets within the coming years, is uncertain to return back to pre-COVID levels.

The calculation uses post tax risk-adjusted cash flow projections and a discount rate of 8.77%.

The discount rate of 8.77% is based on 0.11% risk-free rate, 8.53% market risk premium, 0.23% country risk premium, 0.02% currency risk, a levered beta of 1.12 and a peer group related equity-capital ratio.

Impairment tests for both IXIARO and DUKORAL have resulted in no impairment losses.

8.3 Sensitivity to changes in assumptions

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

- discount rate
- reduction of expected revenues/royalties.

At the date of the impairment test for IXIARO the net present value calculation for IXIARO uses a discount rate of 7.73% . An increase in the discount rate of 8,853 basis points from 7.73 % to 96.26 % would trigger an impairment loss. Furthermore, an increase in the discount rate of one percentage point would result in no impairment loss.

The net present value calculations are based upon assumptions regarding market size and expected sales volumes resulting in sales value expectations. An additional reduction in revenues of 10.0% would result in no impairment loss in 2020.

At the date of the impairment test for DUKORAL the net present value calculation for DUKORAL uses a discount rate of 8.77%. An increase in the discount rate of 7 basis points from 8.77% to 8.84% would trigger an impairment loss. Furthermore, an increase in the discount rate of one percentage point would result in an impairment loss of €4.6 million.

The net present value calculations are based upon assumptions regarding market size, market share and expected sales volumes resulting in sales value expectations. An additional reduction in revenues of 10.0% would result in an impairment loss of €1.8 million in 2020.

9 Right of use assets

In the first nine months of 2020, right of use assets reduced from €49.3 million to €47.5 million, mainly due to amortization expenses. Major lease agreements are for the premises in Austria (book value as of September 30, 2020: €25.0 million, December 31, 2019: €25.6 million) and Sweden (book value as of September 30, 2020: €21.4 million, December 31, 2019: €22.5 million).

10 Property, plant and equipment

In the first nine months of 2020, property, plant and equipment increased from €20.0 million to €24.2 million. This increase mainly refers to investments in land and building and equipment related to the investments for the COVID-19 vaccine on the manufacturing sites in United Kingdom and Sweden. The increase was partly offset by depreciation expenses (€2.7 million).

11 Financial Instruments

As at September 30, 2020, €53.0 million of the outstanding other loans are guaranteed, secured or pledged. These other loans are 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). As at September 30, 2020, the guaranteed other loans with a carrying amount of €4.8 million have a fair value amounting to €4.1 million. The fair value calculation was based on an estimated market interest rate of 9.62% and did not take the interest subsidy into consideration. For more information on secured other loans, please see Note 17.

The fair values of all other financial instruments equal their book values as at September 30, 2020.

12 Inventories

Inventory include the following:

€ in thousand	September 30, 2020	December 31, 2019
Raw materials	3,964	4,191
Work in progress	17,108	14,395
Finished goods	14,960	9,046
	36,032	27,632
Less: write-down	(7,638)	(1,860)
Inventory	**28,394**	**25,772**

The cost of inventories is recognized as an expense and is included in the position “Cost of goods and services” amounted to €20.2 million (September 30, 2019: €23.0 million), of which €6.9 million (September 30, 2019: €2.1 million) related to faulty products, which were written off.

Given the expected reductions in product sales related to Valneva’s commercial stage 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 for the period ending September 30, 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 at the level of COGS/Manufacturing costs per dose. A €4.6 million addition to the write-down has been included in the nine month ended September 30, 2020. In addition, raw material inventories amounted to €0.7 million, which will likely not be consumed before the respective date of expiry, have been written down.

13 Trade receivables

Trade receivables include the following:

€ in thousand	September 30, 2020	December 31, 2019
Trade receivables	109,279	24,030
Less: loss allowance of receivables	(76)	—
Trade receivables, net	**109,203**	**24,030**

The increase in trade receivables relates to the partnership with the UK government for its inactivated COVID-19 vaccine. See Note 1. The related contract liabilities are included in Note 18.

As of September 30, 2020, impairment losses amounted to €76 thousand have been recognized due to the update of the company’s expected credit loss assessment (December 31, 2019: €0 thousand), especially related to the COVID-19 situation.

14 Other assets

Other assets include the following:

€ in thousand	September 30, 2020	December 31, 2019
Deposits and advances	16,049	19,039
Research and development tax credit receivables	11,344	5,853
Tax receivables and consumables and supplies on stock	2,786	4,974
Prepaid expenses	2,786	1,798
Non-current financial assets	664	367
Current financial assets	150	—
Contract Costs	2,929	—
Miscellaneous current assets	175	51
	36,883	**32,081**
Less non-current portion	(19,386)	(17,161)
Current portion	**17,497**	**14,921**

The fair values of other assets equal their book values.

The contract costs related to the collaboration agreement with Pfizer (see Note 1). The full amount referred to costs to obtain a contract and will be amortized in line with the pattern of revenue recognition. No amortization and impairment losses have been included in first nine months of 2020.

15 Cash and cash equivalents

Cash, cash equivalents and short-term deposits include the following:

€ in thousand	September 30, 2020	December 31, 2019
Cash in hand	4	10
Cash at bank	146,132	39,429
Short-term bank deposits (maturity less than 3 months)	10,000	25,000
Restricted cash	43	—
Cash and cash equivalents	**156,178**	**64,439**

As of September 30, 2020, the restricted cash was a Certificate of Deposit with restricted limited access to secure the credit limit for the Company's commercial card (December 31, 2019: € 0 thousand). The minimum liquidity requirement for the Group according to the debt financing agreement with US Healthcare Funds Deerfield and OrbiMed (see Note 17) is €75.0 million (€35.0 million from 2021 on). The minimum liquidity requirement is not hold on accounts with restricted access. Cash net of the US Healthcare Funds Deerfield and OrbiMed financial liability amounts to €107.9 million as of September 30, 2020.

16 Other reserves

€ in thousand	Other regulated reserves[3]	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance as of January 1, 2019	**52,820**	**(5,479)**	**(1,133)**	**5,852**	**(9,474)**	**(42,587)**
Currency translation differences	—	(855)	—	—	—	(855)
Share-based compensation expense:						
- value of services	—	—	—	1,218	—	1,218
Purchase/sale of treasury shares	—	—	(21)	—	—	(21)
Balance at September 30, 2019	**52,820**	**(6,334)**	**(1,154)**	**7,070**	**(9,474)**	**(42,928)**
Balance at January 1, 2020	**52,820**	**(4,836)**	**(1,112)**	**8,357**	**(9,474)**	**(45,756)**
Currency translation differences	—	530	—		—	530
Share-based compensation expense:						
- value of services	—	—	—	3,079		3,079
Purchase/sale of treasury shares	—	—	264	—	—	264
Balance at September 30, 2020	**52,820**	**(4,305)**	**(848)**	**11,436**	**(9,474)**	**(49,629)**

17 Borrowings

Borrowings of the Group include the following:

€ in thousand	September 30, 2020	December 31, 2019
Non-current		
Bank borrowings	—	19,759
Other loans	46,503	4,558
	46,503	**24,317**
Current		
Bank borrowings	—	—
Other loans	7,597	1,999
	7,597	**1,999**
Borrowings	**54,100**	**26,316**

In February 2020, Valneva Austria GmbH signed a debt financing agreement with US Healthcare Funds Deerfield and OrbiMed. The transaction value is up to $85.0 million. Amortization payments will start in 3 years, while the loan will mature in 6 years. 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 of September 30, 2020, $60.0 million (€54.1 million) had been drawn down in two tranches. The interest rate is 9.95% on a quarterly basis (equivalent to 10.09% on an annual basis). The loan is secured substantially by 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 (unrestricted cash on hand and cash equivalent investments on a consolidated basis) 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

3 Regulated non-distributable reserve relating to the merger with Intercell AG

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 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). The Group does not expect these limitations to affect its ability to meet its cash obligations.

The liability referring to this financing agreement is included in other loans (€43.1 million non-current and €5.1 million current as of September 30, 2020).

In March 2020, the bank borrowings from the European Investment Bank have been fully repaid (€20.0 million, the carrying amount was €19.8 million). The Group had to pay €0.6 million penalty for early repayment of the loan. These costs are included in Finance expenses in the consolidated income statement.

The maturity specifications can be found on Note 21.

18 Contract liabilities

€ in thousand	September 30, 2020	December 31, 2019
Non-current portion	223	732
Current portion	146,609	694
Contract liabilities	**146,832**	**1,426**

As of September 30, 2020, €100.3 million are related to the new agreement with the UK government to supply up to 190 million doses of SARS-CoV-2 vaccine (see Note 1), €43.0 million are related to the new collaboration with Pfizer Inc. (see Note 1), €1.6 million (December 31, 2019: €0.0m) are related to the CTM services provided to Batavia and €1.9 million (December 31, 2019: €1.4 million) are related to other payments received from customers.

19 Refund liabilities

€ in thousand	September 30, 2020	December 31, 2019
Non-current portion	65,260	6,105
Current portion	10,304	448
Refund liabilities	**75,565**	**6,553**

As of September 30, 2020, €68.1 million (thereof €59.0 million non-current) are related to the new collaboration with Pfizer Inc. (see Note 1) as Valneva will fund 30% of Phase 3 study costs performed by Pfizer. €6.2 million (December 31, 2019: €6.1 million) of non-current refund liabilities are related to the expected payment to GSK related to the termination of the strategic alliance agreements (see Note 4), signed in June 2019 and €1.2 million (December 31, 2019: €0.5 million) are related to refund labilities to customers related to rebate programs and right to return products.

For maturity specifications see Note 21.

20 Other liabilities

€ in thousand	September 30, 2020	December 31, 2019
Social security on stock options	5,818	—
Deferred income	1,709	3,715
Other financial liabilities	488	269
Miscellaneous liabilities	157	—
Other liabilities	**8,173**	**3,983**
Less non-current portion	(3,245)	(97)
Current portion	**4,928**	**3,886**

As of September 30, 2020, accrued social security expenses on stock options amounted to €5.8 million related to the employer contribution on the date of exercise. The Company has granted various share-based compensation plans, both equity-settled and cash-settled plans. In 2020, a phantom share plan was issued to senior leadership-team with the same conditions as the Free ordinary share plan issued in 2019, but to be settled in cash. The equivalent for 690,000 shares will be paid out in 3 tranches, in December 2021, December 2022 and December 2023, respectively.

Deferred income mainly includes conditional advances from a grant from CEPI amounted to €1.6 million (December 31, 2019: €3.6 million).

21 Contractual obligations

The following tables disclose aggregate information about the company's material long-term contractual obligations 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.

At September 30, 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	7,612	20,911	40,552	9,507	—	—	78,582
Lease liabilities	3,326	6,396	26,856	10,855	11,876	5,636	64,945
Refund liabilities	10,304	24,779	67,143	17,460	—	—	119,686
	21,242	**52,085**	**134,551**	**37,822**	**11,876**	**5,636**	**263,212**

At December 31, 2019 € 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	3,850	17,010	11,644	393	—	—	32,898
Lease liabilities	3,225	6,422	27,572	10,811	11,850	7,545	67,424
Refund liabilities	448	29	7,000	—	—	—	7,477
	7,523	**23,461**	**46,216**	**11,203**	**11,850**	**7,545**	**107,799**

22 Cash Flow information

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

€ in thousand	Nine months ended September 30, 2020	2019
Profit/(Loss) for the year	**(62,334)**	**(2,434)**
Adjustments for		
• Depreciation and amortization	7,134	6,201
• Write-off / impairment fixed assets / intangibles	140	—
• Share-based compensation expense	4,660	1,240
• Income tax expense	(928)	510
• Dividends received from associated companies	—	433
• (Profit)/loss from disposal of fixed assets	6	13
• Share of (profit)/loss from associates	16	(1,695)
• Fair value (gains)/losses on derivative financial instruments	274	178
• Provision for social securities on stock options	5,818	—
• Other non-cash income/expense	1,834	(1,768)
• Interest income	(98)	(168)
• Interest expense	7,397	1,812
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):		
• Other non-current assets	(2,215)	661
• Long term contract liabilities	(501)	(2,174)
• Long term refund liabilities	59,049	5,987
• Other non-current liabilities and provisions	1,116	(157)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
• Inventory	(4,996)	(4,066)
• Trade and other receivables	12,406	(3,006)
• Contract liabilities	45,619	1,281
• Refund liabilities	8,209	—
• Trade, other payables and provisions	(4,699)	3,159
Cash generated from operations	**77,909**	**6,008**

Cash generated from operations includes €116.9 million upfront payment from Pfizer Inc., which is reported in long term refund liabilities and contract liabilities (see Notes 1, 18 and 19).

23 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. The Company is discussing potential settlement agreements. The Company therefore holds a provision of €2.1 million of settlement costs and additional costs in connection with such potential settlements. €0.1 million of additional expenses related to this litigation is included in “other expenses” in the period ended September 30, 2020.

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 at the beginning of 2021. 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.

24 Related party transaction

Key management compensation

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

€ in thousand	Nine months ended September 30,	
	2020	2019
Salaries and other short-term employee benefits[5]	2,775	2,033
Other long-term benefits	12	11
Share-based payments (expense of the year)	704	742
Key management compensation	**3,491**	**2,785**

Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounted to €117 thousand (nine months ended September 30, 2019: €208 thousand).

25 Events after the reporting period

In December 2020, an amendment with the UK Government was signed, to extend the option period for the additional 40 million doses from December 31, 2020 to January 31, 2021.

In January 2021, Valneva announced that the Company is in advanced discussions with the European Commission for the supply of up to 60 million doses of its inactivated COVID-19 vaccine, VLA2001.

Brexit

The Group is of the opinion that Brexit may increase its costs and adversely affect some of the main risks to which the Company is exposed, e.g. by increasing risks related to currency exchange fluctuations, manufacturing & supply, customs duties and tax. The flow of goods between Great Britain and Europe may also be affected. Future performance of the business may also be impacted, as the manufacturing of bulk material for the IXIARO product is conducted in the United Kingdom. The manufacturing for the bulk material for Valneva's SARS-CoV-2 vaccine candidate (see below for details on the agreement with the UK Government) will be also conducted in the United Kingdom, while filling and packaging of this vaccine will take place in the EU. Furthermore, Valneva has commercial operations in the UK, distributing its own vaccines and some third party products in the local market. Valneva UK Ltd reported a revenue of €1.8 million in the nine months ended September 30, 2020. Valneva has prepared for a "Hard Brexit", notably by setting up safety stocks on both sides of the border, thus minimizing the impact of border crossing problems following Brexit and by reviewing its product release processes for IXIARO. An agreement on Brexit was reached mid-December between the UK Governament and the EU. Full details are now being analyzed but will likely result in a setting that is more positive than a hard Brexit scenario.

5 In the nine months ended September 30, 2020 leaving indemnities of €0.9 million have been included.

American Depositary Shares

Ordinary Shares

PROSPECTUS

, 2021

Goldman Sachs & Co. LLC

Jefferies

Guggenheim Securities

Bryan, Garnier & Co.

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 6.Indemnification of Members of the Management and Supervisory Board.

Under French law, provisions of bylaws that limit the liability of directors are prohibited. However, French law allows *société européenne* to contract for and maintain liability insurance against civil liabilities incurred by any of their directors and officers involved in a third-party action, provided that they acted in good faith and within their capacities as directors or officers of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We maintain liability insurance for the members of our Supervisory Board and Management Board, including insurance against liability under the Securities Act of 1933, as amended, and we intend to enter into agreements with the members of our Supervisory Board and Management Board to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements will 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.

Certain of the members of our Supervisory Board may, through their relationships with their employers or partnerships, be insured and/or indemnified against certain liabilities in their capacity as members of our Supervisory Board.

In any underwriting agreement we enter into in connection with the sale of ADSs being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

ITEM 7.Recent Sales of Unregistered Securities.

Set forth below is information regarding share capital issued since January 1, 2018. None of the transactions described below involved any underwriters, underwriting commissions, or any public offering. Some of the transactions described below involved members of our Supervisory Board and Management Board and 5% shareholders and more are fully described under the section of the prospectus titled "Certain Relationships and Related Party Transactions."

From January 1, 2018 through December 31, 2020, we have issued securities in the following transactions that were not registered under the Securities Act:

- On October 1, 2018, we issued 13,333,334 ordinary shares, in connection with a private placement whose total cash contributions amounted to €50,000,002.50 (including €2,000,000.10 in nominal).
- On May 3, 2019, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on April 24, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On July 29, 2019, after a four-year vesting period, 19,725 free convertible preferred shares (previously granted to employees and Management Board members) vested. They were included in the share capital through incorporation of issue premiums of 2,958.75 Euros.
- On November 4, 2019, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on October 25, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On May 15, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on May 12, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).

- On July 29, 2020, we issued 4,875 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on July 27, 2020 carried out by cash contribution of €19,110 (including €731.25 as nominal value).
- On August 31, 2020, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on August 25, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 1, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on November 26, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 10, 2020, we issued 12,500 new ordinary shares to former and current Supervisory Board members, in connection with the exercise of equity warrants on December 4, December 7 and December 9, 2020 carried out by a total cash contribution of €32,175 (including €1,875 as nominal value).

The issuances of the securities described above were exempt from registration either (a) under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and sophisticated investors or members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2), (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States or (c) under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation.

ITEM 8.Exhibits and Financial Statement Schedules.

(a) Exhibits

		Incorporated by Reference			
Exhibit Number	**Description of Document**	**Schedule/Form**	**File Number**	**Exhibits**	**Filing Date**
1.1*	Form of Underwriting Agreement				
3.1	Bylaws (*statuts*) of the Registrant (English translation)				
4.1*	Form of Deposit Agreement				
4.2*	Form of American Depositary Receipt (included in Exhibit 4.1)				
5.1*	Opinion of Hogan Lovells Paris LLP				
10.1†	Research Collaboration and License Agreement, dated April 29, 2020, by and between Pfizer Inc. and Valneva Austria GmbH.				
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.				
10.3*†	Supply Agreement, dated September 12, 2020, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.				
10.4*†	Funding Agreement, dated April 1, 2019, by and between Coalition for Epidemic Preparedness Innovations and Valneva SE.				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibits	Filing Date
10.5†	Distribution Agreement, dated December 9, 2015, by and between GlaxoSmithKline GmbH & Co. KG and Valneva Austria GmbH.				
10.6†	Sublicense Agreement, dated April 14, 2003, by and between VaccGen International LLC and Intercell AG, as assigned to the Registrant and as amended.				
10.7†	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.				
10.8†	Contract dated September 9, 2020, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.				
10.9†*	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.				
21.1	List of subsidiaries				
23.1*	Consent of Deloitte & Associés and PricewaterhouseCoopers				
23.2*	Consent of Hogan Lovells Paris LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (included on signature page)				

* To be filed by amendment.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

(b) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the consolidated financial statements and notes thereto.

ITEM 9.Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities, other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless, in the opinion of its counsel, the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question, whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A, and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Saint-Herblain, France on , 2021.

VALNEVA SE

By: _____
Name: Thomas Lingelbach
Title: Chief Executive Officer and President

POWER OF ATTORNEY

We, the undersigned members of the directors, officers and authorized representative of Valneva SE hereby severally constitute and appoint Thomas Lingelbach and Franck Grimaud, and each of them singly, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Thomas Lingelbach	Chief Executive Officer, President and Chairman of the Management Board (principal executive officer)	, 2021
	Principal Financial and Accounting Officer	, 2021
Frédéric Grimaud	Chairman of the Supervisory Board	, 2021
James Sulat	Member of the Supervisory Board	, 2021
Anne-Marie Graffin	Member of the Supervisory Board	, 2021
Thomas Casdagli	Member of the Supervisory Board	, 2021
Sharon Tetlow	Member of the Supervisory Board	, 2021
Johanna Willemina Pattenier	Member of the Supervisory Board	, 2021

Signature of Authorized U.S. Representative of Registrant

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Valneva SE has signed this registration statement on the day of , 2021.

Valneva USA, Inc.

By: _____
Name:
Title:

Exhibit 3.1

VALNEVA SE

European company with an Management Board and Supervisory Board
with a share capital of 13,645,584.30 Euros
Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain
Identification N° 422 497 560 RCS[1] Nantes

ARTICLES OF ASSOCIATION

As amended by Management Board decisions of December 10, 2020

1 RCS – Trade and Companies Register

TITLE I

FORM - COMPANY NAME - COMPANY OBJECT -

REGISTERED OFFICE - DURATION

Article 1. Form

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

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

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

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

Article 2. Name

The company name is: Valneva.

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

Article 3. Object

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

- research and development within the field of biomedicine and pharmacology;
- the commercial exploitation of patents and know-how;
- trading in products of all kinds and the provision of services in the field of data processing and information technology;
- the production, monitoring and marketing of all products, services and research programmes with applications to human and animal health, using the technologies of molecular and cellular biology and all of the associated techniques;

- the participation of the Company by all means, direct or indirect, in all operations which may be associated with its company object, through the creation of new companies, contributions, subscription or purchase of securities or company rights, mergers or otherwise, the creation, acquisition, leasing, lease management of all operating assets or facilities; the acquisition, exploitation or sale of all procedures and patents regarding these activities, within France and abroad;
- and more generally, all industrial, commercial or financial, securities or property operations, which may be directly or indirectly associated with its business object or likely to favour its exploitation, realisation or development.

Article 4. Registered office

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

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

Article 5. Duration - Financial year

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

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

TITLE II

SHARE CAPITAL - SHARES

Article 6. Share Capital

The share capital is set at 13,645,584.30 Euros. It is divided into:

- 90,950,048 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 1 st, 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 1st, 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.

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 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 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 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:

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

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 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 *Directeur Général Délégué* 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 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 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 of the 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 following decisions:

– verification and control of the annual financial statements and, as appropriate, of the consolidated accounts;

– appointment of the members of the Management Board ;

– appointment of the Chairman or of the Deputy Chairman of the Supervisory Board and determination of their remuneration.

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.

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 *Directeur Général*. 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 Commercial Code, to the rules set forth in Articles L. 225-89 through L. 225-90 of the Commercial Code, which 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 executive officers, 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

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 its *Directeur Général*, one of its *Directeur Général Délégué*, one of its directors, 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 Board of Directors.

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 the *Directeur Général*, one of the *Directeur Général Délégué* or one of the directors 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 directly or indirectly concerned party is required to 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 may not 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 Board of Directors is required, which are concluded without such prior authorization by the Board of Directors, 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 Shareholder's 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. 226-1 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' MEETING

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, a copy of which may be obtained under the conditions indicated by the notice of calling of the Meeting.

A shareholder may be represented 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.

A shareholder may furthermore be represented by any other natural or legal person of his/her choice and this under the conditions provided in Articles L. 225-106, L. 225-106-1 and R. 225- 79 of the 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. 2323-64 and L. 2323-65 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.

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.
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.
4. For the purposes of calculating the quorum and majority, shareholders shall be considered to be resent who take part in 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 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, albeit with the exception of resolutions relating to the approval of the company accounts, and as per the case, the approval of the consolidated accounts.

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, albeit with the exception of resolutions relating to a modification of the share capital, a merger, division or partial contribution of assets.

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 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 (1/15th) 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 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 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 10.1

Execution Copy

[***] = 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.

RESEARCH COLLABORATION AND LICENSE AGREEMENT

by and between

PFIZER INC.

and

VALNEVA AUSTRIA GMBH

April 29, 2020

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RESEARCH COLLABORATION AND LICENSE AGREEMENT

This Research Collaboration and License Agreement (the "**Agreement**") is entered into as of April 29, 2020 (the "**Execution Date**"), by and between Pfizer Inc., a corporation organized and existing under the laws of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York 10017 ("**Pfizer**") and Valneva Austria GmbH, a company organized and existing under the laws of Austria and having a principal place of business at Campus Vienna Biocenter 3, 1030 Vienna, Austria ("**Valneva**"). Pfizer and Valneva may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Valneva Controls (as defined below) certain patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to the identification, research and development of Vaccines (as defined below);

WHEREAS, Pfizer has extensive experience and expertise in the development and commercialization of pharmaceutical and biopharmaceutical products;

WHEREAS, subject to the terms of this Agreement, Valneva wishes to grant to Pfizer, and Pfizer wishes to receive from Valneva, an exclusive license in the Field (as defined below) in the Territory (as defined below) under Valneva's patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to Vaccines and Products to use, research, develop, manufacture and commercialize Vaccines and Products;

WHEREAS, Pfizer and Valneva wish to engage in collaborative clinical development pursuant to the Development Plan (as defined below) to Products (as defined below) to be advanced through clinical trials and commercialized by Pfizer; and

WHEREAS, subject to the terms of this Agreement, Valneva wishes to grant to Pfizer, and Pfizer wishes to receive from Valneva, an exclusive license in the Field under Valneva's patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to Vaccines and Products to use, research, develop, manufacture, commercialize and otherwise exploit Vaccines and Products;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

As used in this Agreement, the following terms will have the meanings set forth below:

1.1 "**ACIP**" means the Advisory Committee on Immunization Practices established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended.

1.2 "**Affiliate**" means any entity directly or indirectly controlled by, controlling, or under common control with, a Person, but only for so long as such control will continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of more than 50% (or the maximum ownership interest permitted by applicable Law) of the voting securities or other ownership or general partnership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity; *provided*, *however*, that where an entity owns a majority of the voting power necessary to elect a majority of the board of directors or other governing board of another entity, but is restricted from electing such majority by contract or otherwise, such entity will not be considered to be in control of such other entity until such time as such restrictions are no longer in effect.

1.3 "**Antitrust Clearance Date**" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act and any Foreign Antitrust Laws with respect to consummation of the transactions contemplated hereunder have expired or have been terminated.

1.4 "**Bankruptcy Code**" means Section 101(35A) of Title 11 of the United States Code, as amended.

1.5 "**Binding Obligation**" means, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party's operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party's charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party's operations or property are bound.

1.6 "**Biologics License Application**" or "**BLA**" means an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce, or any similar application or submission for marketing authorization of a product filed with a Regulatory Authority to obtain Regulatory Approval for such product in a country or group of countries.

1.7 "**Biosimilar Notice**" means a copy of any application submitted by a Third Party to the FDA under 42 U.S.C. § 262 (K) of the Public Health Service Act (or, in the case of a country of the Territory outside the United States, any similar law) for Regulatory Approval of a biopharmaceutical product, which application identifies a Licensed Product as the Reference Product with respect to such product, and other information that describes the process or processes used to manufacture the biopharmaceutical product.

1.8 "**Biosimilar Version**" means, with respect to a Product that is being sold in a country or regulatory jurisdiction in the Territory (the "**Reference Product**"), a biopharmaceutical product sold by a Third Party (other than a Third Party acting on behalf of or in concert with Pfizer or any Pfizer Affiliate or Sublicensee or assignee) in such country or regulatory jurisdiction in the Territory that through reference to the Regulatory Approval of the Reference Product, is eligible for and has achieved Regulatory Approval in such country or regulatory jurisdiction pursuant to an abbreviated follow-on biological approval pathway established by the Regulatory Authority in such country or regulatory jurisdiction pursuant to the applicable Law, or otherwise is approved for marketing and sale in such country or regulatory jurisdiction by an abridged procedure in reliance, in whole or in part, on the prior Regulatory Approval of the Reference Product or on the safety and efficacy data generated for the prior Regulatory Approval (in such country or regulatory jurisdiction) of the Reference Product, including any such biopharmaceutical product that (i) with respect to such biopharmaceutical product in the United States, has been approved as a biosimilar or interchangeable product by the FDA pursuant to 42 U.S.C. § 262 of the Public Health Service Act, (ii) with respect to such biopharmaceutical product subject to the regulatory jurisdiction of the EMA, has been approved as a similar biological medicine product by EMA as described in CHMP/437/04, issued 30 October 2005, as may be amended, or any subsequent or superseding law, statute or regulation or (iii) with respect to such biopharmaceutical product outside the United States and in a country which is not subject to the regulatory jurisdiction of the EMA, has otherwise obtained Regulatory Approval from a Regulatory Authority pursuant to similar statutory or regulatory requirement as that described in the foregoing subsections (i) and (ii) in such other country or regulatory jurisdiction in the Territory.

1.9 "**Business Day**" means a day other than a Saturday, Sunday or bank or other public holiday in New York, New York.

1.10 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.11 "**Calendar Year**" means any twelve (12) month period beginning on January 1 and ending on the next subsequent December 31.

1.12 "**Change of Control**" means, with respect to a Party (a) the acquisition of beneficial ownership, directly or indirectly, by any Person (other than such Party or an Affiliate of such Party, and other than by virtue of obtaining irrevocable or other proxies) of securities or other voting interest of such Party representing a majority or more of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination involving such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, (c) any sale, lease, exchange, contribution or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates, other than a sale or disposition of such assets to an Affiliate of such party or (d) the approval of any plan or proposal for the liquidation or dissolution of such Party (other than in circumstances where such Party is deemed a Debtor pursuant to section 9.8).

1.13 "**Clinical Trial**" mean a human clinical study conducted on sufficient numbers of humans subjects that is designed to (a) established that a pharmaceutical product is reasonably safe for continued testing, (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product. Without limiting the foregoing, Clinical Trial includes any Phase 2 Clinical Trial, Phase 3 Clinical Trial or Phase 4 Clinical Trial conducted by or on behalf of one or both Parties in connection with this Agreement.

1.14 "**Combination Product**" means a Product containing a Vaccine and one or more other therapeutically or prophylactically active ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package.

1.15 "**Commercialize**" or "**Commercializing**" means to (a) market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a Vaccine, Product or diagnostic assay for a Product and (b) conduct discovery, pre-clinical, research or other Development activities with respect to a Vaccine, Product or diagnostic assay for a Product after such Vaccine, Product or diagnostic assay for such Product has received Regulatory Approval. When used as a noun, "**Commercialization**" means any and all activities involved in Commercializing.

1.16 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to any efforts relating to the Development, Regulatory Approval or Commercialization of a Vaccine or Product by a Party, generally or with respect to any particular country in the Territory, a Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by such Party, in the relevant country, with respect to a Vaccine or protein, product or product candidate, as applicable (a) of similar modality Controlled by such Party, or (b) (i) to which such Party has similar rights, (ii) which is of similar market potential in such country, and (iii) which is at a similar stage in its development or product life cycle, as any Vaccine or Product, in each case, taking into account all Relevant Factors in effect at the time such efforts are to be expended. Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform

its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations. Notwithstanding anything to the contrary contained herein, it is understood and agreed that, with respect to Pfizer, "Commercially Reasonable Efforts" will not take into account any amounts paid or payable to Valneva under this Agreement.

1.17 "**Compliance**" means the adherence by the Parties in all material respects to all applicable Laws and Party Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

1.18 "**Confidential Information**" means, with respect to each Party, all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party's or its Representatives' technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the Execution Date, but only to the extent that such Know-How or other information does not include any Know-How or other information that (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the receiving party in breach of its obligations under this agreement, (d) was disclosed to the receiving party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing party not to disclose such information to the Receiving Party or (e) was independently discovered or developed by or on behalf of the receiving party without the use of any Disclosing Party. The terms and conditions of this Agreement will be considered Confidential Information of both Parties.

1.19 "**Control**" or "**Controlled**" means with respect to any Intellectual Property Right or material (including any Patent Right, Know-How or other data, information or material), the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to this Agreement) to, without violating the terms of any agreement with a Third Party, grant a license or sublicense or provide or provide access or other right in, to or under such Intellectual Property Right or material.

1.20 "**Copyright**" means any copyright Controlled by Pfizer, which copyright pertains to the promotional materials and literature utilized by Pfizer in connection with the Commercialization of Products in the Territory.

1.21 "**Costs**" means both internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate), all calculated in accordance with GAAP or IFRS, as applicable.

1.22 "**Cover**" means, with respect to a given Vaccine or Product and Patent Right, that a Valid Claim of such Patent Right would, absent a license hereunder or thereunder or ownership thereof, be infringed by the sale, offer for sale, use, manufacture, having manufactured or importation of such Vaccine or Product.

1.23 "**Develop**" or "**Developing**" means to discover, research or otherwise develop a process, Vaccine or Product, including conducting non-clinical and clinical research and development activities prior to Regulatory Approval. When used as a noun, "Development" means any and all activities involved in Developing.

1.24 "**Development Budget**" means the Development Budget attached hereto as Exhibit A, as it may be amended from time to time pursuant to Section 4.3.

1.25 "**Development Costs**" means, with respect to each Vaccine and associated Product, the Costs listed below to the extent the same are incurred by a Party, on a country-by-country basis prior to Regulatory Approval in each such country (provided that any Costs associated with closing out and completing activities set forth in the Development Plan and Development Budget that commenced prior to such applicable Regulatory Approval will be included in Development Costs), during the Agreement Term and in connection with such Party's performance under this Agreement, and, in each case, subject to the applicable Development Plan and Development Budget:

1.25.1 all Costs associated with preparing, submitting and obtaining Regulatory Filings and Regulatory Approvals pertaining to such Product;

1.25.2 all Internal Qualified Expenses or out-of-pocket costs incurred by the Parties or their respective Affiliates in performing activities designated to the Parties under the Development Plan, as applicable (including, to the extent included in the applicable Development Plan, the Costs of any development activities for clinical trials and related support to obtain Regulatory Approval for a Product and other lifestyle management activities, development of related devices, global medical affairs activities including observational research and any economic value evidenced generation in support of reimbursement activities such as health technology assessment submissions);

1.25.3 Costs of primary, secondary or tertiary packaging and labeling of Product with respect to Development of Vaccines and Products;

1.25.4 Costs associated with Development, including stability testing and other chemistry, manufacturing and controls support costs;

1.25.5 all Costs for other materials (such as placebo) obtained for use in Clinical Trials of or related to such Product;

1.25.6 all Costs incurred in connection with prosecution and maintenance of Valneva Lyme Genus Patent Rights, Valneva VLA-15 Species Patent Rights and Pfizer Patent Rights in accordance with Section 6.2 (but not including (a) any in-house legal costs incurred by either Party, or (b) Costs incurred by a Party in fulfilling its indemnification obligations hereunder; and

1.25.7 all Costs for Development activities conducted by Third Parties to the extent permitted by and conducted in accordance with the Development Plan.

1.25.8 Development Costs are exclusive of and do not include any Costs for which a Party is solely responsible under this Agreement. Except to the extent already included in Internal Qualified Expenses, Development Costs shall not include either Party's Costs to the extent they solely relate to activities associated with overseeing execution of and compliance with this Agreement.

1.26 "**Development Event**" means each Development event listed in the table that appears in Section 3.3.

1.27 "**Development Plan**" means the Development Plan attached hereto as Exhibit B, as it may be amended from time to time pursuant to Section 4.3.

1.28 "**Development Program Know-How**" means any and all Know-How, Vaccines and Products, whether or not patentable, made solely by or on behalf of either Party or its Representatives on and after the Effective Date during the Term in the conduct of activities under the Development Plan or made jointly by or on behalf of (i) Valneva or its Representatives and (ii) Pfizer or its Representatives in the conduct of activities under the Development Plan.

1.29 "**Development Program Patent Rights**" means any and all Patent Rights claiming or disclosing any invention included in Development Program Know-How.

1.30 "**Development Program Technology**" means the Development Program Patent Rights and Development Program Know-How.

1.31 "**Development Term**" means the period of time beginning on the Effective Date and expiring on completion of the Development Plan.

1.32 "**Effective Date**" means the later of (a) the Execution Date, (b) if a determination is made pursuant to Section 9.2 that a notification of this Agreement is not required to be made under the HSR Act or under any antitrust, competition or other similar laws, rules, regulations and judicial doctrines of jurisdictions other than the United States ("**Foreign Antitrust Laws**"), the date of such determination, or (c) if notification of this Agreement is required to be made under the HSR Act or any Foreign Antitrust Laws, the Antitrust Clearance Date.

1.33 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.34 "**Exploit**" means to Develop, Manufacture, Commercialize, use or otherwise exploit. Cognates of the word "Exploit" will have correlative meanings.

1.35 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

1.36 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.37 "**Field**" means all therapeutic, diagnostic and prophylactic human and veterinary use.

1.38 "**First Commercial Sale**" means, with respect to any Product and with respect to any country of the Territory, the first sale of such Product by Pfizer or an Affiliate or Sublicensee of Pfizer to a Third Party in an indication in the Field in such country after such Product has been granted Regulatory Approval by the appropriate Regulatory Authority for such indication in such country.

1.39 "**FTE**" means, with respect to a person, the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of [***] hours per year, or such other number as may be agreed to by the JDC). [***].

1.40 "**FTE Rate**" means, for the period commencing on the Effective Date until such time as the JDC agrees otherwise, [***] per FTE. The FTE Rate shall be increased or decreased on each anniversary of the Effective Date by a percentage equivalent to [***]. The FTE Rate shall include costs of salaries, benefits, supplies, travel, other employee costs, and supporting general and administration allocations.

1.41 "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.42 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

1.43 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.44 "**Government Official**", to be broadly interpreted, means (a) any elected or appointed government official (e.g.. a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official. Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, and (d) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals will be considered Government Officials.

1.45 "**Human Material**" means cells, cell cultures, blood, fluids, tissues, genetic material and genetic information (including data or results derived from DNA or RNA) of one or more Subjects provided or utilized by Valneva to conduct the Development Plan pursuant to this Agreement.

1.46 "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.47 "**HSR Filing**" means filings by Pfizer and Valneva with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.48 "**ICF**" means an informed consent form that was approved by a qualified Institutional Review Board or Independent Ethics Committee in accordance with all applicable Laws and recognized international standards for the protection of human research subjects.

1.49 "**IND**" means an Investigational New Drug Application submitted under the FD&C Act, or an analogous application or submission with any analogous agency or Regulatory Authority outside of the United States for the purposes of obtaining permission to conduct Clinical Trials.

1.50 "**IFRS**" means International Financial Reporting Standards.

1.51 "**Intellectual Property Rights**" means any and all (a) Patent Rights, (b) proprietary rights in Know How, including trade secret rights, (c) proprietary rights associated with works of authorship and software, including copyrights, moral rights, and copyrightable works, and all applications, registrations, and renewals relating thereto, and derivative works thereof, (d) other forms of proprietary or intellectual property rights however denominated throughout the world, other than trademarks, service marks, trade names, domain names and other indicators of origin.

1.52 "**Internal Qualified Expenses**" means any expenses incurred by either Party in the performance of activities directly related to the Development (including activities related to such Party's efforts to obtain Regulatory Approval) of Vaccines or Products, as the case may be, in each case subject to the Development Plan and Development Budget, and, to the extent not already included in Development Costs, Manufacturing Costs. Internal Qualified Expenses shall be charged by each Party [***] unless otherwise mutually agreed by the JDC; provided that such expenses exclude managerial, secretarial, clerical and administrative activities. For purposes of this Section 1.52, the term "managerial" shall mean activities performed by individuals who are not (i) directly performing Development or Manufacturing-related activities, or (ii) directly overseeing individuals directly performing Development or Manufacturing-related activities (e.g., "managerial" activities include activities performed by individuals overseeing those that directly oversee individuals directly performing Development or Manufacturing- related activities).

1.53 "**Joint Committee**" means JSC and JDC.

1.54 "**Joint Development Committee**" or "**JDC'** means the committee described in Section 4.3.2.

1.55 "**Joint Steering Committee**" or "**JSC**" means the steering committee described in Section 4.3.1.

1.56 "**Know-How**" means any proprietary invention, discovery, development, data, information, process, method, technique, material (including any chemical or biological material), technology, result, cell line, cell, antibody or other protein, Vaccine, probe, nucleic acid, (including RNAi) or other sequences or other know-how, whether or not patentable, and any physical embodiments of any of the foregoing.

1.57 "**Law**" means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.

1.58 "**Major EU Market Country**" means any of [***].

1.59 "**Major Market Country**" means any [***].

1.60 "**Manufacture**" or "**Manufacturing**" means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store, and for the purposes of further Manufacturing, distribute, import or export, a Vaccine or product or any component thereof. When used as a noun, "Manufacture" or "Manufacturing" means any and all activities involved in Manufacturing a Vaccine or protein, device or product or any component thereof.

1.61 "**Net Sales**" means: (a) with respect to a Product that is not a Combination Product, gross receipts from sales by Pfizer and its Affiliates and Sublicensees of such Product to Third Parties in the Territory or (b) with respect to any diagnostic assay Developed using the Valneva Technology for a Product, gross receipts from sales by Pfizer and its Affiliates from the Exploitation of such diagnostic assay for a Product, less in each case of (a) and (b), (i) [***] and (ii) [***]; and (c) with respect to a Product that is a Combination Product, that percentage of the Net Sales of such Combination Product (as determined in accordance with clause (a)) in a country that relates to the Product as Pfizer may reasonably determine (on a prorated basis) based on the then-prevailing mean average wholesale acquisition costs of the Product in such country and the other active ingredient(s) in such Combination Product when sold separately. Net Sales will be determined from books and records maintained in accordance with GAAP, as consistently applied by Pfizer with respect to sales of the Product. No individual deductions described in this definition of "Net Sales" may be taken more than once for any one sale of an individual Product. [***].

1.62 "**New Phase 2 Clinical Trial**" means a Phase 2 Clinical Trial to be initiated by Valneva following the Effective Date to evaluate a modified dosing volume, dose and dosing schedule of the Product.

1.63 "**On-going Phase 2 Clinical Trials**" means the VLA-201 and VLA-202 Clinical Trials being conducted by Valneva as of the Effective Date.

1.64 "**Packaging and Labeling**" means primary, secondary or tertiary packaging and labeling of Product (whether in clinical or commercial packaging presentation) for use in the Field in the Territory, including insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed or graphic materials accompanying the Product and any brand security or anti-counterfeiting measures included in the packaging elements for the Product considered to be part of the finished packaged Product, and all testing and release thereof.

1.65 "**Party Specific Regulations**" means all non-monetary judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.66 "**Patent Rights**" means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.

1.67 "**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 government or political subdivision or department or agency of a government.

1.68 "**Pfizer Diligence Obligations**" means Pfizer's Development and Regulatory Approval diligence obligations under Section 5.3.1 and Pfizer's Commercialization diligence obligations under Section 5.3.2.

1.69 "**Pfizer Know-How**" means (a) all Development Program Know-How and (b) any other Know-How that (i) is Controlled by Pfizer on the Effective Date or that comes into the Control of Pfizer during the Term (other than through the grant of a license by Valneva) and (ii) relates to one or more Vaccines or Products or the Development, Manufacture, Commercialization or use of any of the foregoing.

1.70 "**Pfizer Patent Right**" means any Patent Right that (i) is Controlled by Pfizer on the Effective Date or that comes into the Control of Pfizer during the Term (other than through the grant of a license by Valneva) or (ii) is conceived, discovered, developed or otherwise made, by or on behalf of Pfizer (other than by or on behalf of Valneva) under this Agreement and, in each of (i) and (ii), claims any (w) Vaccine or Product (including the composition of matter thereof), (x) method of making any Vaccine or Product, (y) methods of using any Vaccine or Product or (z) Pfizer Know-How.

1.71 "**Pfizer Quarter**" means each of the four (4) thirteen (13) week periods (a) with respect to the United States, commencing on January 1 of any Pfizer Year and (b) with respect to any country in the Territory other than the United States, commencing on December 1 of any Pfizer Year.

1.72 "**Pfizer Technology**" means the Pfizer Patent Rights and Pfizer Know-How.

1.73 "**Pfizer Year**" means the twelve month fiscal periods observed by Pfizer (a) commencing on January 1 with respect to the United States and (b) commencing on December 1 with respect to any country in the Territory other than the United States.

1.74 "**Phase 2 Clinical Trial**" means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product's efficacy or immunogenicity, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

1.75 "**Phase 3 Clinical Trial**" means a pivotal Clinical Trial with a defined dose or a set of defined doses of a pharmaceutical product designed to ascertain efficacy or immunogenicity and safety of such product, in a manner that is generally consistent with 21 CFR § 312.2l (c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of a BLA.

1.76 "**Phase 4 Trial**" means any study initiated in the Territory for a Product following the first Regulatory Approval for the sale of such Product for the Indication being studied whether or not required by a Governmental Authority. Phase 4 Trials may include epidemiological studies, modeling and pharmacoeconomic studies, and post-marketing surveillance studies, as well as any clinical study or research study sponsored and conducted by a Person not employed by or on behalf of either Party.

1.77 "**Price Approval**" means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.78 "**Product**" means any pharmaceutical or biopharmaceutical product in a formulation suitable for administration to patients which contains one or more Vaccines as an active ingredient.

1.79 "**Public Health Service Act**" means the United States Public Health Service Act (42 U.S.C. 201 *et seq*), as amended from time to time (including any rules and regulations promulgated thereunder) or any subsequent or superseding law, statute or regulation.

1.80 "**Regulatory Approval**" means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of BLAs, supplements and amendments, pre- and post-approvals and labeling approvals) of any Regulatory Authority, necessary or useful for the use. Development, Manufacture, and Commercialization of a pharmaceutical or biopharmaceutical product in a regulatory jurisdiction, including commercially reasonable Price Approvals and commercially reasonable Third Party reimbursement approvals.

1.81 "**Regulatory Authority**" means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or, to the extent required in such country. Price Approval, for pharmaceutical products in such country.

1.82 "**Relevant Factors**" means all relevant factors that may affect the Development, Regulatory Approval or Commercialization of a Vaccine or Product, including (as applicable): [***].

1.83 "**Representatives**" means (a) with respect to Pfizer, Pfizer, its Affiliates, its Sublicensees and each of their respective officers, directors, employees, consultants, contractors and agents and (b) with respect to Valneva, Valneva, its Affiliates and each of their respective officers, directors, employees, consultants, contractors and agents.

1.84 "**Reversion Technology**" means, as of the effective date of termination of this Agreement and with respect to a Continuation Product, (a) any Pfizer Know-How that was invented, discovered or developed during the Term and in connection with Pfizer's or its Affiliates' activities under the Agreement and (b) any Pfizer Patent Right if and solely to the extent such Pfizer Patent Right claims any Pfizer Know-How described in clause (a) above, in each case of clause (a) and (b) to the extent actually used by Pfizer to Develop, Commercialize or Manufacture such Continuation Product as of the time of termination

1.85 "**Royalty Term**" means, with respect to any particular Product in any particular country in the Territory (on a country-by-country basis), the period commencing on the First Commercial sale of such Product in such country and ending on the last to occur of (a) the date on which the sale, offer for sale or importation of such Product in such country would infringe, but for the license granted hereunder, a Valid Claim Covering such Product in such country and (b) [***] years after First Commercial Sale of such Product in such country.

1.86 "**Subject**" means the individual donor of the Human Material or of the original tissues from which the Human Material was derived.

1.87 "**Sublicensee**" means any Person to whom Pfizer grants or has granted, directly or indirectly, a sublicense of rights licensed by Valneva to Pfizer under this Agreement.

1.88 "**Territory'**" means worldwide.

1.89 "**Third Party**" means any Person other than Pfizer, Valneva or their respective Affiliates.

1.90 "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.91 "**Vaccine**" means Valneva's multivalent vaccine known as VLA-15 as described in the Valneva Patent Rights.

1.92 "**Valid Claim**" means, with respect to a particular country and Vaccine or Product, a claim of an issued and unexpired Valneva Patent Right licensed to Pfizer that Covers the Product and that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed; provided, that if a claim of a pending patent application shall not have issued within [***] years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim unless and until a patent right issues with such claim (from and after which time the same would be deemed a Valid Claim).

1.93 "**Valneva Know-How**" means any Know-How, other than Valneva Materials, or Development Program Know-How, that (a) is Controlled by Valneva or any of its Affiliates as of the Effective Date or that comes into the Control of Valneva or any of its Affiliates during the Term (other than through the grant of a license by Pfizer) and (b) relates to any Vaccine or Product and is useful, desirable or necessary for the Development, Manufacture, Commercialization or use of any Vaccine or Product. Know-How of any Person that becomes an Affiliate of Valneva after the Effective Date as a result of a Change of Control of Valneva will not be included within Valneva Know-How; provided that, and only so long as, no Valneva Know-How or Valneva Confidential Information used in the Development or Manufacture of a Vaccine or Product is disclosed to such Person and used by such Person or its Affiliates, other than Valneva, in the Development or Manufacture of any vaccine, product or antibody, alone or in combination with any vaccine, antibody, compound or other product, for the intended prevention of Lyme disease. If such Person uses, in any manner Valneva Know-How or Valneva Confidential Information for the Development or Manufacture of a vaccine, product or antibody, alone or in combination with any vaccine, antibody, compound or other product, for the intended or approved prevention of Lyme disease then any Intellectual Property Rights conceived, discovered, developed or otherwise made, by or on behalf of such Person in the course of such use will be included in Valneva Know-How.

1.94 "**Valneva Lyme Genus Patent Rights**" means (a) those Valneva Patent Rights listed in Schedule 8.3.4 attached hereto under the heading "Valneva Lyme Genus Patents" and any Valneva Patent Rights that claim priority to at least one of those Valneva Patent Rights attached hereto under the heading "Valneva Lyme Genus Patents" as well as (b) any Valneva Patent Right which (i) is Controlled by Valneva or its Affiliates that arises after the Effective Date during the Term, (ii) explicitly claims a method for the prevention of Lyme disease specifically, and (iii) is not a Valneva VLA-15 Species Patent Rights.

1.95 "**Valneva Materials**" means any tangible materials (but not information about or contained in such materials) owned or Controlled by Valneva that relate to or embody the Valneva Technology.

1.96 "**Valneva Patent Right**" means any Patent Right, other than a Development Program Patent Right, that (a) is Controlled by Valneva or any of its Affiliates as of the Effective Date or is Controlled by Valneva or any of its Affiliates during the Term (other than through the grant of a license by Pfizer) and (b) claims any (i) Vaccine or Product (including the composition of matter thereof), (ii) method of making

any Vaccine or Product, (iii) methods of using any Vaccine or Product or (iv) Valneva Know-How. Patent Rights of any Person that becomes an Affiliate of Valneva after the Effective Date as a result of a Change of Control of Valneva will not be included within Valneva Patent Rights; provided that, and only so long as no Valneva Know-How or Valneva Confidential Information used in the Development or Manufacture of a Vaccine or Product is disclosed to such Person and used by such Person or its Affiliates, other than Valneva, in the Development or Manufacture of any vaccine, product or antibody alone or in combination with any vaccine, antibody, compound or other product, for the intended or approved prevention of Lyme disease. If such Person uses Valneva Know-How or Valneva Confidential Information, in any manner for the Development or Manufacture of a vaccine, product or antibody, alone or in combination with any vaccine, antibody, compound or product, for the intended or approved prevention of Lyme disease then any Intellectual Property Rights conceived, discovered, developed or otherwise made, by or on behalf of such Person in the course of such use will be included in Valneva Patent Rights. Valneva Patent Rights include the existing Patent Rights listed in Schedule 8.3.4 and, for clarity, includes all Valneva Lyme Genus Patent Rights, Valneva VLA-15 Species Patent Rights and Valneva Platform Patent Rights.

1.97 "**Valneva Phase 2 Clinical Trials**" means the On-Going Phase 2 Clinical Trials and the New Phase 2 Clinical Trial.

1.98 "**Valneva Platform Patent Rights**" means (a) those Valneva Patent Rights listed in Schedule 8.3.4 attached hereto under the heading "Valneva Platform Patents" and any Valneva Patent Rights that claim priority to at least one of those Patent Rights attached hereto under the heading "Valneva Platform Patents" as well as (b) any Valneva Patent Right which is Controlled by Valneva or its Affiliates that arises after the Effective Date during the Term that is not either a Valneva Lyme Genus Patent Rights or Valneva VLA-15 Species Patent Rights.

1.99 "**Valneva Technology**" means the Valneva Patent Rights and Valneva Know-How.

1.100 "**Valneva Third Party Agreement**" means any agreement between Valneva (or any of its Affiliates) and any Third Party (such Third Party, a "**Third Party Licensor**") that (a) relates to any of the Valneva Technology, Valneva Materials or Development Program Technology or (b) otherwise grants a license or otherwise transfers any right to practice under any Patent Rights or Know-How, in each case that relate to the Vaccines, Products or activities under this Agreement.

1.101 "**Valneva VLA-15 Species Patent Rights**" means (a) those Valneva Patent Rights listed in Schedule 8.3.4 attached hereto under the heading "Valneva VLA-15 Species Patents" and any Valneva Patent Rights that claim priority to at least one of those Valneva Patent Rights attached hereto under the heading "Valneva VLA-15 Species Patents" as well as (b) any Valneva Patent Right which (i) is Controlled by Valneva or its Affiliates that arises after the Effective Date during the Term, (ii) explicitly claims the protein sequences that comprise VLA-15 specifically, and (iii) is not either a Valneva Lyme Genus Patent Rights or a Valneva Platform Patent Rights.

1.102 The following terms are defined in the section of this Agreement listed opposite each term:

Defined Term	**Section in Agreement**
Additional Third Party License	3.4.4(a)
Agreement	Preamble
Alliance Managers	4.3.4(b)
Antitrust Filings	9.1
Clinical Data	2.14
Continuation Product	9.7.1(a)(ii)(A)
Continuing Party	6.2.1(d)
Courts	11.14

Debtor	9.8.1
Declining Party	6.2.1(d)
Development Payment	3.3
Diligence Issue	5.3.5
Disclosing Party	7.1
Excess Costs	3.2
Execution Date	Preamble
Foreign Antitrust Laws	1.32
Global Trade Control Laws	11.11
HCPs	8.3.10
Indemnified Party	10.4.1
Indemnifying Party	10.4.1
Infringement Claim	6.2.7
IRS Form	3.5.3(b)
JDC Chair	4.3.2(a)
Liabilities	10.2
Licensed Activities	6.2.6(a)
Litigation Conditions	10.4.2
Manufacturing Process	4.2.5
Marginal Royalty Rates	3.4.1
Notice of Dispute	11.12.1
Party or Parties	Preamble
Per Product Annual Net Sales	3.4.1
Pfizer	Preamble
Pfizer Enforcement Valneva Patent Rights	6.2.2(a)
Pfizer Indemnified Party	10.3
Pfizer Prosecuted Valneva Patent Rights	6.2.1(b)
Policies	8.3.11
Program Director and Program Directors	4.3.4(a)
Receiving Party	7.1
Reconciliation Report	3.2.1(b)
Restricted Market	11.11.1
Restricted Parties	11.11.2
Review Period	7.4.2
Shared Costs	3.2
Technology Transfer Plan	2.15
Term	9.4
Third Party Claim	10.4.1
Third Party IP Rights	6.2.6(b)
Up-Front Payment	3.1
US-Austria DTAA	3.5.3(b)
Valneva	Preamble
Valneva Indemnified Party	10.2
Valneva Prosecuted Valneva Patent Rights	6.2.1(a)
VAT	3.5.3(a)
VPPR Infringement	6.2.2(b)

2. LICENSE GRANTS AND TECHNOLOGY TRANSFER.

2.1 **Exclusive License from Valneva to Pfizer**. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Valneva hereby grants, and will cause its Affiliates to hereby grant, to Pfizer an exclusive (exclusive even as to Valneva except to the extent necessary to perform Valneva's activities under the Development Plan during the Development Term) sublicensable license and,

to the extent any Valneva Technology or Valneva Materials are Controlled by Valneva pursuant to a Valneva Third Party Agreement, a sublicense, as applicable, under the Valneva Technology and Valneva Materials, to use, have used. Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit Vaccines and Products in the Field in the Territory.

2.2 **Non-Exclusive License from Valneva to Pfizer**. Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, Valneva, effective as of the Effective Date, hereby grants, and shall cause its Affiliates to hereby grant, to Pfizer a non-exclusive, sublicensable license under all Patent Rights, Know-How and other Intellectual Property Rights Controlled (as of the Effective Date or at any time during the Term) by Valneva or its Affiliates (to the extent such Patent Rights, Know-How and other Intellectual Property Rights are not exclusively licensed or sublicensed to Pfizer pursuant to Section 2.1), to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit Vaccines and Products in the Field in the Territory during the Term.

2.3 **Pfizer Sublicensees**. Pfizer will have the right to grant sublicenses to its Affiliates and Third Parties of any and all rights granted to Pfizer under this Agreement by Valneva, including any and all rights licensed to Pfizer pursuant to Section 2.1 or Section 2.2. Pfizer will provide Valneva with a copy of each agreement containing any such sublicense within [***] of execution, with reasonable redactions that will enable Valneva to reasonably monitor compliance with the terms and conditions of this Agreement. No sublicense will diminish, reduce or eliminate any obligation of Pfizer, as the sublicensing Party, under this Agreement, and Pfizer will remain responsible for its obligations under this Agreement and will be responsible for the performance of the relevant sublicensee as if such sublicensee were the sublicensing Party hereunder (including, without limitation, reporting obligations imposed upon Pfizer in accordance with this Agreement). Each sublicense granted by Pfizer, as the sublicensing Party, to any rights licensed to it hereunder will terminate immediately upon the termination of the original license with respect to such rights.

2.4 **Direct Licenses to Affiliates**. Pfizer may, from time to time, request that Valneva grant licenses or sublicenses directly to Affiliates of Pfizer by giving written notice, upon receipt of which Valneva agrees to enter into and sign a separate direct license or sublicense agreement with such designated Affiliate of Pfizer. All such direct license or sublicense agreements will be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by applicable Laws in the country in which the direct license or sublicense will be exercised. The Parties further agree to make any amendments to this Agreement that are necessary to conform the combined terms of such direct licenses or sublicenses and this Agreement to the terms of this Agreement as set forth on the Execution Date. All reasonable costs of making such direct license or sublicense agreement(s), including Valneva's reasonable attorneys' fees, under this Section 2.4 will be borne by Pfizer.

2.5 **Non-Exclusive License from Pfizer to Valneva**. During the Development Term and subject to the terms and conditions of this Agreement, Pfizer hereby grants to Valneva a non-exclusive, royalty-free, fully paid-up license in the Territory, with no right to grant sublicenses other than to permitted subcontractors under Section 4.2.2, under the Pfizer Technology and Development Technology solely to the extent necessary to perform Valneva's activities under the Development Plan.

2.6 **Reciprocal Non-Exclusive Research License for Disclosed Know-How and Confidential Information**. Subject to any pre-existing exclusive license grants to Third Parties as of the Effective Date, and without limiting any other license granted to either Party under this Agreement:

2.6.1 Pfizer hereby grants to Valneva a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up, worldwide license, with the right to sublicense to Valneva Affiliates, to use for research purposes all Pfizer Know-How or Pfizer Confidential Information that is disclosed to Valneva during the Term; provided that nothing in this Section 2.6.1 shall give Valneva any right to practice under any Patent Right owned or Controlled by Pfizer or its Affiliates.

2.6.2 Valneva hereby grants, and shall cause its Affiliates to hereby grant, to Pfizer a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up, worldwide license, with the right to sublicense to Pfizer Affiliates, to use for research purposes all Valneva Know-How, Valneva Materials or Valneva Confidential Information that is disclosed to Pfizer during the Term; provided that nothing in this Section 2.6.2 shall give Pfizer any right to practice under any Patent Right owned or Controlled by Valneva or its Affiliates.

2.7 **Right of Reference**. Valneva hereby grants to Pfizer, its Affiliates and its Sublicensees a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any analogous Law recognized outside of the United States), to all data (including any regulatory filings or Regulatory Approvals) Controlled by Valneva or its Affiliates that relates to any Vaccine or Product, in all cases solely for the Development, Manufacture, Commercialization and Exploitation of the Product pursuant to the terms and conditions of this Agreement, and Valneva will provide a signed statement to this effect, if requested by Pfizer, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Law outside of the United States).

2.8 **Exclusivity**. During the Term, except to the extent necessary for Valneva to perform its activities under the Development Plan, Valneva shall not, and shall cause its Affiliates not to (a) directly or indirectly, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit or have Exploited any Vaccine, antibody, or product, alone or in combination, for Lyme disease for itself, an Affiliate or with or on behalf of a Third Party, or (b) license, authorize, appoint, or otherwise enable any Third Party to perform any of the activities under clause (a); provided, however, that in the event of a Change of Control of Valneva the foregoing limitations shall not apply to the acquiring company with respect to any research, development or commercialization efforts that such acquiring company had on-going as of the date of such Change of Control. Except as provided in this Agreement, such acquiring company will not use, in any manner, any Valneva Technology for the Exploitation, alone or with any Third Party, of any vaccine, antibody, biosimilar, compound or product, alone or in combination, for the intended or approved prevention of Lyme disease.

2.9 **No Implied Rights**. Except as expressly provided in this Agreement, neither Party will be deemed to have granted the other Party (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any Patent Rights, Know-How or other Intellectual Property Rights or information Controlled by such Party.

2.10 **Safe Harbor**. This Agreement is not intended to restrict or waive any rights that the Parties may otherwise have under applicable law, including without limitation 35 U.S.C. § 271(e)(1).

2.11 **Initial Data Transfer**. Within a reasonable time not to exceed [***] following the Effective Date, Valneva will disclose to Pfizer true, accurate and complete copies of all Valneva Know-How, including all preclinical and Phase 1 data, in each case to the extent developed by Valneva on or prior to the Effective Date and in its current (electronic or other) format as Pfizer may reasonably request (including by download of digital files to a secure website or e-room designated and controlled by Pfizer).

2.12 **Samples of Tangible Materials**. Within a reasonable time not to exceed [***] from the Effective Date, Valneva will furnish to Pfizer any Valneva Materials, including research grade samples of all Vaccines discovered or developed by Valneva prior to the Effective Date. Nothing in this Section 2.12 shall limit or in any way change Valneva's obligations under this Agreement with respect to any Human Material it provides or uses under this Agreement.

2.13 **Continuing Disclosure and Knowledge Transfer**. On a [***] basis, or more frequently at the reasonable request of Pfizer during the Development Term, Valneva, to the extent not previously provided to Pfizer, will provide to Pfizer a written summary of all Valneva Technology that is licensed or developed by Valneva or that otherwise comes into the Control of Valneva that relates to the Development of any Vaccine, antibody, or Product, alone or in combination, for Lyme disease. Further, Valneva will make appropriate personnel (directly, or through an Affiliate) available to Pfizer at reasonable times and places in a way that does not require Valneva to form a permanent establishment in the United States of America for US tax purposes and upon reasonable prior notice for the purpose of assisting Pfizer to understand and use the Valneva Technology in connection with Pfizer's Development, Manufacture, Commercialization and use of Vaccines and Products for Lyme Disease.

2.14 **Clinical Data Transfer**. Valneva shall provide to Pfizer copies of all clinical data and results from any and all completed Clinical Trials for the Vaccine or Product as well as the Valneva Phase 2 Clinical Trials ("**Clinical Data**"), in electronic form or other mutually agreeable alternate form on timelines agreed to by the JDC, and a complete copy of the Clinical Data shall be provided to Pfizer no later than [***] following interim readouts and completion of each Valneva Phase 2 Clinical Trial. Valneva shall ensure that all patient authorizations and consents required under Applicable Law in connection with the Valneva Phase 2 Clinical Trials permit such sharing of Clinical Data with Pfizer.

2.15 **Technology Transfer Plan**. Notwithstanding Sections 2.11, 2.12, 2.13 and 2.14, Valneva will provide Pfizer with all reasonable assistance necessary or desirable (a) to effect the timely and orderly transfer of Valneva Technology in accordance with the Technology Transfer Plan, (b) to enable Pfizer to perform its obligations under Section 5.1 and (c) for Pfizer to exercise its rights under the licenses and sublicenses granted in Section 2.1 and Section 2.2. Without limiting Valneva's obligations set forth elsewhere under this Agreement, Valneva will perform all technology transfer activities as set forth under the technology transfer plan agreed to by the Parties prior to the Effective Date (the "**Technology Transfer Plan**"), which Technology Transfer Plan shall become part of this Agreement. Valneva will cause all technology transfer activities to be performed under the Technology Transfer Plan to be carried out by the specific individuals identified to perform such activities in the Technology Transfer Plan.

3. PAYMENTS AND COST SHARING.

3.1 **Up-Front Payment**. Pfizer will make a one-time non-refundable, non-creditable payment of one hundred thirty million US dollars ($130,000,000) to Valneva (the "**Up-Front Payment**") within [***] of receipt of Valneva's invoice (such invoice to be delivered on or following the Effective Date of this Agreement).

3.2 **Development Program Expenses**. Subject to the terms and conditions of this Agreement, the Development Costs incurred by the Parties pursuant to the Development Plan in accordance with the Development Budget ("**Shared Costs**") will be borne seventy percent (70%) by Pfizer and thirty percent (30%) by Valneva. Unless otherwise agreed by the Parties in advance, in writing, any Development Costs by the Parties with respect to the Development Plan in excess of the aggregate amounts set forth in the Development Budget ("**Excess Costs**"), shall not be included in the calculation of the Shared Costs as set forth above; provided, that a given Excess Cost shall be included in the calculation of the Shared Costs to the extent such Excess Cost is or was attributable to: (i) a change in Applicable Law; (ii) a Force Majeure event; (iii) variation in sites and countries or actual patient enrollment from projected patient enrollment as well as treatment duration; or (iv) a change required by any Regulatory Authority to support Regulatory Approval for the proposed target Product profile. [***].

3.2.1 **Reconciliation and Reimbursement**.

(a) Within (i) [***] after the end of each of the first three (3) Calendar Quarters during each Calendar Year and (ii) within [***] after the fourth (4th) Calendar Quarter of each Calendar Year, each Party will provide the other Party with a detailed, activity-based statement of the Development Costs incurred after the Effective Date pursuant to this Section 3.2 in a format to be agreed upon by the Parties. The Parties will work together to establish an optimal inter-Party financial operating structure (including, if necessary, procedures and agreements between the Parties) which is consistent with the economic result contemplated herein and consistent to the extent feasible with each Party's internal structures and procedures.

(b) Within (i) [***] after the end of each of the first three (3) Calendar Quarters during each Calendar Year and (ii) within [***] after the fourth (4th) Calendar Quarter of each Calendar Year, Pfizer will provide Valneva with a written report (the "**Reconciliation Report**") setting forth, in a format to be agreed-upon by the Parties, the calculations of each Party's share of such Development Costs for the previous Calendar Quarter. Such Reconciliation Report will include for such Calendar Quarter (i) the total Development Costs incurred by each Party in accordance with this Section 3.2, and each Party's respective share thereof, and (ii) the net payment due from one Party to the other Party in accordance with this Section 3.2.

(c) Any net payment owed from one Party to the other Party will be paid within [***] following delivery of the Reconciliation Report; provided that if a Party disputes an amount provided in such Reconciliation Report then such disputed amount will be reviewed by the JDC, and any net payment owed with respect to the undisputed amounts will be paid within the above set forth timeline. If requested by a Party, any invoices or other supporting documentation for any payments to a Third Party will be promptly provided.

(d) Within [***] after the other Party's request, a Party will provide copies of invoices or other appropriate supporting documentation with respect to its Development Costs, The receiving Party will treat all information subject to review under this Section 3.2 in accordance with the confidentiality provisions of Article 7.

3.3 **Development Payments**. Pfizer will pay Valneva the non-refundable, non-creditable amounts set forth below within [***] following the first occurrence of each event described below for the first Product Covered by a Valid Claim in the applicable country of Development or Commercialization in the Territory to achieve such event (each, a "**Development Payment**").

	Development Event	Development Payment
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***]	[***]
(v)	[***]	[***]

Each of the Development Payments set forth above will be payable one time only (regardless of the number of Products with respect to which, or the number of times with respect to any Product, the specified Development Event occurs). No Development Payments will be payable by Pfizer for any subsequent Product regardless of the number of Products Developed. For clarification, if one Product replaces another Product in Development, then such replacement Product will only be subject to Development Payments that have not previously been triggered by one or more prior Products. The maximum amount payable by Pfizer under this Agreement with respect to all Development Payments if all Development Events occur will be one hundred seventy-eight million dollars ($178,000,000).

3.4 **Royalty Payments**.

3.4.1 **Royalties**. Subject to the provisions of Section 3.4.4, Pfizer will pay Valneva royalties on a tiered marginal royalty rate basis as set forth below (the "**Marginal Royalty Rates**") based on the annual aggregate Territory-wide Net Sales resulting from the sale of each Product, on a Product-by-Product basis, during each Pfizer Year of the applicable Royalty Term for each Product (each, the "**Per Product Annual Net Sales**"):

Per Product Annual Territory-Wide Net Sales	Marginal Royalty Rate (% of Per Product Annual Net Sales)
[***]	19%
[***]	[***]
[***]	[***]
[***]	[***]

Each Marginal Royalty Rate set forth in the table above will apply only to that portion of the Net Sales of a given Product in the applicable country or countries in the Territory during a given Pfizer Year that falls within the indicated range. An example calculation of royalties under this Section 3.4.1 is set forth in Schedule 3.4.1.

3.4.2 **Royalty Offset**. The Parties acknowledge and agree that Pfizer is entitled to immediately offset [***] against any royalties that may become due and owing to Valneva pursuant to Section 3.4.1. Such offset, pursuant to this Section 3.4.2, will be applied to any royalty amounts owed to Valneva prior to any payment being made to Valneva until such offset is fully realized by Pfizer.

3.4.3 **Fully Paid-Up, Royalty Free License**. Following expiration of the Royalty Term for any Product in a given country, no further royalties will be payable in respect of sales of such Product in such country and, thereafter the license granted to Pfizer under Sections 2.1 and 2.2 with respect to such Product in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free.

3.4.4 **Royalty Adjustments**. The following adjustments will be made, on a Product-by -Product and country-by-country basis, to the royalties payable pursuant to Section 3.4.1:

(a) **Third Party Patents**. If it is necessary or desirable for Pfizer to license one or more Patent Rights from one or more Third Parties in order to Develop, Manufacture, Commercialize or use any Product, whether directly or through any Pfizer Affiliate or Sublicensee in any country in the Territory, then Pfizer may, in its sole discretion, negotiate and obtain a license under such Patent Right(s) (each such Third Party license referred to herein as an "**Additional Third Party License**"). On a country-by-country basis, any royalty otherwise payable to Valneva under this Agreement with respect to Net Sales of any Product in the applicable country by Pfizer, its Affiliates or Sublicensees will be reduced by [***] of the amounts payable to Third Parties pursuant to any Additional Third Party Licenses, such reduction to continue until all such amounts have been expended, *provided that* in no event (other than in the case of Valneva's breach of any representation, warranty or covenant hereunder) will the total royalty payable to Valneva for any Product (with respect to Net Sales of any Product in the applicable country) be less than [***] of the royalty amounts otherwise payable for such Product.

(b) **No Adjustment for Valneva Third Party Agreements**. Valneva will be solely responsible for (i) all obligations (including any royalty or other obligations that relate to the Valneva Technology, Valneva Materials or Valneva's interest in the Joint Technology) under its agreements with Third Parties that are in effect as of the Effective Date and (ii) all payments to inventors (other than inventors that are Representatives of Pfizer) of Valneva Technology, Valneva Materials, Development Program Technology or Joint Technology, including payments under inventorship compensation Laws.

(c) **Existing Pfizer Third Party Agreements**. Pfizer will be solely responsible for all obligations (including royalty obligations) that relate to Products under its agreements with Third Parties that are in effect on or prior to the Effective Date.

(d) **Biosimilar Entry**. Notwithstanding the foregoing, for Net Sales based on sales of a Product in a country in the Territory, on a country-by-country basis, any payments owed with respect to such Product pursuant to this Section 3.4 will be reduced by [***] for the remainder of the applicable Royalty Term, such reduction to be prorated for the then-current Pfizer Quarter, if at any time (X) one or more Biosimilar Versions of such Product is available in such country and (Y) such one or more Biosimilar Versions in the aggregate have achieved in excess of [***] market penetration ([***]) for the period of [***] as applicable from time to time.

(e) **No Valid Claim**. Notwithstanding the foregoing, In the event that, with respect to any particular Product in any particular country in the Territory, the Royalty Term for such Product in such country extends beyond the date on which such Product is not Covered by any Valid Claim in such country, Net Sales in any such country shall be reduced by [***] for the remainder of the applicable Royalty Term.

(f) **Royalty Floor**. Notwithstanding anything to the contrary contained in this Agreement, in the case where the Exploitation of a Product in a specific country: (i) is Covered by a Valid Claim in such country, the maximum reduction of royalties under this Section 3.4 with respect to royalties owed in such country shall be [***] of the royalty amounts required to be paid pursuant to Section 3.4.1 (as if no other adjustments pursuant to this Section 3.4 had been given effect for the purposes of calculating the maximum [***] reduction amounts); and (i) is not Covered by a Valid Claim in such country, the maximum reduction of royalties under this Section 3.4 with respect to royalties owed in such country shall be [***] of the royalty amounts required to be paid pursuant to Section 3.4.1 (as if no other adjustments pursuant to this Section 3.4 had been given effect for the purposes of calculating the maximum [***] reduction amounts).

3.5 **Reports and Payments**.

3.5.1 **Cumulative Royalties**. The obligation to pay royalties under this Agreement will be imposed only once with respect to any sale of any Product.

3.5.2 **Royalty Statements and Payments**. Within [***] of the end of each Calendar Quarter, Pfizer will deliver to Valneva a report setting forth, for the most recent Pfizer Quarter ending during such Calendar Quarter, the following information, on a Product-by-Product, country-by-country and Territory-wide basis: (a) Net Sales of each Product, (b) the basis for any adjustments to the royalty payable for the sale of any such Product and (c) the royalty due hereunder for the sale of each such Product. No such reports will be due for any such Product (i) before the First Commercial Sale of such Product or (ii) after the Royalty Term for such Product has expired in all countries in the Territory. The total royalty due for the sale of all such Products during such Pfizer Quarter will be remitted at die time such report is made.

3.5.3 **Taxes and Withholding**.

(a) It is understood and agreed between the Parties that any payments made by Pfizer to Valneva under this Agreement are exclusive of any value added or similar tax ("**VAT**") imposed upon such payments. Where VAT is properly added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance with the laws and regulations of the country in which the VAT is chargeable without reduction in the amount otherwise payable to Valneva. In addition, the Parties shall co-operate in accordance with applicable Laws to minimize VAT in connection with this Agreement, as applicable.

(b) The Parties agree that, subject to the delivery by Valneva to Pfizer of a duly completed applicable Internal Revenue Service Form W-8 (or a successor form) ("**IRS Form**"), payments by Pfizer to Valneva under this Agreement are not subject to US withholding tax under the current form of the US-Austria double taxation avoidance agreement (the "**US-Austria DTAA**") and accordingly (subject to the next sentence) Pfizer and its assignees will make all payments under this Agreement without deduction or withholding for taxes. If any taxes are withheld or deducted as a result of:

(i) the failure by Valneva to provide the IRS Form, no additional payment shall be required to be made by Pfizer,

(ii) a change in the applicable Laws or regulations of any jurisdiction or Governmental Authority (other than the Laws of or Governmental Authority of Austria), Pfizer shall make such additional payments to Valneva in an amount necessary to cause Pfizer to bear [***] of such taxes (including taxes imposed on payments made pursuant to this sentence) reduced by the amount of any foreign tax credit resulting from such withheld or deducted taxes to the extent such credit reduces the income tax liability otherwise payable by Valneva in the year that such tax is credited, or

(iii) a change in, revocation or termination of the US-Austria DTAA or any other reason not described in the foregoing clauses (i) or (ii), Pfizer shall make such additional payments to Valneva in an amount necessary to cause Valneva to bear [***] of such taxes (including taxes imposed on payments made pursuant to this sentence) reduced by [***] of the amount of any foreign tax credit resulting from such withheld or deducted taxes to the extent such credit reduces the income tax liability otherwise payable by Valneva in the year that such tax is credited.

In each of (ii) and (iii) the additional payment by Pfizer shall be due and payable upon Valneva issuing a related invoice for the additional payment. In case of subsequent change of the creditable amount (e.g. in the course of a tax inspection) Valneva shall credit or invoice an additional amount, as the case may be, to Pfizer. The Parties agree that before making any such deduction or withholding, Pfizer shall give Valneva notice of the intention to make such deduction or withholding (and such notice, which shall set forth the amount and basis of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for Valneva to obtain reduction of or relief from such deduction or withholding). Pfizer will provide Valneva with reasonable assistance to enable Valneva to recover such taxes as permitted by applicable Laws or regulations. The Parties shall reasonably cooperate with each other in claiming refunds or reductions or exemptions from such deductions and withholdings under any Law, agreement or treaty in effect at the relevant time to ensure that any amounts required to be withheld pursuant to this Section 3.5.3(b) are reduced in amount to the fullest extent permitted by Law.

(c) Notwithstanding anything in this Agreement to the contrary, if an action (including but not limited to a re-domiciliation or similar action, any assignment or sublicense of its rights or obligations under this Agreement, or any failure to comply with applicable Laws or filing or record retention requirements) by a Party leads to the imposition of withholding tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then (i) the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such action occurred, (ii) otherwise, the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable Law.

(d) Tax Cooperation. Upon request, each Party shall use Commercially Reasonable Efforts to cooperate with the other Party to mitigate, reduce or eliminate adverse tax consequences to such other Party from changes in applicable Law, US-Austria DTAA, the use of present or future Affiliates of either Party to engage in transactions described in or contemplated by this Agreement, or from other activities or transactions described in or contemplated by this Agreement.

3.5.4 **Currency**. All amounts payable and calculations under this Agreement will be in United States dollars. As applicable, Net Sales and any royalty deductions will be translated into United States dollars at the exchange rate used by Pfizer for public financial accounting purposes. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Article 3, the Parties will consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then Pfizer may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

3.5.5 **Method of Payment**. Except as permitted pursuant to Section 3.5.4, each payment hereunder will be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Pfizer's election, to such bank account as the Valneva will designate in writing to Pfizer at least [***] before the payment is due. All invoice or billing related questions should be referred to Pfizer's Accounting Department at [***] or go to the Accounts Payable Invoice Portal at [***].

3.5.6 **Record Keeping**. Pfizer will keep and will cause its Affiliates to keep books and accounts of record in connection with the sale of Products in sufficient detail to permit accurate determination of all figures necessary for verification of royalties and Sales Milestone Payments to be paid hereunder. Pfizer and its Affiliates will maintain such records for a period of at least three years after the end of the Pfizer Quarter in which they were generated.

3.5.7 **Audits**. Upon [***] prior notice from Valneva, Pfizer will permit an independent certified public accounting firm of nationally recognized standing selected by Valneva and reasonably acceptable to Pfizer, to examine, at Valneva' s sole expense, the relevant books and records of Pfizer and its Affiliates as may be reasonably necessary to verify the amounts reported by Pfizer in accordance with Section 3.5.2 and the payment of royalties and Sales Milestone Payments hereunder. An examination by Valneva under this Section 3.5.7 will occur not more than [***] in any Calendar Year and will be limited to the pertinent books and records for any Calendar Year ending not more than [***] before the date of the request. The accounting firm will be provided access to such books and records at Pfizer's or its Affiliates' facility(ies) where such books and records are normally kept and such examination will be conducted during Pfizer's normal business hours. Pfizer may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to Pfizer's or its Affiliates' facilities or records. Valneva shall submit to Pfizer, along with any notice of an audit under this Section 3.5.7, a written list identifying all Patent Rights that Valneva believes in good faith are relevant to the audit request. Upon completion of the audit, the accounting firm will provide both Pfizer and Valneva a written report disclosing any discrepancies in the reports submitted by Pfizer or the royalties or Sales Milestone Payments paid by Pfizer, and, in each case, the specific details concerning any discrepancies. No other information will be provided to Valneva.

3.5.8 **Underpayments/Overpayments**. If such accounting firm concludes that additional royalties or Sales Milestone Payments were due to Valneva, then Pfizer will pay to Valneva the additional royalties or Sales Milestone Payments within [***] of the date Pfizer receives such accountant's written report. Further, if the amount of such underpayments exceeds more than [***] of the amount that was properly payable to Valneva, then Pfizer will reimburse Valneva for Valneva's out-of-pocket costs in connection with the audit. If such accounting firm concludes that Pfizer overpaid royalties or Sales Milestone Payments to Valneva, then Valneva will refund such overpayments to Pfizer, within [***] of the date Valneva receives such accountant's report.

3.5.9 **Confidentiality**. Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of Pfizer, its Affiliates or its Sublicensees which are provided to or subject to review by Valneva under this Article 3 will be deemed to be Pfizer's Confidential Information and subject to the provisions of Article 7.

3.6 **No Guarantee of Success**. Pfizer and Valneva acknowledge and agree that payments to Valneva pursuant to Section 3.3 and Section 3.4: (a) have been included in this Agreement on the basis that they are only payable or otherwise relevant if a certain Product is successfully Developed or Commercialized in such country, as applicable; (b) are solely intended to allocate amounts that may be achieved upon successful Development or Commercialization of such Product as applicable, between Pfizer (who will receive all Product sales revenues) and Valneva; (c) are not intended to be used and will not be used as a measure of damages if this Agreement is terminated for any reason, including pursuant to Pfizer's right to terminate for convenience, before any such success is achieved and such amounts become due; and (d) will only be triggered, and will only be relevant as provided, in accordance with the terms and conditions of such provisions. Pfizer and Valneva further acknowledge and agree that nothing in this Agreement, or in any document or presentation provided by Pfizer to Valneva prior to the Effective Date will be construed as representing any estimate or projection of (i) the successful Development or Commercialization of any Product under this Agreement, (ii) the number of Products that will or may be

successfully Developed or Commercialized under this Agreement, (iii) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement or (iv) the damages, if any, that may be payable if this Agreement is terminated for any reason. Pfizer makes no representation, warranty or covenant, either express or implied, that (A) it will successfully Develop, Manufacture, Commercialize or continue to Develop, Manufacture or Commercialize any Product in any country, (B) if Commercialized, that any Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (C) Pfizer will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Product in any country, or in the Territory in general, other than is expressly required under Section 5.1.

4. DEVELOPMENT PLAN

4.1 **Scope of Development Plan**. Pfizer and Valneva will collaborate during the Development Term to conduct assay and diagnostic development, toxicology studies, manufacturing development and technology transfer as well as Clinical Trials in accordance with the Development Plan and the terms and conditions set forth in this Article 4. The Development Plan and Development Budget may be amended during the Development Term in accordance with Section 4.3.

4.2 **Allocation of Responsibilities**.

4.2.1 **General**. Each Party will use Commercially Reasonable Efforts to perform its obligations under the Development Plan in a professional and timely manner. Further, each Party will perform its obligations under the Development Plan in compliance with all Laws applicable to its activities under the Development Plan.

4.2.2 **Valneva Obligations; Subcontractors**. During the Development Term, Valneva will devote sufficient internal personnel to conduct activities under the Development Plan. Valneva will not subcontract any of its responsibilities under the Development Plan without Pfizer's prior written consent; *provided* that any subcontractors expressly identified in the Development Plan to conduct specific activities thereunder shall be deemed to have received such consent from Pfizer. Valneva shall be responsible for the management of all permitted subcontractors. The engagement by Valneva or its Affiliate of any subcontractor in compliance with this Section 4.2.2 shall not relieve Valneva of its obligations under this Agreement or the Development Plan. Any agreement between Valneva or its Affiliate and a permitted subcontractor pertaining to the Development Plan activities shall be consistent with the provisions of this Agreement including (i) an obligation to assign all Intellectual Property rights generated during its performance of such Development Plan to Pfizer and (ii) terms and conditions under which such Third Party is obligated to preserve the confidentiality of any Confidential Information of Pfizer received by such Third Party from the Valneva that are at least as restrictive as those described in Article 7. Furthermore, unless otherwise agreed by Pfizer in writing, prior to or at the time of engagement of any subcontractor to perform any obligations hereunder, Valneva or its Affiliate shall cause such Subcontractor to agree in writing to be bound by terms providing for Pfizer rights no less favorable to Pfizer than the rights granted to Pfizer in this Agreement.

4.2.3 **Valneva Personnel Matters**. Valneva acknowledges and agrees that it is solely responsible for the compensation of the personnel assigned to implement Valneva's obligations under the Development Plan, and shall be responsible for withholding all national, state, local or other applicable taxes and similar items for such personnel. Valneva also shall be responsible for all other employer related obligations, including providing appropriate insurance coverage and employee benefits, and making all other deductions required by law affecting the gross wages of each Valneva employee. Valneva personnel assigned to the Development Plan activities are not nor shall they be deemed to be employees of Pfizer.

4.2.4 **Pfizer Oversight of Development Activities**. Pfizer will oversee and retain final decision-making authority with respect to all Development activities performed under this Agreement, in accordance with the terms of this Agreement.

4.2.5 **Manufacturing Technology Transfer**. Valneva shall cooperate with Pfizer, and use Commercially Reasonable Efforts to facilitate, a transfer to Pfizer or, at Pfizer's election, to an Affiliate or a Third Party manufacturer of its choice, all Valneva Know-How in Valneva' s Control as reasonably necessary for Pfizer to implement the then-current process for the Manufacture of the Vaccine and Product (the "**Manufacturing Process**") at Pfizer's facilities or those of an Affiliate or Third Party manufacturing provider designated by Pfizer (such transfer and implementation, as more fully described in the Technology Transfer Plan). All Costs incurred by Pfizer and Valneva in performing activities pursuant to this Section 4.2.5 shall be included as Shared Costs.

4.2.6 **Valneva Disclosure and Knowledge Transfer Obligations**. Without limiting Valneva's obligations pursuant to Section 2.10, Section 2.11, Section 2.12, Section 2.13, Section 2.14, Section 2.15 or Section 4.2.5, during the Development Term, Valneva will:

(a) no less frequently than [***], furnish to Pfizer true, accurate and complete copies of all newly developed Clinical Trial Data and all other newly generated data developed in connection with the Development Plan, in each case in such format as Pfizer may reasonably request (including by download of digital files to a secure website or e-room designated and controlled by Pfizer);

(b) provide to Pfizer a written summary of all activities, discoveries, developments and results attained by Valneva under the Development Plan no less frequently than every [***];

(c) participate in [***] teleconferences to be scheduled by Pfizer;

(d) promptly notify Pfizer of any suspected or actual misconduct, issues pertaining to data integrity or any other information that could reasonably signify or result in a lack of confidence in the accuracy or collection methods of data, each as such may relate to the activities being conducted under the Development Plan;

(e) transfer the IND for the Vaccine to Pfizer immediately following [***]; and

(f) provide Pfizer with all reasonable assistance necessary or desirable (i) to effect the timely and orderly transfer of Valneva Technology and Valneva Materials to Pfizer for Pfizer's use under the Development Plan, (ii) to effect the timely and orderly transfer of Valneva Technology and Valneva Materials to Pfizer in order to enable Pfizer to perform its obligations under Section 5.1 and (iii) for Pfizer to exercise its rights under the licenses and sublicenses set forth in Article 2 that are effective at any given time during the Term.

4.3 **Governance**.

4.3.1 **Joint Steering Committee**.

(a) **Formation**. As soon as practical, but no later than [***] after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"), comprised of individuals with appropriate decision-making authority, to provide high-level oversight and decision-making regarding the activities of the Parties under this Agreement. The Parties anticipate that the JSC will not be involved in day-to-day implementation of activities under this Agreement. [***].

(b) **JSC Term**. The JSC will be dissolved immediately upon expiration of the Development Term unless the Parties otherwise agree in writing.

4.3.2 **Joint Development Committee**.

(a) *Composition.* The Parties will establish a Joint Development Committee, comprised of three (3) representatives of Valneva (including the Program Director for Valneva) and three (3) representatives of Pfizer (including the Program Director for Pfizer). Each Party may replace its representatives to the JDC at any time upon notice to the other Party, *provided that* at all times an equal number of representatives from each Party are appointed to the JDC. Each Party may invite non-voting employees and consultants to attend meetings of the JDC. All members of the JDC and any invitees of either Party described above will agree in writing to be bound to obligations of confidentiality and assignment of inventions no less restrictive than those that bind the Parties under this Agreement. Pfizer shall select from its representatives the chairperson for the JDC (the "**JDC Chair**"). Pfizer may replace the JDC Chair at any time upon notice to Valneva. The JDC shall meet at least [***], or as otherwise agreed to by the Parties, and such meetings may be conducted by telephone, video-conference or in person as determined by the JDC members, provided that with respect to in person meetings, unless otherwise agreed the location of such meetings shall alternate between locations designated by Pfizer and locations designated by Valneva and at least one meeting per year shall be in-person, unless otherwise agreed to by the Parties

(b) [***].

(c) [***].

4.3.3 **General Provisions Applicable to Joint Committees**.

(a) **Meetings and Minutes**. Meetings of any Joint Committee may be called by either Party on no less than [***] notice. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least [***] in advance of the applicable meeting; *provided*, that under exigent circumstances requiring input by the applicable Joint Committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld or delayed. The chairperson of the applicable Joint Committee (or designee of their choosing) shall prepare and circulate for review and approval of the Parties minutes of each meeting within [***] after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the Joint Committee, and such approved minutes shall be signed by each Alliance Manager.

(b) **Procedural Rules**. Each Joint Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement; provided that such rules shall not be subject to a deciding vote of either Party under Section 4.3.3(c) below. A quorum of the Joint Committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on a Joint Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. Each Joint Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party. Employees or consultants of either Party that are not representatives of the Parties on a Joint Committee may attend meetings of such Joint Committee; provided, that such attendees (i) shall not vote or otherwise participate in the decision-making process of the Joint Committee, and (ii) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article 7.

(c) **Joint Committee Dispute Resolution**.

(i) If the JDC, with the assistance of the Alliance Managers cannot, or docs not, reach consensus on an issue at a meeting or within a period of [***] thereafter, then the dispute shall be referred to the JSC to reach mutually acceptable resolutions on all such disputed matters. If the JSC cannot resolve such dispute within a period of [***] thereafter or if the JSC cannot, or docs not, reach consensus on an issue at a meeting of the JSC or within a period often [***] thereafter, then, Pfizer shall have the light to resolve the matter and shall not be subject to resolution pursuant to Section 11.12; provided, however, that Pfizer shall not have the right to resolve disputes with respect to (I) amending the Development Plan to transfer from Valneva the responsibility for the conduct of the Valneva Phase 2 Clinical Trials unless such trials are deemed to be more than [***] behind their planned timelines as outlined in the Development Plan, (II) amending the Development Plan and Development Budget to increase the aggregate amount of Shared Costs pursuant to the Development Plan and Development Budget or (III) assign any additional material obligations to Valneva that arc not otherwise contemplated by the Development Plan or Development Budget (which is reasonable under the circumstances and constitutes a Shared Cost);

(ii) Disputes arising between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, and that are outside of the jurisdiction of the JSC and not within a Party's sole decision-making authority, shall be resolved pursuant to Section 11.12.

(d) **Limitations on Authority**. Notwithstanding any provision of this Section 4.3 to the contrary, (i) each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC or JDC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing, (ii) neither the JSC nor JDC will not have the power to amend this Agreement or otherwise modify or waive compliance with this Agreement in any manner and (iii) neither Party will require the other Party to (A) breach any obligation or agreement that such other Party may have with or to a Third Party or (B) perform any activities that are materially different or greater in scope or more costly than those provided for in the Development Plan then in effect.

4.3.4 **Collaboration Management**.

(a) *Program Directors*. Each Party will appoint a program director to oversee all activities conducted under the Development Plan (each, a "**Program Director**" and together the "**Program Directors**"). Each Party may change its designated Program Director at any time upon written notice to the other Party. The Program Directors will coordinate the efforts of their respective Party in conducting activities under the Development Plan.

(b) *Alliance Managers*. Each Party will appoint a single individual to act as the primary point of contact between the Parties to support the activities under the Development Plan (the "**Alliance Managers**"). Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. The Alliance Managers will:

(i) use good faith efforts to attend (either in person or by telecommunications) all meetings of the JDC and JSC, but will be non-voting members at such meetings;

(ii) be responsible for setting dates and agendas for JDC and JSC meetings, and for capturing and distributing the associated minutes; and

(iii) be the first point of referral for all matters of conflict resolution and bring disputes to the attention of the JDC in a timely manner.

4.4 **Development Plan Expenses**. Except as expressly set forth in Section 3.2, each Party will bear all costs and expenses it incurs in connection with its activities under the Development Plan.

5. PRODUCT DEVELOPMENT AND COMMERCIALIZATION

5.1 **General**. Subject to the provisions of Article 4 and Section 5.3, Pfizer will have sole authority over and control of the Development, Manufacture, Regulatory Approval and Commercialization of Vaccines and Products and will retain final decision-making authority with respect thereto.

5.2 **Valneva Phase 2 Clinical Trials**

5.2.1 Valneva shall continue to act as the sponsor of the On-Going Phase 2 Clinical Trials, will act as the sponsor for initiation of the New Phase 2 Clinical Trial and shall hold the IND relating to the Phase 2 Clinical Trials, subject to Section 4.2.6(e). Valneva will be solely responsible for all Costs associated with the On-Going Phase 2 Clinical Trials.

5.2.2 Valneva shall ensure that the Valneva Phase 2 Clinical Trials are performed in accordance with this Agreement, the applicable protocols and all Applicable Law, including GCP. In the event that any Regulatory Authority, ethics committee or institutional review board has questions related to a protocol or the conduct of the Valneva Phase 2 Clinical Trials Valneva will immediately notify Pfizer of such questions and will work with Pfizer to respond to such questions.

5.2.3 Valneva shall ensure that all directions from any Regulatory Authority and/or ethics committee with jurisdiction over the Valneva Phase 2 Clinical Trials are followed. Further, Valneva shall ensure that all Regulatory Approvals from any Regulatory Authority and/or ethics committee with jurisdiction over the New Phase 2 Clinical Trial are obtained prior to initiating performance of the New Phase 2 Clinical Trial. Pfizer shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority regarding the Valneva Phase 2 Clinical Trials.

5.2.4 Valneva shall ensure that all reports and related documentation required for the Valneva Phase 2 Clinical Trials are maintained in good scientific manner and in compliance with Applicable Law.

5.3 **Diligence**.

5.3.1 **Development Diligence**. Pfizer will use its Commercially Reasonable Efforts to Develop and seek Regulatory Approval for one Product in one indication in the Field in the United States and [***]. Pfizer will have no other diligence obligations with respect to the Development or Regulatory Approval of Products under this Agreement. Valneva will use its Commercially Reasonable Efforts to complete the Valneva Phase 2 Clinical Trials.

5.3.2 **Commercial Diligence**. Pfizer will use its Commercially Reasonable Efforts to Commercialize a given Product in an indication in the Field in each Major Market Country in the Territory where Pfizer has received Regulatory Approval for such Product in such indication. Pfizer will have no other diligence obligations with respect to the Commercialization of Products under this Agreement.

5.3.3 **Exceptions to Diligence Obligations**. Notwithstanding any provision of this Agreement to the contrary, Pfizer will be relieved of all Pfizer Diligence Obligations to the extent that:

(a) Pfizer or Valneva receives, generates, or otherwise becomes aware of, any safety, tolerability or other data indicating or signaling that a Product has or would have an unacceptable risk-benefit profile or is otherwise not suitable for initiation or continuation of Clinical Trials;

(b) Pfizer or Valneva receive any notice, information or correspondence from any applicable Regulator) Authority, or any applicable Regulatory Authority takes any action, that indicates that a Product is unlikely to receive Regulatory Approval;

(c) Valneva fails to fulfill its Development or other obligations under the Development Plan or this Agreement and such failure prevents Pfizer from fulfilling the Pfizer Diligence Obligations; or

(d) the transfer of the Manufacturing Process by Valneva to Pfizer's facilities or those of an Affiliate or Third Party manufacturing provider designated by Pfizer is not completed within the timelines set forth in the Development Plan or Technology Transfer Plan.

5.3.4 **Deemed Satisfaction of Pfizer Diligence Obligations**. Without in any way expanding Pfizer's obligations under this Agreement:

(a) Pfizer's achievement of any Development Event entitling Valneva to receive a specific Development Payment described in Section 3.3 will be conclusive evidence that Pfizer has satisfied all Pfizer Diligence Obligations under this Agreement up to the date that such Development Event is achieved;

(b) Pfizer's payment, and Valneva's acceptance, of any royalties to Valneva pursuant to Section 3.4 will be conclusive evidence that Pfizer has satisfied all Pfizer Diligence Obligations under this Agreement to the date of such payment; provided that if Valneva does not return in full a payment of royalties by Pfizer with a written rejection of such payment within [***] of receipt, Valneva shall be deemed to have accepted such royalty payment.

For the avoidance of doubt, the provisions of Sections 5.3.4(a) and 5.3.4(b) are intended only as examples of diligence constituting satisfaction of the Pfizer Diligence Obligations. Pfizer may fully satisfy the Pfizer Diligence Obligations without achieving any of the specific diligence examples set forth in Sections 5.3.4(a) and 5.3.4(b), above, *provided that* Pfizer otherwise complies with the provisions of Section 5.3.1 or Section 5.3.2, as applicable.

5.3.5 **Assertion of Pfizer Diligence Obligation Claims**. If Valneva is, becomes or reasonably should be aware of facts that might form a reasonable basis to allege that Pfizer has failed to meet any Pfizer Diligence Obligation, then Valneva will promptly notify Pfizer in writing of such potential alleged performance failure (each such potential alleged performance failure, a "**Diligence Issue**"). Promptly upon Pfizer's receipt of any notice of a Diligence Issue pursuant to this Section 5.3.5, the Pfizer Alliance Manager will contact the Valneva Alliance Manager to discuss the specific nature of such Diligence Issue and seek to identify an appropriate corrective course of action. If, no later than [***] after Pfizer's receipt of such a notice, (a) the Parties have not reached consensus regarding whether Pfizer has failed to satisfy its obligations pursuant to Section 5.3.1 or Section 5.3.2 and (b) the Parties' respective Alliance Managers have not agreed upon an appropriate corrective course of action for such Diligence Issue, then such Diligence Issue will be escalated and resolved pursuant to the dispute resolution provisions set forth in Section 11.12. If Valneva fails to notify Pfizer of a Diligence Issue pursuant to this Section 5.3.5 within [***] after the date that Valneva first discovers or reasonably should have discovered such Diligence Issue, then Pfizer will be deemed to have satisfied its obligations under Section 5.3.1 and Section 5.3.2 with respect to such Diligence Issue.

5.3.6 **Remedies for Breach of Pfizer Diligence Obligations**. If Pfizer materially breaches any Pfizer Diligence Obligation and fails to remedy such breach within [***] of Pfizer's receipt of notice of such breach from Valneva, then Valneva may, in its sole discretion, elect to either (a) terminate this Agreement pursuant to the provisions of Section 9.5 on a Product-by-Product and country-by-country basis, but only to the extent that a Product in a given country in the Territory is directly and adversely impacted by such uncured material breach or (b) convert any exclusive license or sublicense granted to Pfizer under this Agreement with respect to a Product in a given country in the Territory into non-exclusive license or sublicense, as applicable, but only to the extent that such Product in such country is directly and adversely impacted by such uncured material breach. Valneva acknowledges and agrees that the elections set forth in this Section 5.3.6: (i) have been negotiated by the Parties to fully address any harm that Valneva may incur as a result of Pfizer's material breach of the Pfizer Diligence Obligations and (ii) constitute Valneva's sole and exclusive remedies with respect to any breach by Pfizer of any Pfizer Diligence Obligation.

5.3.7 **Performance by Pfizer's Affiliates or Sublicensees**. For avoidance of doubt, any actions taken by Pfizer's Affiliates or Sublicensees (or their respective subcontractors) under this Agreement shall be treated as actions taken by Pfizer in regard to satisfaction of the requirements of this Section 5.1.

5.4 **Regulatory Matters**.

5.4.1 **Regulatory Reporting**. Except as necessary for Valneva to complete the Valneva Phase 2 Clinical Trials, Pfizer or its designated Affiliate(s) will have the sole authority to make or file all filings, reports and communications with all Regulatory Authorities with respect to any Vaccine or Product in the Field in the Territory, including all reports required to be filed in order to obtain or maintain any Regulatory Approvals granted for Products in the Field in the Territory and adverse drug experience reports. Upon Pfizer's request, Valneva will provide to Pfizer any data or other information in Valneva's possession and otherwise provide reasonable assistance to Pfizer in connection with any such filings, reports and communications.

5.4.2 **Regulatory Approvals**. Pfizer or its designated Affiliate(s) will have the sole authority to prepare and file applications, in its own name, for Regulatory Approval for Products in the Field in the Territory, including communicating with any Regulatory Authority both prior to and following Regulatory Approval. Subject to Section 4.2.6(e), Valneva hereby assigns any and all INDs, Regulatory Approvals or any other rights or permissions granted by any Regulatory Authority to Pfizer, together with all other regulatory filings and development data, to the extent such assignment is permissible under applicable Law. Further, Valneva will take all actions and provide all assistance reasonably requested by Pfizer to effect the assignments in this Section 5.4.2 immediately following full enrollment of the New Phase 2 Clinical Trial, not including the expansion stage, or at such time as directed by Pfizer.

5.4.3 **Cooperation**. If reasonably requested by Pfizer, Valneva shall assist and cooperate with Pfizer in connection with the preparation of filings, reports and communications to Regulatory Authorities with respect to any Vaccine or Product in the Field in the Territory, at Pfizer's sole expense. Valneva will and will cause its Affiliates to cooperate with Pfizer and all Pfizer Representatives in the event of any inspection by a Regulatory Authority related to any Vaccine or Product or any activities to be performed under this Agreement.

5.5 **Commercialization Activities**.

5.5.1 **General**. Subject to Section 5.1, Pfizer will have sole and exclusive control over all matters relating to the Commercialization of Products in the Field in the Territory, including sole and exclusive control over (a) pricing of Products and (b) the negotiation of Product pricing with Regulatory Authorities and other Third Parties, in each case in the Field in the Territory.

5.5.2 **Branding**. Pfizer or its designated Affiliates or Sublicensees will select and own all Trademarks and Copyrights used in connection with the Commercialization of any and all Products in the Field in the Territory (other than Valneva's corporate names and logos). Neither Valneva nor its Affiliates will use or seek to register, anywhere in the world, any Trademark which is confusingly similar to any Trademark used by or on behalf of Pfizer, its Affiliates or Sublicensees in connection with any Product.

5.6 **Manufacturing**. Except to the extent Valneva has Manufacturing obligations under the Development Plan, Pfizer will have the exclusive right and responsibility to Manufacture such Products itself or through one or more Affiliates or Third Parties selected by Pfizer in its sole discretion. For clarity, Pfizer will have no diligence obligations with respect to the Manufacture of Products except to the extent necessary to fulfill its obligations under Section 5.3.1 or Section 5.3.2.

5.7 **Progress Reporting**. Pfizer will provide Valneva with [***] written reports summarizing Pfizer' s activities to Develop and Commercialize Products. Any information or written report provided by Pfizer to Valneva pursuant to this Section 5.7 will be deemed to be Pfizer's Confidential Information and subject to the provisions of Article 7.

5.8 **Other Pfizer Programs**. Valneva understands and acknowledges that Pfizer may have present or future initiatives or opportunities, including initiatives or opportunities with its Affiliates or Third Parties, involving products, programs, technologies or processes that are similar to, and in some instances may compete with, a Vaccine, Product, program, technology or process covered by this Agreement. Valneva acknowledges and agrees that nothing in this Agreement will be construed as a representation, warranty, covenant or inference that Pfizer will not itself Develop, Manufacture or Commercialize or enter into business relationships with one or more of its Affiliates or Third Parties to Develop, Manufacture or Commercialize products, programs, technologies or processes that are similar to or that may compete with any Vaccine, Product, program, technology or process covered by this Agreement, *provided that*, for clarity, Pfizer will not use Valneva's Confidential Information in breach of this Agreement.

6. INTELLECTUAL PROPERTY.

6.1 **Ownership of Development Program Technology**. Notwithstanding any provision of this Agreement to the contrary, Pfizer will own all right, title and interest in and to Development Program Know-How and Development Program Patent Rights. Valneva agrees to assign and hereby perpetually and irrevocably assigns and agrees to assign, and will cause its Representatives to assign, to Pfizer all right, title and interest throughout the world in and to any and all Development Program Technology. Further, Valneva will, and will cause its Representatives to, execute any and all assignments, applications for domestic and foreign patents and other documents and to do such other acts (including the execution and delivery of instruments of further assurance or confirmation) reasonably requested by Pfizer to assign the Development Program Technology to Pfizer and to permit Pfizer to practice and enforce the Development Program Technology.

6.2 **Patent Rights**.

6.2.1 **Filing, Prosecution and Maintenance of Patent Rights**.

(a) *Valneva Prosecuted Valneva Patent Rights.* Valneva will have the first right to file, prosecute and maintain the Valneva Lyme Genus Patent Rights and the Valneva Platform Patent Rights (the "**Valneva Prosecuted Valneva Patent Rights**") in the Territory using (x) in the case of the Valneva Platform Patent Rights, counsel of its own choice at Valneva's sole expense, and (Y) in the case of the Valneva Lyme Genus Patent Rights, legal counsel reasonably acceptable to Pfizer, which counsel shall be [***] unless the Parties otherwise mutually consent, which consent shall not be unreasonably withheld or delayed (for clarity, it is agreed that Valneva may use internal patent counsel and agents, filing clerks, and paralegals employed by Valneva for directly instructing US and ex-US outside counsel and patent agents, including by providing draft applications and responses). At Valneva's request, Pfizer will cooperate and assist Valneva and outside counsel and agents in the preparation and prosecution of such Patent Rights. Valneva will keep Pfizer advised on the status of the preparation, filing, prosecution, and maintenance of all patent applications and issued patents included within the Valneva Prosecuted Valneva Patent Rights that Valneva is prosecuting and maintaining. Further, Valneva will (i) allow Pfizer a reasonable opportunity and reasonable time to review and provide comment to Valneva's counsel regarding relevant substantive communications to Valneva and drafts of any responses or other proposed substantive filings by Valneva before any applicable filings are submitted to any relevant patent office (or Governmental Authority) in a Major Market Country and (ii) reflect any reasonable and timely comments offered by Pfizer in any final filings submitted by Valneva to any relevant patent office (or Governmental Authority) in a Major

Market Country unless Valneva believes doing so may delay issuance or otherwise compromise patent coverage for the Products. If Valneva elects not to file a patent application included in the Valneva Prosecuted Valneva Patent Rights in any country or elects to cease the prosecution or maintenance of all patent applications and patents of a particular Valneva Prosecuted Valneva Patent Right in any country, Valneva will provide Pfizer with written notice of its decision not less than [***] before any action is required to avoid abandonment or lapse. If Pfizer elects to file or continue such prosecution or maintenance, (v) Pfizer will promptly identify and engage the attorneys and agents who will conduct further activities on Pfizer's behalf and Valneva will reasonably cooperate to promptly transfer the necessary files and execute the necessary forms regarding such transfer, (w) except as set forth in (v), Valneva will have no responsibility with respect to the filing, prosecution or maintenance of, or any expenses incurred in connection with, any such Valneva Prosecuted Valneva Patent Right following Valneva's notice, (x) Pfizer will not disclose any Valneva Confidential Information in connection with such filing, prosecution or maintenance without Valneva' s prior written approval (y) Pfizer will keep Valneva advised on the status of the preparation, filing, prosecution, and maintenance of all such Valneva Prosecuted Valneva Patent Rights and will reasonably consider any comments made by Valneva in connection therewith. Valneva will be solely responsible for all costs incurred in connection with prosecution and maintenance of the Valneva Prosecuted Valneva Patent Rights following the end of the Development Term.

(b) *Pfizer Prosecuted Valneva Patent Rights.* Pfizer will have the first right to file, prosecute and maintain the Valneva VLA-15 Species Patent Rights (the "**Pfizer Prosecuted Valneva Patent Rights**") in the Territory using counsel of its own choice reasonably acceptable to Valneva, which counsel shall be [***] unless the Parties otherwise mutually consent, which consent shall not be unreasonably withheld or delayed (for clarity, it is agreed that Pfizer may use internal patent counsel and agents, filing clerks, and paralegals employed by Pfizer for directly instructing US and ex- US outside counsel and patent agents, including by providing draft applications and responses). At Pfizer's request, Valneva will cooperate and assist Pfizer and outside counsel and agents in the preparation and prosecution of such Patent Rights. Pfizer will keep Valneva advised on the status of the preparation, filing, prosecution, and maintenance of all patent applications and issued patents included within the Pfizer Prosecuted Valneva Patent Rights that Pfizer is prosecuting and maintaining. Further, Pfizer will (i) allow Valneva a reasonable opportunity and reasonable time to review and provide comment to Pfizer's counsel regarding relevant substantive communications to Pfizer and drafts of any responses or other proposed substantive filings by Pfizer before any applicable filings are submitted to any relevant patent office (or Governmental Authority) in a Major Market Country and (ii) reflect any reasonable and timely comments offered by Valneva in any final filings submitted by Pfizer to any relevant patent office (or Governmental Authority) in a Major Market Country unless Pfizer believes doing so may delay issuance or otherwise compromise patent coverage for the Products. It Pfizer elects not to file a patent application included in the Pfizer Prosecuted Valneva Patent Rights in any country or elects to cease the prosecution or maintenance of all patent applications and patents of a particular Pfizer Prosecuted Valneva Patent Right in any country, Pfizer will provide Valneva with written notice of its decision not less than [***] before any action is required to avoid abandonment or lapse. If Valneva elects to file or continue such prosecution or maintenance, (v) Valneva will promptly identify and engage the attorneys and agents who will conduct further activities on Valneva's behalf and Pfizer will reasonably cooperate to promptly transfer the necessary files and execute the necessary forms regarding such transfer, (w) except as set forth in (v), Pfizer will have no responsibility with respect to the filing, prosecution or maintenance of, or any expenses incurred in connection with, any such Pfizer Prosecuted Valneva Patent Right following Pfizer's notice, (x) Valneva will not disclose any Pfizer Confidential Information in connection with such filing, prosecution or maintenance without Pfizer's prior written approval (y) Valneva will keep Pfizer advised on the status of the preparation, filing, prosecution, and maintenance of all such Pfizer Prosecuted Valneva Patent Rights and will reasonably consider any comments made by Pfizer in connection therewith, and (z) Valneva will promptly, and no later than [***] after written request by Pfizer, by written notice to Pfizer update Schedule 8.3.4 to identify all such Valneva Patent Rights to be added thereto, provided that in the absence of such prompt notification, any such Patent Rights will be excluded from the Valid Claim definition. Pfizer will be solely responsible for all costs incurred in connection with prosecution and maintenance of the Pfizer Prosecuted Patent Rights following the end of the Development Term.

(c) *Pfizer Patent Rights and Development Patent Rights*. Pfizer will have the sole right, but no obligation, to file, prosecute and maintain the Patent Rights that it owns or to which it otherwise has control of prosecution rights, including the Pfizer Patent Rights and Development Patent Rights, in its sole discretion. Upon Valneva's reasonable request not more than [***] per twelve (12) month period, Pfizer will provide a status report listing the status of all patent applications and issued patents included within the Development Patent Rights that Pfizer is prosecuting and maintaining. Pfizer will be solely responsible for all costs incurred in connection with prosecution and maintenance of the Pfizer Patent Rights and Development Patent Rights following the end of the Development Term.

(d) *Patent Term Restoration and Extension.* Pfizer will have the exclusive right, but not the obligation, to seek, at its sole expense, in Valneva's name if so required, patent term extensions, and supplemental protection certificates and the like available under Law, including 35 U.S.C. § 156 and applicable foreign counterparts, in any country in the Territory in relation to the Valneva Patent Rights. Valneva and Pfizer will cooperate in connection with all such activities. Pfizer, its agents and attorneys will give due consideration to all suggestions and comments of Valneva regarding any such activities, but in the event of a disagreement between the Parties, Pfizer will have the final decision-making authority; provided, however, that Pfizer will seek (or allow Valneva to seek) to extend any Valneva Patent Right at Valneva's request, including through the use of supplemental protection certificates and the like, unless in Pfizer's reasonable legal determination such Valneva Patent Right may not be extended under Law without limiting Pfizer's right to extend any other Patent Right.

(e) *Clarifications*. For clarity, (i) prosecution under this Section 6.2.1 includes opposition, revocation, post-grant review or other patent office proceedings, unless such proceedings are concurrent with Third Party litigation under Section 6.2.2, in which case the provisions of Section 6.2.2 shall govern the Parties' rights and obligations with respect to such proceedings, and (ii) Third Party declaratory judgment actions or other court actions relating to Patent Rights shall be governed by Section 6.2.2, and by Section 6.2.3 if applicable.

(f) *Liability*. To the extent that a Party is obtaining, prosecuting or maintaining a Patent Right or otherwise exercising its rights under this Section 6.2.1, such Party, and its Affiliates, employees, agents or representatives, will not be liable to the other Party in respect of any act, omission, default or neglect on the part of any such Party, or its Affiliates, employees, agents or representatives, m connection with such activities undertaken in good faith.

(g) *Recording*. If Pfizer deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority(ies) in one or more jurisdictions in the Territory, Valneva will reasonably cooperate to execute and deliver to Pfizer any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Pfizer's reasonable judgment, to complete such registration or recordation.

(h) *Joint Research Agreement*. This Agreement shall be understood to be a joint research agreement under 35 U.S.C. § 103(c)(3) entered into for the purpose of researching, identifying and Developing Pfizer Licensed Products.

6.2.2 **Enforcement and Defense of Patent Rights**.

(a) *Enforcement of Valneva Patent Rights.* Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of a patent under the Valneva VLA-15 Species Patent Rights and Valneva Lyme Genus Patent Rights (the "**Pfizer Enforcement Valneva Patent Rights**") by any Third Party. As between Pfizer and Valneva, Pfizer will have the sole right, but not the obligation, to institute litigation or take other steps to remedy infringement in connection with the Pfizer Enforcement Valneva Patent Rights in the Territory, and any such litigation or steps will be at Pfizer's expense, subject to Valneva's obligation to indemnify Pfizer for such expenses pursuant to Article 10; *provided that* any infringement recoveries resulting from such litigation or steps relating to a claim of Third

Party infringement, after deducting Pfizer's out of pocket expenses (including counsel fees and expenses) in pursuing such claim, will be deemed Net Sales. Pfizer will not, without the prior written consent of Valneva, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Pfizer Enforcement Valneva Patent Right or (ii) requires Pfizer to abandon any Pfizer Enforcement Valneva Patent Right Valneva, upon request of Pfizer, agrees to timely commence or to join in any such litigation, at Pfizer's expense, and in any event to cooperate with Pfizer in such litigation or steps at Pfizer's expense. Valneva will have the right to consult with Pfizer about such litigation and to participate in and be represented by independent counsel in such litigation at Valneva's own expense. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Article 10) as a consequent of any litigation initiated or pursued pursuant to this Section 6.2.2(a) or any unfavorable decision resulting therefrom, including any decision holding any Pfizer Enforcement of Valneva Patent Right or Joint Patent Right invalid or unenforceable.

(b) *Enforcement of Valneva Platform Patent Rights*. Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of a patent under the Valneva Platform Patent Rights by any Third Party. As between Pfizer and Valneva, Valneva will have the first right, but not the obligation, to institute litigation or take other steps to remedy infringement in connection with the Valneva Platform Patent Rights with respect to activities competitive or relevant to those of Pfizer under this Agreement as and to the extent involving the prevention of Lyme Disease (a "**VPPR Infringement**") or with respect to any other matter, and any such litigation or steps will be at Valneva's expense. Pfizer, upon the request of Valneva, agrees to timely join in any such litigation regarding VPPR Infringement, at Valneva's expense, and in any event to cooperate with Valneva in such litigation or steps at Valneva's expense. Pfizer will have the right to consult with Valneva about such litigation regarding VPPR Infringement and to be represented by independent counsel in such litigation at Pfizer's own expense. If Valneva fails to institute and prosecute an action or proceeding to abate any VPPR Infringement within [***] after the first notice of such VPPR Infringement under this section 6.2.2(b), or as soon as possible and in any event no later than [***] if preliminary injunction proceedings are a potential or likely recourse to remedy the infringement, or [***] before the time limit, if any, set forth in the applicable Laws for the filing of such actions, then upon Valneva's written consent (not to be unreasonably withheld), Pfizer shall have the second right, but not the obligation, to commence a suit or take other action to enforce the applicable Valneva Platform Patent Right pursuant to (i) patents described in Section 1 of Schedule 8.3.4 under the heading entitled "Valneva Patent Platform Rights; provided there is no applicable Valid Claim under which Pfizer or Valneva may institute litigation or take other steps to remedy infringement in connection with the Pfizer Enforcement Valneva Patent Rights pursuant to Section 6.2.2(a) and (ii) patents described in Section 2 of Schedule 8.3.4 under the heading entitled "Valneva Patent Platform Rights" in each case of (i) and (ii) against such VPPR Infringement at its own cost and expense, subject to Valneva's obligation to indemnify Pfizer for such expenses pursuant to Article 10; *provided that* any infringement recoveries resulting from such litigation or steps relating to a claim of VPPR Infringement, after deducting Pfizer's out of pocket expenses (including counsel fees and expenses) in pursuing such claim, will be deemed Net Sales. Pfizer will not, without the prior written consent of Valneva, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Valneva Platform Patent Rights or (ii) requires Pfizer to abandon any Valneva Platform Patent Rights. Valneva, upon Pfizer's request, agrees to timely join in any such litigation regarding VPPR Infringement, at Pfizer's expense, and in any event to cooperate with Pfizer in such litigation or steps at Pfizer's expense. Valneva will have the right to consult with Pfizer about such litigation and to be represented by independent counsel in such litigation at Valneva's own expense. Pfizer may request Valneva to institute and prosecute an action or proceeding to abate any VPPR Infringement pursuant to any Valneva Platform Patent Right described in Section 1 of Schedule 8.3.4 under the heading entitled "Valneva Patent Platform Rights." In the event Pfizer makes such a request and Valneva fails to institute and prosecute an action or proceeding to abate such VPPR Infringement within [***] after such request, then, on a country-by country basis, any payments owed with respect to a Product pursuant to Section 3.4 will be reduced by [***] for the remainder of the applicable Royalty Term or until such VPPR Infringement ceases, whichever occurs first.

(c) *Enforcement of Pfizer Patent Rights and Development Patent Rights*. Pfizer will have the sole right, but no obligation, to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringing or challenging the validity or enforceability of any Pfizer Patent Right or Development Patent Right.

(d) *Biosimilar Notices*.

(i) *Valneva Cooperation*. Upon Pfizer' s request, Valneva will use Commercially Reasonable Efforts to assist and cooperate with Pfizer in (A) establishing a strategy for responding to requests for information from Regulatory Authorities and Third Party requestors and (B) preparing submissions responsive to any Biosimilar Notices received by Pfizer; provided that Pfizer will make the final decisions with respect to such strategy and any such responses.

(ii) *Compliance with Biosimilar Notices.* Pfizer will have the sole right in its discretion to comply with the applicable provisions of 42 U.S.C. § 262(1) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future regarding biologic products in the United States, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction, in each case, with respect to any Biosimilar Notice received by Pfizer from any Third Party regarding any Product that is being Commercialized in the applicable jurisdiction, and the exchange of information between any Third Party and Pfizer pursuant to such requirements; provided that, prior to any submission of information by Pfizer to a Third Party, Valneva will have the right to review the patent information included in such proposed submission, solely with respect to Valneva Patent Rights, and to make suggestions as to any changes to such patent information that Valneva reasonably believes to be necessary; *provided* further that Pfizer will determine the final content of any such submission. In the case of a Product approved in the United States under the PHS Act (or, in the case of a country in the Territory other than the United States, any similar Law), to the extent permitted by applicable Law, Pfizer, as the sponsor of the application for the Product, will be the "reference product sponsor" under the PHS Act. Pfizer will give written notice to Valneva of receipt of a Biosimilar Notice received by Pfizer with respect to a Product, and Pfizer will consult with Valneva with respect to the selection of any Valneva Patent Rights to be submitted pursuant to 42 U.S.C. § 262(1) (or any similar law in any country of the Territory outside the United States); *provided* that Pfizer will have final say on such selection of Valneva Patent Rights. Valneva agrees to be bound and will cause its Affiliates and all Third Party Licensors to be bound by the confidentiality provisions of 42 U.S.C. § 262(1)(1)(B)(iii). In connection with any action brought by Pfizer under this Section 6.2.2(d). Valneva, upon Pfizer's request, will reasonably cooperate and will cause its Affiliates and all Third Party Licensors to reasonably cooperate with Pfizer in any such action, including timely commencing or joining in any action brought by Pfizer under this Section 6.2.2(d). Solely to the extent any Valneva Patent Rights are involved in any such action, the Parties' rights and responsibilities regarding any action will be determined in accordance with this Section 6.2.2(d).

6.2.3 **Other Actions by Third Parties**. Each Party will promptly notify the other Party in the event of any legal or administrative action by any Third Party involving any Valneva Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, interference, reexamination or compulsory license proceeding. Pfizer will have the first right, but no obligation, to defend against any such action involving any Pfizer Enforcement of Valneva Patent Right or Joint Patent Right, in its own name (to the extent permitted by applicable Law), and any such defense will be at Pfizer' s expense, subject to Valneva' s indemnification obligations under Article 10. Valneva, upon Pfizer' s request, agrees to join in any such action at Pfizer's expense and in any event to cooperate with Pfizer at Pfizer' s expense. If Pfizer fails to defend against any such action involving a Valneva Patent Right or Joint Patent Right, then Valneva will have the right to defend such action, in its own name, and any such defense will be at Valneva's expense. Valneva will have the sole right, but no obligation, to defend against any such action involving any Valneva Platform Patent Right, in its own name, and any such defense will be at Valneva's expense.

6.2.4 **Purple Book Listings**. To the extent of any Valneva Patent Rights Covering a Product, the Parties shall cooperate with each other to enable Pfizer to make filings with Regulatory Authorities, as required or allowed in connection with (i) in the United States, the FDA's Purple Book and the Biologics Price Competition and Innovation Act and (ii) outside the United States, under the national implementations of Article 10.l(a)(iii) of Directive 2001/EC/83 or other international equivalents thereof. Pfizer shall consider Valneva's reasonable requests in connection therewith, including meeting any submission deadlines, in each case, to the extent required or permitted by Applicable Law.

6.2.5 **Paragraph IV Type Notices**. Notwithstanding any provision of this Agreement to the contrary, each Party will immediately (but in no event later than [***] following receipt or discovery, whichever occurs first) give written notice to the other of any certification of which it becomes aware filed pursuant to any statutory or regulatory requirement in any country in the Territory similar to 21 U.S.C. § 355(b)(2)(A)(iv) or§ 355(j)(2)(A)(vii)(IV) (or any amendment or successor statute thereto) claiming that any Valneva Patent Right covering any Vaccine or Product is invalid or that infringement will not arise from the Development, Manufacture, use or Commercialization in the Territory of such Vaccine or Product by a Third Party. Upon the giving or receipt of such notice, Pfizer will have the sole right, but not the obligation, to bring an infringement action against such Third Party. In connection with any action brought by Pfizer under this Section 6.2.5, Valneva, upon Pfizer's request, will reasonably cooperate with Pfizer in any such action at Pfizer's expense and will timely commence or join in any such action at Pfizer's request and expense. In the event of any conflict between the terms of this Section 6.2.5 and the terms of Section 6.2.2(a), the terms of this Section 6.2.5 will control and govern.

6.2.6 **Allegations of Infringement and Right to Seek Third Party Licenses**.

(a) *Notice.* If the Development, Manufacture, Commercialization or use of any Vaccine or Product, the practice of any Valneva Technology, or the exercise of any other right granted by Valneva to Pfizer hereunder (collectively, the "**Licensed Activities**") by Pfizer or any of its Affiliates or Sublicensees is alleged by a Third Party to infringe, misappropriate or otherwise violate such Third Party's Patent Rights or other Intellectual Property Rights or the Valneva otherwise identifies any Third Party Patent Rights or other Intellectual Property Rights that may be relevant to such activities, Valneva will, promptly upon becoming aware of such allegation or identification, notify Pfizer in writing.

(b) *Pfizer Option to Negotiate*. If Pfizer determines, in its sole discretion, that, in order for Pfizer, its Affiliates or Sublicensees to engage in the Licensed Activities, it is necessary or desirable to obtain a license under one or more Patent Rights or other Intellectual Property Rights Controlled by a Third Party (collectively, "**Third Party IP Rights**"), then Pfizer will have the sole right, but not the obligation, to negotiate and enter into a license or other agreement with such Third Party. All amounts payable under any such license or agreement with a Third Party will reduce Pfizer's royalty obligations under this Agreement as and to the extent provided in Section 3.4.4(a).

6.2.7 **Third Party Infringement Suits**. Each of the Parties will promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Pfizer or Valneva or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture, Commercialization or use of any Vaccine or Product or the practice of any Valneva Technology or Joint Technology (any such suit or other action referred to herein as an "**Infringement Claim**"). In the case of any Infringement Claim against Pfizer (including its Affiliates or Sublicensees) alone or against both Pfizer and Valneva (including its Affiliates), Pfizer will have the right, but not the obligation, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. Valneva, upon request of Pfizer, agrees to cooperate with Pfizer at Pfizer's expense. Valneva will have the right to consult with Pfizer concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which Valneva is a party at Valneva's own expense. If Pfizer elects to control the defense of any Infringement Claim and Valneva is obligated under Section 10.3 to indemnify Pfizer (including any Pfizer Indemnified Party) with respect to such Infringement Claim, then (a) Pfizer will bear [***] of its own attorneys' fees incurred in investigating, preparing or defending such Infringement Claim notwithstanding the provisions of Section 10.3 and (b) Valneva will otherwise indemnify Pfizer and any applicable Pfizer Indemnified Parties to the full extent provided for under Section 10.3. In the case of any Infringement Claim against Valneva alone, Pfizer will have the right to consult with Valneva concerning such Infringement Claim and Pfizer, upon request of Valneva, will reasonably cooperate with Valneva at Valneva's expense.

6.3 **Enforcement and Defense of Know-How**.

6.3.1 **Misappropriation Actions Relating to Valneva Know-How and Joint Know-How**. Each Party will promptly notify the other in the event of any actual, potential or suspected misappropriation of any Valneva Know-How or Joint Know-How by any Third Party. As between Pfizer and Valneva, Pfizer will have the first right, except as otherwise provided in this Section 6.3.1, but not the obligation, to institute litigation or take other steps to remedy misappropriation in connection therewith, and any such litigation or steps will be at Pfizer's expense, subject to Valneva's obligation to indemnify Pfizer for such expenses pursuant to Article 10. Pfizer will not, without the prior written consent of Valneva, enter into any compromise or settlement relating to such litigation that (a) admits that all or any portion of the Valneva Know-How or Joint Know- How is not protectable under relevant trade secret Laws or (b) requires Pfizer to abandon trade secret protection for any Valneva Know-How or Joint Know-How. In order to establish standing, Valneva, upon request of Pfizer, agrees to timely commence or to join in any such litigation, at Pfizer's expense, and in any event to cooperate with Pfizer in such litigation or steps at Pfizer's expense. Valneva will have the right to consult with Pfizer about such litigation and to participate in and be represented by independent counsel in such litigation at Valneva's own expense. If Pfizer fails to institute such litigation or otherwise take steps to remedy the misappropriation of any Valneva Know-How or Joint Know-How (i) within [***] of its receipt of notice thereof in the case of any Valneva Know-How, or (ii) within [***] of its receipt or notice thereof in the case of any Joint Know-How, then Valneva will have the right, but not the obligation, upon [***] prior notice to Pfizer, at Valneva's expense, to institute any such litigation; *provided, however*, that Valneva will only have the foregoing right if Pfizer would not be required (by Law or otherwise) to join such litigation as a party and such litigation would not involve any Pfizer Technology that covers or relates to a then-existing Product. Pfizer will have no obligation to cooperate with Valneva in any such litigation.

6.3.2 **Misappropriation Actions Relating to Pfizer Know-How**. Pfizer will have the sole right, but no obligation, to take action to obtain a discontinuance of misappropriation or bring suit against a Third Party that is misappropriating, or that is suspected of misappropriating, any Pfizer Know-How.

7. CONFIDENTIALITY.

7.1 **Confidentiality**. Except to the extent expressly authorized by this Agreement, the Parties agree that, during the Term and for [***] years thereafter, each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement.

7.2 **Authorized Disclosure**.

7.2.1 **Disclosure to Party Representatives**. Notwithstanding the foregoing provisions of Section 7.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's Representatives who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 7.

7.2.2 **Disclosure to Third Parties**. Notwithstanding the foregoing prov1s1ons of Section 7.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:

(a) to Governmental Authorities (i) to the extent desirable to obtain or maintain INDs or Regulatory Approvals for any Vaccine or Product within the Territory, and (ii) in order to respond to inquiries, requests or investigations relating to Vaccines, Products or this Agreement;

(b) to outside consultants (including any professional advisor), potential acquisition partners (including any potential successors in interest), private investors or financing sources, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent desirable to develop, register or market any Vaccine or Product; provided that the Receiving Party will obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information;

(c) in connection with filing or prosecuting Development Program Patent Rights or Joint Patent Rights or Trademark rights as permitted by this Agreement;

(d) in connection with prosecuting or defending litigation pursuant to Sections 6.2 or 6.3 or any other litigation directly related to a Vaccine or Product in the Field;

(e) subject to the provisions of Section 7.4.2, in connection with or included in scientific presentations and publications relating to Vaccines or Products, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites;

(f) Pfizer may disclose Confidential Information belonging to Valneva (including the terms of the Agreement) to any bona fide or potential sublicensee or co-development or co-promotion partner who has agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 7; and

(g) to the extent necessary or desirable in order to enforce its rights under this Agreement.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to clause (a) or any of clauses (c) through (e) of this Section 7.2.2, then the disclosing Party will to the extent possible give reasonable advance written notice of such disclosure to the other Party and take such measures to ensure confidential treatment of such information as is reasonably required by the other Party, at the other Party's expense.

7.3 **SEC and AMF Filings and Other Disclosures**. Either Party may disclose the terms of this Agreement and make any other public written disclosure regarding the existence of, or performance under, this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with (a) applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or the French *Reglement general de l'Autorite des marches financiers* or (b) any equivalent Governmental Authority, securities exchange or securities regulator in any country in the Territory. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 7.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the Party disclosing pursuant to this Section 7.3 providing as much advance notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 7.3, such Party will, at its own expense, seek such confidential treatment of confidential portions of this Agreement and such other terms, as may be reasonably requested by the other Party and limit its disclosure of such Confidential Information to only that required to comply with applicable Law.

7.4 **Public Announcements; Publications**.

7.4.1 **Announcements**. Except as may be expressly permitted under Section 7.3, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. For the sake of clarity, nothing in this Agreement will prevent Pfizer from making any scientific publication or public announcement with respect to any Product under this Agreement; *provided however*, that, except as permitted under Section 7.2, Pfizer will not disclose any of Valneva's Confidential Information in any such publication or announcement without obtaining Valneva's prior written consent to do so.

7.4.2 **Publications**. During the Term, Valneva will submit to Pfizer for review and approval any proposed academic, scientific and medical publication or public presentation which contains Pfizer's Confidential Information. In addition, Valneva will submit to Pfizer for review and approval any proposed publication or public presentation proposed by Valneva or its Affiliates or any of their respective Representatives that relates to the activities conducted under this Agreement, including the Development Plan, or otherwise relating to the Valneva Technology, the Valneva Materials, the Pfizer Technology or any Vaccine or Product. In both instances, such review and approval will be conducted for the purposes of preserving the value of the Valneva Technology, Valneva Materials, the Pfizer Technology, the Joint Technology and the rights granted or to be granted to Pfizer hereunder and determining whether any portion of the proposed publication or presentation containing Pfizer's Confidential Information should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted to Pfizer no later than [***] before submission for publication or presentation (the "**Review Period**"). Pfizer will provide its comments with respect to such publications and presentations within [***] of its receipt of such written copy. The Review Period may be extended for an additional [***], or such longer time as agreed to by the Parties, in the event Pfizer can, within [***] of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. Valneva will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 7.4.2, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

7.5 **Obligations in Connection with Change of Control**. If Valneva is subject to a Change of Control, Valneva will, and it will cause its Representatives to, ensure that no Confidential Information of Pfizer is released to (a) any Affiliate of Valneva that becomes an Affiliate as a result of the Change of Control or (b) any other Representatives of Valneva (or of the relevant surviving entity of such Change of Control) who become Valneva Representatives as a result of the Change of Control, unless such Affiliate or other Representatives, as applicable, have signed individual confidentiality agreements which include equivalent obligations to those set out in this Article 7. If any Change of Control of Valneva occurs, Valneva will promptly notify Pfizer, share with Pfizer the policies and procedures it plans to implement in order to protect the confidentiality of Pfizer's Confidential Information prior to such implementation and make any adjustments to such policies and procedures that are reasonably requested by Pfizer.

8. REPRESENTATIONS AND WARRANTIES.

8.1 **Mutual Representations and Warranties**. Each of Valneva and Pfizer hereby represents and warrants to the other Party that:

8.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

8.1.2 the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

8.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

8.1.4 this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms; and

8.1.5 the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Execution Date.

8.2 **Mutual Covenants**. Each of Valneva and Pfizer hereby covenants to the other Party that, from the Execution Date until expiration or termination of this Agreement, it will perform its obligations under this Agreement in compliance with applicable Laws.

8.3 **Representations and Warranties of Valneva**. Valneva hereby represents and warrants to Pfizer that:

8.3.1 except as expressly disclosed in Schedule 8.3.1, Valneva is the sole and exclusive owner of the Valneva Technology and Valneva Materials, all of which is free and clear of any claims, liens, charges or encumbrances;

8.3.2 Valneva has and will have the full right, power and authority to (i) grant all of the right, title and interest in the licenses and other rights granted or to be granted to Pfizer, Pfizer's Affiliates or Pfizer's Sublicensees under this Agreement and (ii) perform its obligations under this Agreement;

8.3.3 Schedule 8.3.3 sets forth a true and complete list of all Vaccines discovered or developed by Valneva or its Affiliates on or prior to the Execution Date;

8.3.4 as of the Execution Date (a) Schedule 8.3.4 sets forth a true and complete list of all Patent Rights (i) owned or otherwise Controlled by Valneva or its Affiliates or (ii) to which Valneva or its Affiliates have been granted or otherwise transferred any right to practice under, in each case that relate to the Vaccines or Products or the Parties' activities in the Development Program, (b) each such Patent Right remains in full force and effect and (c) Valneva or its Affiliates have timely paid, or caused the appropriate Third Parties to pay, all filing and renewal fees payable with respect to such Patent Rights;

8.3.5 as of the Execution Date, Valneva has disclosed to Pfizer all material scientific and technical information and all information relating to safety and efficacy known to it or its Affiliates with respect to the Vaccines and Products;

8.3.6 to Valneva's knowledge, the Valneva Patent Rights, are valid and enforceable patents and, as of the Execution Date, no Third Party (a) is infringing any Valneva Patent Right or (b) has challenged or threatened to challenge the ownership, scope, validity or enforceability of, or Valneva's or any Current Licensor's rights in or to, any Valneva Patent Right (including, by way of example, through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);

8.3.7 Valneva, its Affiliates and third parties and Representatives acting on Valneva's behalf in connection with this Agreement have complied in all material respects with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Valneva Patent Rights;

8.3.8 Valneva, its Affiliates, and to its knowledge all third parties and Representatives acting on Valneva's behalf, have and will comply in all material respects with all applicable Law and accepted pharmaceutical industry business practices, including, to the extent applicable, the FD&C Act (21 U.S.C. § 301, et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA, consistent with the 'Compliance Program Guidance for Pharmaceutical Manufacturers' published by the Office of Inspector General, U.S. Department of Health and Human Services;

8.3.9 with respect to any Vaccines, Products, payments or services provided under this Agreement, Valneva, its Affiliates, and to its knowledge all third parties and Representatives acting on Valneva's behalf, have not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment;

8.3.10 Valneva, its Affiliates, and to its knowledge all third parties and Representatives acting on Valneva's behalf, have and will continue to comply with the laws and regulations of the countries where it operates, including anti-bribery and anti-corruption laws, including, to the extent applicable, the U.S. Foreign Corrupt Practices Act of 1977 and the U.K. Bribery Act 2010, accounting and record keeping laws, and laws relating to interactions with healthcare professionals or healthcare providers (collectively, "**HCPs**") and Government Officials;

8.3.11 Valneva has implemented policies and procedures commensurate with its current risk profile and shall review said policies from time to time setting out rules governing interactions with HCPs and Government Officials, engagement of Third Parties, including, where appropriate, due diligence ("**Policies**"), and its Policies mandate a robust set of internal controls, including accounting controls, designed to ensure the making and keeping of fair and accurate books, records and accounts, on its operations around the world and apply worldwide to all its employees, subsidiaries, and Third Parties acting on its behalf;

8.3.12 Valneva provides training to its officers, directors, employees and where appropriate, its other Representatives on its Policies;

8.3.13 Valneva has an assurance program involving regular monitoring and auditing of activities to ensure compliance with its Policies and the adequacy of internal controls, and remediation of identified issues;

8.3.14 Valneva regularly reviews its Policies as part of its internal processes of improvement, and, from time to time, benchmarks it against the standards of the industry; and

8.3.15 Valneva is, as between the Parties, solely responsible to ensure Compliance by it and its Affiliates.

8.3.16 except as expressly disclosed in Schedule 8.3.16, Valneva has independently developed all Valneva Know-How and Valneva Materials or otherwise has a valid right to use, and to permit Pfizer, Pfizer's Affiliates and Pfizer's Sublicensees to use, the Valneva Know-How and Valneva Materials for all permitted purposes under this Agreement;

8.3.17 Valneva has obtained from all inventors of Valneva Technology existing as of the Execution Date, valid and enforceable agreements assigning to Valneva each such inventor's entire right, title and interest in and to all such Valneva Technology;

8.3.18 no Valneva Technology existing as of the Effective Date is subject to any funding agreement with any government or Governmental Authority;

8.3.19 neither Valneva nor any of its Affiliates are party to or otherwise subject to any agreement or arrangement which limits the ownership or licensed or sublicensed rights of Pfizer or its Affiliates with respect to, or limits the ability of Pfizer or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any Intellectual Property Right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned to Pfizer or its Affiliates pursuant to this Agreement;

8.3.20 there are no Valneva Third Party Agreements and no Third Party has any right, title or interest in or to, or any license under, any Valneva Technology or Valneva Materials for the use, Development, Manufacture, Commercialization or Exploitation by Valneva or Pfizer (or their respective Affiliates or Sublicensees) of any Vaccine or any Product;

8.3.21 to Valneva's knowledge, as of the Execution Date, the use, Development, Manufacture or Commercialization by Valneva or Pfizer (or their respective Affiliates or Sublicensees) of any Vaccine or any Product (a) does not and will not infringe any issued patent of any Third Party or (b) will not infringe the claims of any published Third Party patent application when and if such claims issue;

8.3.22 as of the Execution Date, there is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the knowledge of Valneva, threatened against Valneva or any of its Affiliates or (b) judgment or settlement against or owed by Valneva or any of its Affiliates, in each case in connection with the Valneva Technology, the Valneva Materials, any Vaccine or any Product or relating to the transactions contemplated by this Agreement for the use, Development, Manufacture or Commercialization by Valneva or Pfizer (or their respective Affiliates or Sublicensees) of any Vaccine or any Product;

8.3.23 Valneva has valid and enforceable agreements with all Persons acting by or on behalf of Valneva or its Affiliates under this Agreement which require such persons to assign to Valneva their entire right, title and interest in and to all Valneva Technology and Development Program Technology;

8.3.24 as of the Execution Date, Valneva is not, and to Valneva's knowledge, no Current Licensor, Representative of Valneva or Third Party acting on behalf of Valneva (in each case, as applicable) is, debarred by any Regulatory Authority or the subject of debarment proceedings by any Regulatory Authority and, in the course of the discovery or pre-clinical development of any Vaccine or Product. Valneva has not and, to the knowledge of Valneva, no Current Licensor, Representative of Valneva or any Third Party' acting on behalf of Valneva (in each ease, as applicable) have used any employee or consultant that is debarred by any Regulatory Authority or, to the knowledge of Valneva, is the subject of debarment proceedings by any Regulatory Authority; and

8.3.25 as of the Execution Date, Valneva has no knowledge of (a) any prior art or other facts that Valneva believes would result in the invalidity or unenforceability of any issued or pending claims included in the Valneva Patent Rights, (b) any inequitable conduct or fraud on any patent office with respect to any of the Valneva Patent Rights or (c) any Person (other than Persons identified in the applicable patent applications or patents, as inventors of inventions disclosed in the Valneva Patent Rights) who claims to be an inventor of an invention disclosed in the Valneva Patent Rights.

8.4 **Accuracy of Representations and Warranties**.

8.4.1 Valneva will take no action which would render any representation or warranty contained in Section 8.1 or Section 8.3 inaccurate or untrue in any material respect.

8.4.2 Valneva will promptly notify Pfizer of any lawsuits, claims, administrative actions, regulatory inquiries or investigations, or other proceedings asserted or commenced against Valneva or its Representatives involving in any material way the ability of Valneva to deliver the rights, licenses and sublicenses granted herein.

8.4.3 Valneva will promptly notify Pfizer in writing of any facts or circumstances which come to Valneva' s attention and which cause, or through the passage of time may cause, any of the representations and warranties contained in Section 8.1, Section 8.3, Section 11.11 or otherwise in this Agreement to be untrue or misleading in any material respect at any time during the Term; and in addition to the foregoing, with regard to any of the representations under Section 11.11, Valneva will suspend all affected activities (including making any related payments) under this Agreement, unless and until Pfizer determines that Valneva may resume such activities.

8.5 **Valneva Covenants**. In addition to the covenants made by Valneva elsewhere in this Agreement, Valneva hereby covenants to Pfizer that, from the Execution Date until expiration or termination of this Agreement:

8.5.1 Valneva will not, and will cause its Affiliates not to (a) license, sell, assign (other than in a connection with a permitted assignment of this Agreement by Valneva pursuant to Section 11.1) or otherwise transfer to any Person (other than Pfizer or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any Valneva Technology, Valneva Materials or Development Program Technology (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any Valneva Technology or Development Program Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding Obligation that is or would be inconsistent with the licenses and other rights granted (or that may be granted) to Pfizer or its Affiliates under this Agreement;

8.5.2 Valneva will not (a) take any action that diminishes the rights under the Valneva Technology, Valneva Materials or Development Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement or (b) fail to take any action that is reasonably necessary to avoid diminishing the rights under the Valneva Technology, Valneva Materials or Development Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement;

8.5.3 With respect to Human Material used, including collection or transfer, by Valneva, its Affiliates or permitted subcontractors in conducting activities under this Agreement, (a) such use shall be solely as described in the Development Plan and shall be within the scope of and consistent with Valneva's ethical approval policies, (b) Valneva will, and will cause its Affiliates or permitted subcontractors to, handle and use the Human Material in accordance with all applicable Laws and the ICF, (c) Valneva will provide the ICF to Pfizer upon request by Pfizer, (d) Valneva will only allow its employees, contractors or agents trained in handling similar materials or data in their assigned job functions to handle the Human Material, (e) the Human Material will be used for research purposes only and not be used for treatment of or administration to humans and (f) if Valneva procures any Human Material from a third party such as a sample bank, Valneva shall ensure that the collection and transfer of the Human Material and the use of the Human Material for purposes of the Development Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects;

8.5.4 Valneva will (a) not enter into any Valneva Third Party Agreement that adversely affects (i) the rights granted (or that may be granted) to Pfizer, Pfizer's Affiliates or Sublicensees hereunder or (ii) Valneva's ability to fully perform its obligations hereunder; (b) not amend or otherwise modify any Valneva Third Party Agreement or consent or waive rights with respect thereto in any manner that (A) adversely affects the rights granted (or that may be granted) to Pfizer or Pfizer's Affiliates or Sublicensees hereunder or (B) Valneva's ability to fully perform its obligations hereunder; (c) promptly

furnish Pfizer with true and complete copies of all Valneva Third Party Agreements and related amendments executed following the Execution Date; (d) remain, and cause its Affiliates to remain, in compliance in all material respects with all Valneva Third Party Agreements; and (e) furnish Pfizer with copies of all notices received by Valneva or its Representatives relating to any alleged breach or default by Valneva or its Representatives under any Valneva Third Party Agreement within [***] after receipt thereof;

8.5.5 Valneva will not enter into or otherwise allow itself or its Representatives to be subject to any agreement or arrangement which limits the ownership or licensed rights of Pfizer or its Affiliates with respect to, or limits the ability of Pfizer or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any Intellectual Property Right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned (or that may be licensed or assigned) to Pfizer or its Affiliates pursuant to this Agreement;

8.5.6 Valneva will maintain valid and enforceable agreements with all Persons acting by or on behalf of Valneva or its Affiliates under this Agreement which require such Persons to assign to Valneva their entire right, title and interest in and to all Valneva Technology, Valneva Materials and Development Program Technology;

8.5.7 Valneva has made or will make any payments owing to any inventor of any Valneva Technology, Development Program Technology or Joint Technology or any other Person that is required in connection with the creation or exploitation of or transfer of rights to such Valneva Technology, Valneva Materials or Development Program Technology; and

8.5.8 during the Term, Valneva will promptly notify Pfizer in the event that it learns of:

(a) any prior art or other facts that Valneva believes would result in the invalidity or unenforceability of any of the claims including in any of the Valneva Patent Rights or Development Program Patent Rights; or

(b) any inequitable conduct or fraud on the patent office with respect to any of the Valneva Patent Rights or Development Program Patent Rights; or

(c) any Person (other than Persons identified as inventors of inventions disclosed in the Valneva Patent Rights) who claims to be an inventor of an invention disclosed in the Valneva Patent Rights; or

(d) any lawsuits, claims, administrative actions, government inquiries or investigations, or other proceedings related to the activities contemplated under this Agreement.

8.5.9 Valneva has received a copy of and will comply with Pfizer's Anti-Bribery and Anti-Corruption Principles attached hereto as Exhibit C.

8.6 **Representation by Legal Counsel**. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

8.7 **Disclaimer**. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

9. GOVERNMENT APPROVALS; TERM AND TERMINATION.

9.1 **Antitrust Filing**. Each of Valneva and Pfizer will, within [***] after the Execution Date (or such later time as may be agreed to in writing by the Parties) make an appropriate filing under the HSR Act or any Foreign Antitrust Laws (the "**Antitrust Filings**") if applicable in the reasonable opinion of either Party with respect to the transactions contemplated under this Agreement. The Parties will cooperate with one another to the extent necessary in the preparation of any such Antitrust Filings. Valneva will not agree to any voluntary extension or delay of any statutory waiting period or withdraw any of its Antitrust Filings pursuant to the HSR Act or any Foreign Antitrust Laws unless Pfizer has given its prior written consent to such extension or delay. Each Party will be responsible for its own costs, expenses, and filing fees associated with any Antitrust Filing; *provided*, *however*, that Pfizer will be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of Valneva) required to be paid to any Governmental Authority in connection with submitting any such HSR Filing.

9.2 **Termination Upon Antitrust Filing Denial**. In the event that the Parties make an Antitrust Filing under Section 9.1, this Agreement will terminate (a) at Pfizer's option, immediately upon notice to Valneva, in the event that any Governmental Authority seeks a temporary restraining order, preliminary or permanent injunction or other legal restraint under the HSR Act or any Foreign Antitrust Laws against Valneva and Pfizer to enjoin the transactions contemplated by this Agreement, (b) at the election of either Party, immediately upon notice to the other Party, in the event that any Governmental Authority obtains a temporary restraining order, preliminary or permanent injunction or other legal restraint under the HSR Act or any Foreign Antitrust Laws against Valneva or Pfizer to enjoin the transactions contemplated by this Agreement or (c) at the election of either Party, immediately upon notice to the other Party, in the event that the Antitrust Clearance Date will not have occurred on or prior to [***] after the effective date of any applicable Antitrust Filings. Notwithstanding the foregoing, this Section 9.2 will not apply in the event that Pfizer reasonably determines that no Antitrust Filing is required. Termination of this Agreement pursuant to this Section 9.2 will be subject to the terms of Section 9.8.1.

9.3 **Other Government Approvals**. Each of Valneva and Pfizer will cooperate with the other Party and use Commercially Reasonable Efforts to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated hereby including the collection of Human Material.

9.4 **Term**. The term of this Agreement (the "**Term**") will commence on the Effective Date and extend on a country-by-country basis (in the Territory), unless this Agreement is terminated earlier in accordance with this Article 9, until the last to expire of any Royalty Term for any Product in such country in the Territory. Notwithstanding any provision of this Agreement to the contrary, upon expiration of this Agreement, Pfizer will retain the fully paid-up, perpetual, irrevocable royalty-free license to each Product as set forth in Section 3.4.3.

9.5 **Termination by Valneva**. Valneva may terminate this Agreement for cause, at any time during the Term, by giving written notice to Pfizer in the event that Pfizer commits a material breach of its obligations under this Agreement and such material breach remains uncured (a) [***] for a material breach that is a failure of Pfizer to make an undisputed payment owed to Valneva under this Agreement and (b) [***] for all other material breaches, in each case measured from the date written notice of such material breach is given to Pfizer; *provided*, *however*, that if any breach is not reasonably curable within [***] and if Pfizer is using Commercially Reasonable Efforts to cure such breach, such termination will be delayed for a time period to be agreed by both Parties in order to permit Pfizer a reasonable period of time to cure such breach. If the alleged material breach relates to non-payment of any amount due under this Agreement, the cure period will be tolled pending resolution of any bona fide dispute between the Parties as to whether such payment is due.

9.6 **Termination by Pfizer**.

9.6.1 **Termination for Convenience**. Upon at least [***] prior written notice to Valneva, Pfizer may terminate this Agreement on a Product-by-Product and country-by-country basis, or in its entirety, without cause, for any or no reason.

9.6.2 **Termination for Cause**.

(a) *General*. Pfizer may terminate this Agreement for cause with respect to one or more Products in one or more countries in the Territory or may terminate this Agreement in its entirety, at any time during the Term, by giving written notice to Valneva in the event that Valneva commits a material breach of its obligations under this Agreement and such material breach remains uncured for [***], measured from the date written notice of such material breach is given to Valneva; provided, however, that if any breach is not reasonably curable within [***] and if Valneva is using its Commercially Reasonable Efforts to cure such breach, such termination will be delayed for a time period to be agreed by both Parties in order to permit Valneva a reasonable period of time to cure such breach.

(b) Notwithstanding anything to the contrary in this Agreement, Pfizer may terminate this Agreement in whole or relevant part, immediately and without regard to any cure period, if, in Pfizer's reasonable opinion, a violation of Global Trade Control Laws has occurred prior to the first Regulatory Approval of a Product anywhere in the Territory which will materially and adversely affect Pfizer's ability to Commercialize the Product. Any such termination will be deemed for cause under Section 9.7.1(b), under which Pfizer will not be responsible for any related payments due, even if activities have already occurred. Valneva will be responsible for reimbursing Pfizer for any payments due to Pfizer under this Agreement that are blocked due to violation of Global Trade Control Laws.

9.6.3 **Termination for Compliance with the Law-related Breach**. Pfizer may terminate this Agreement if Valneva breaches any of the representations and warranties set forth in Sections 8.3.8 through 8.3.10 in any material respect or if Pfizer learns that improper payments are being or have been made to Government Officials by Valneva with respect to services performed in connection with this Agreement which will materially and adversely affect Pfizer's ability to Develop and Commercial the Product. Further, in the event of such termination, Valneva shall not be entitled to any further payment, regardless of any activities undertaken or agreements with additional third parties entered into prior to termination, and Valneva shall be liable for damages or remedies as provided by law.

9.7 **Effects of Termination**.

9.7.1 **Effect of Termination**.

(a) *Termination for Cause by Valneva; Termination for Convenience by Pfizer*. In the event that Valneva terminates this Agreement for cause pursuant to Section 9.5 or Pfizer terminates this Agreement for convenience pursuant to Section 9.6.1, the following will apply:

(i) Except as otherwise expressly provided herein, all rights and obligations of each Party hereunder will cease (including all rights and licenses and sublicenses granted by either Party to the other Party hereunder).

(ii) On Valneva's written notice to Pfizer, which notice may only be delivered within [***] following the effective date of termination, the Parties will negotiate in good faith for a period not to exceed [***] regarding:

(A) an agreement, containing customary terms and conditions, under which Pfizer would grant to Valneva a royalty-bearing, license under the Reversion Technology, with a royalty on net sales as mutually agreed by Pfizer and Valneva (applying the Net Sales and other payment and reporting obligations of Pfizer to Valneva on a *mutatis mutandis* basis), permitting Valneva to continue to Develop, Commercialize and Manufacture any Product under Development or Commercialization by Pfizer under this Agreement at the time of termination, in the form in which such Product then exists (a "**Continuation Product**"), *provided, however*, that any such Agreement will include a release by Valneva in favor of Pfizer with respect to any and all claims that Valneva may have against Pfizer arising on or before the later of such agreement or the effective date of any such termination under this Agreement. If Pfizer and Valneva are unable to agree on the applicable royalty rate within [***] of the effective date of termination, the Parties will select [***] not affiliated with either Party or any of its Affiliates who possesses appropriate expertise to resolve such disputed rate and will simultaneously submit to such [***] their proposed royalty rate. Such [***] will select the rate proposed by one party that is [***];

(B) the related transfer to Valneva of development data and regulatory filings specifically relating to such Continuation Product or the granting to Valneva of rights of reference with respect to such data and filings; and

(C) the provision by Pfizer to Valneva of transitional supplies of such Continuation Product at a commercially reasonable supply price for a commercially reasonable period of time.

(iii) Each Party will be obligated to reasonably negotiate, but be under no obligation, to enter into any transaction described in Section 9.7.l(a)(ii).

(b) *Termination for Cause by Pfizer*.

(i) *Partial Termination*. In the event that Pfizer terminates this Agreement pursuant to Section 9.6.2 with respect to any Product in any country in the Territory as permitted by this Agreement: (A) all licenses and sublicenses granted under this Agreement by Valneva to Pfizer with respect to such Product in such country will remain in effect in accordance with their terms, provided that the amounts payable by Pfizer to Valneva pursuant to Article 3 of this Agreement will be reduced to [***] of the amounts which would otherwise be payable with respect to such Product in such county pursuant to Article 3 of this Agreement if such termination occurs following the Effective Date and prior to the [***] of the first Regulatory Approval of a Product and [***] of the amounts which would otherwise be payable with respect to such Product in such county pursuant to Article 3 of this Agreement if such termination occurs following the [***] of the first Regulatory Approval of a Product; (B) Valneva will, within [***] following the effective date of termination, deliver to Pfizer all information and samples described in Sections 2.12, 4.2.6(a) and 4.2.6(b) and with respect to such Product in such country; (C) Valneva will, for a period of [***] following the effective date of termination, provide Pfizer with the knowledge transfer assistance set forth in Sections 2.13, 2.14, 2.15, 2.6(a), 4.2.6(b) and 4.2.6(e) with respect to such Product in such country; and (D) except as otherwise expressly provided herein, all other rights and obligations of each Party with respect to such Product in such country will cease.

(ii) *Complete Termination.* In the event that Pfizer terminates this Agreement in its entirety pursuant to Section 9.6.2: (A) all licenses and sublicenses granted under this Agreement by Valneva to Pfizer will remain in effect in accordance with their terms, provided that the amounts payable by Pfizer to Valneva pursuant to Article 3 of this Agreement will be reduced to [***] of the amounts which would otherwise be payable with respect to any Product pursuant to Article 3 of this Agreement if such termination occurs prior to the [***] of the first Regulatory Approval of a Product and will be reduced to [***] of the amounts which would otherwise be payable with respect to such Product in such county pursuant to Article 3 of this Agreement if such termination occurs following the [***] of the first Regulatory Approval of a Product; (B) Valneva will, within [***] following the effective date of termination, deliver to Pfizer all information and samples described in Sections 2.12, 4.2.6(a) and 4.2.6(b); (C) Valneva will, for a period of [***] following the effective date of termination, provide Pfizer with the knowledge transfer assistance set forth in Sections 2.13, 2.14, 2.15, 4.2.6(a), 4.2.6(b) and 4.2.6(e); and (E) except as otherwise expressly provided herein, all other rights and obligations of each Party with respect to all Products throughout the Territory will cease.

9.7.2 **Accrued Rights**. Subject to any release granted pursuant to Section 9.7.1(a)(ii), expiration or termination of this Agreement for any reason will be without prejudice to any right which will have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement will not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination.

9.7.3 **Survival Period**. The following sections, together with any sections that expressly survive (including any perpetual licenses and sublicenses granted hereunder), will survive expiration or termination of this Agreement for any reason: Sections 1 (Definitions), 2.6 (Reciprocal Non-Exclusive Research License for Disclosed Know-How and Confidential Information), 3.5.3 (Taxes and Withholding), 3.5.6 (Record Keeping), 3.5.7 (Audits), 3.5.8 (Underpayments/Overpayments), 3.5.9 (Confidentiality), 7 (Confidentiality), 9.7 (Effects of Termination), 9.8 (Provision for Insolvency), 10.1 (No Consequential Damages), 10.2 (Indemnification by Pfizer), 10.3 (Indemnification by Valneva), 11 (Miscellaneous) and, to the extent this Agreement expires or is terminated, either in whole or in part, for any reason except by Valneva for cause pursuant to Section 9.5 or by Pfizer without cause pursuant to Section 9.6.1, Sections 6.2 (Patent Rights) and 6.3 (Enforcement and Defense of Know-How).

9.8 **Provision for Insolvency**.

9.8.1 **Termination Right**. Valneva will be deemed a "**Debtor**" under this Agreement if, at any time during the Term (a) a case is commenced by or against Valneva under the Bankruptcy Code, (b) Valneva files for or is subject to the institution of bankruptcy, reorganization, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) Valneva assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for Valneva's business or (e) a substantial portion of Valneva's business is subject to attachment or similar process; *provided*, *however*, that in the case of any involuntary case under the Bankruptcy Code, Valneva will not be deemed a Debtor if the case is dismissed within [***] after the commencement thereof. If Valneva is deemed a Debtor, then Pfizer may terminate this Agreement by providing written notice to Valneva. If Pfizer terminates this Agreement pursuant this Section 9.8.1, then: (i) all licenses granted to Pfizer under this Agreement will become irrevocable and perpetual, and Pfizer will have no further obligations to Valneva under this Agreement other than (A) those obligations that expressly survive termination in accordance with Section 9.7.3 and (B) an obligation to pay royalties with respect to Net Sales of Products in an amount equal to [***] of the amount that would otherwise have been payable under this Agreement, such amount to be paid in accordance with and subject to the other terms of this Agreement governing the payment of royalties; (ii) such termination will not be construed to limit Valneva's right to receive payments that accrued before the effective date of such termination; (iii) Pfizer will have the right to offset, against any payment owing to Valneva as provided for under clause (i), above, any damages found or agreed by the Parties to be owed by Valneva to Pfizer; and (iv) Nothing in this Section 9.8.1 will limit any other remedy Pfizer may have for any breach by Valneva of this Agreement.

9.8.2 **Rights to Intellectual Property**. All rights and licenses now or hereafter granted by Valneva to Pfizer under or pursuant to any Section of this Agreement, including Sections 2.1, 2.2, 2.3, 2.6.2, 2.7, 2.10, 2.12 and 2.13 hereof, are rights to "intellectual property" (as defined in the Bankruptcy Code). The Parties hereto acknowledge and agree that the payments provided for under Sections 3.1 and 3.3 and all other payments by Pfizer to Valneva hereunder, other than royalty payments pursuant to Section 3.4, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. If (a) a case under the Bankruptcy Code is commenced by or against Valneva, (b) this Agreement is rejected as provided in the Bankruptcy Code and (c) Pfizer elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then Valneva (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) will provide to Pfizer all intellectual property licensed hereunder, and agrees to grant and hereby grants to Pfizer and

its Affiliates a right to access and to obtain possession of and to benefit from and, in the case of any chemical or biological material or other tangible item of which there is a fixed or limited quantity, to obtain a pro rata portion of, each of the following to the extent related to any Vaccine or Product, or otherwise related to any right or license granted under or pursuant to this Agreement: (i) copies of pre-clinical and clinical research data and results; (ii) all of the following (to the extent that any of the following are so related): Valneva Materials; (iii) Product samples; (iv) Valneva Technology, (v) laboratory notes and notebooks; (vi) Product data or filings, and (vii) Rights of Reference in respect of regulatory filings and approvals, all of which constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code, and (viii) all other embodiments of such intellectual property, whether any of the foregoing are in Valneva' s possession or control or in the possession and control of any Third Party but which Valneva has the right to access or benefit from and to make available to Pfizer. Valneva will not interfere with the exercise by Pfizer or its Affiliates of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist Pfizer and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or desirable for Pfizer or its Affiliates or Sublicensees to exercise such rights and licenses in accordance with this Agreement.

9.8.3 **No Limitation of Rights**. All rights, powers and remedies of Pfizer provided in this Section 9.8 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at Law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code involving Valneva.

10. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE

10.1 **No Consequential Damages**. Except with respect to liability arising from a breach of Section 6 or 7, from any willful misconduct or intentionally wrongful act, or to the extent such Party may be required to indemnify the other Party under this Article 10, in no event will either Party or its Representatives be liable under this Agreement for any special (only as related to indirect, incidental or consequential damages), indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of profits or revenue suffered by the other Party or any of its Representatives. Without limiting the generality of the foregoing, "consequential damages" will be deemed to include, and neither Party will be liable to the other Party or any of such other Party's Representatives or stockholders for any damages based on or measured by loss of projected or speculative future sales of the Products, any Development Payment due upon any unachieved Development Event under Section 3.3, any unearned royalties under Section 3.4 or any other unearned, speculative or otherwise contingent payments provided for in this Agreement.

10.2 **Indemnification by Pfizer**. Pfizer will indemnify, defend and hold harmless Valneva, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "**Valneva Indemnified Party**") from and against any and all claims, causes, or allegations (whether threatened or pending), judgments, expenses, damages, liabilities, obligations, fees (including the reasonable fees of attorneys and other consulting or testifying professionals), costs and losses (collectively, "**Liabilities**") that the Valneva Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

(a) Development, Manufacture, Commercialization or use of any Product by, on behalf of, or under the authority of, Pfizer (other than by any Valneva Indemnified Party); or

(b) the material breach by Pfizer of any of its representations, warranties or covenants set forth in Section 8.1 or 8.2;

except, in each case, to the extent caused by the negligence, recklessness or intentional acts of Valneva or any Valneva Indemnified Party.

10.3 **Indemnification by Valneva**. Valneva will indemnify, defend and hold harmless Pfizer, its Affiliates, Sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a "**Pfizer Indemnified Party**") from and against any and all Liabilities that the Pfizer Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

(a) Development, Manufacture, Commercialization or use of any Product by, on behalf of, or under the authority of, Valneva (other than by any Pfizer Indemnified Party);

(b) the material breach by Valneva or any of its Representatives of any of its representations, warranties or covenants set forth in Section 8.1, Section 8.2, Section 8.3, Section 8.4 or Section 8.5;

except, in each case, to the extent caused by the negligence, recklessness or intentional acts of Pfizer or any Pfizer Indemnified Party

10.4 **Procedure**.

10.4.1 **Notice**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the "**Indemnified Party**") is entitled to indemnification hereunder (a "**Third Party Claim**"), then the Indemnified Party will promptly notify the Party obligated to indemnify the Indemnified Party (the "**Indemnifying Party**") thereof; *provided*, *however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

10.4.2 **Control**. Subject to Pfizer's right to control any actions described in Sections 6.2.3, 6.2.5, 6.2.7 or 6.3 (even where Valneva is the Indemnifying Party), the Indemnifying Party will have the right, exercisable by notice to the indemnified Party within [***] after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above arc collectively referred to as the "**Litigation Conditions**"). Within [***] after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party docs not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within [***] after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with

counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

10.4.3 **Settlement**. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party will have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but will not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party will not make any admission of liability in respect of any Third Party Claim without the prior-written consent of the other party, and the Indemnified Party will use reasonable efforts to mitigate Liabilities arising from such Third Party Claim.

10.5 **Insurance**. Each Party further agrees to obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance (or clinical trials insurance, if applicable), with minimum [***] rated insurance carriers to cover its indemnification obligations under Section 10.2 or Section 10.3, as applicable, in each case with limits of not less than [***] per occurrence and in the aggregate. All deductibles and retentions will be the responsibility of the named insured. Pfizer and its Affiliates will be an additional insured on Valneva' s commercial general liability and products liability policies (or clinical trials insurance, if applicable), and be provided with a waiver of subrogation. For U.S. exposures, additional insured status on Valneva's commercial general liability and products liability policies shall be via form [***] or its equivalent. Products liability coverage shall be maintained for [***] following termination of this Agreement. To the extent of its culpability or negligence, all coverages of Valneva will be primary and non-contributing with any similar insurance, carried by Pfizer. Notwithstanding any provision of this Section 10.5 to the contrary, Pfizer may meet its obligations under this Section 10.5 through self-insurance. Neither Party's insurance will be construed to create a limit of liability with respect to its indemnification obligations under this Article 10.

11. MISCELLANEOUS.

11.1 **Assignment**. Neither this Agreement nor any interest hereunder will be assignable by a Party without the prior written consent of the other Party; provided however, that (a) either Party may assign its rights and obligations under this Agreement to any of its Affiliates and (b) Pfizer may assign its rights and obligations under this Agreement to a Third Party without Valneva's consent where Pfizer or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition, *provided that* in both cases the assignee will expressly agree to be bound by such Party's obligations under this Agreement. Each Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 11.1. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.1 will be void. For the avoidance of doubt, neither Pfizer nor its Affiliates will assign to a Third Party any rights to any diagnostic assay Developed using the Valneva Technology for a Product, except as set forth in (a) and (b) above in this Section 11.1, without the prior written consent of Valneva; provided that Pfizer and its Affiliates will be able to grant a sublicense to such rights in accordance with Section 2.3.

11.2 **Change of Control of Valneva**. Valneva will notify Pfizer in writing promptly (and in any event within [***]) following the entering into of a definitive agreement with respect to a Change of Control of Valneva.

11.3 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

11.4 **Force Majeure**. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes Commercially Reasonable Efforts to remove the condition. For purposes of this Agreement, "force majeure" will include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation. Law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, pandemic, quarantine, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

11.5 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation", (c) the word "will" will 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 will 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 will be construed to include the Person's successors and assigns, (f) the words "herein", "hereof' and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

11.6 **Notices**. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) will be in writing and will be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), [***] after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next Business Day if sent by overnight delivery using a nationally recognized express courier service and specifying next Business Day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as will be specified by like notice, *provided*, *however*, that notices of a change of address will be effective only upon receipt thereof):

All correspondence to Pfizer will be addressed as follows:

Pfizer Inc.
Notices: Vaccines Business Development
235 East 42nd Street

New York, NY 10017
Attn.: Vaccines BD Contract Notice

with a copy to:

Pfizer Inc.
Notices: Pfizer Legal Division
235 East 42nd Street
New York, NY 10017
Attn.: Chief Counsel, Vaccines

To help expedite Pfizer's awareness and response, copies of notices may be provided to Pfizer by email but must be supplemented by one of the following methods: (a) personal delivery, (b) first class certified mail with return receipt requested, or (c) next-day delivery by major international courier, with confirmation of delivery. Electronic copies may be sent via email to [***].

All correspondence to Valneva will be addressed as follows:

Valneva Austria GmbH
Campus Vienna Biocenter 3
1030 Vienna
Vienna, Austria
FB-Nr: FN 389960 x / HG Wien
Attention: Chief Executive Officer

with a copy to:

With a copy to:

[***]

11.7 **Amendment**. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

11.8 **Waiver**. No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.9 **Severability**. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause of portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

11.10 **Descriptive Headings**. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

11.11 **Global Trade Control Laws**. The Parties acknowledge that certain activities covered by or performed under this Agreement may be subject to law, regulations or orders regarding economic sanctions, import controls or export controls ("**Global Trade Control Laws**"). Each of the Parties will perform all activities under this Agreement in compliance with all applicable Global Trade Control Laws. Furthermore, with respect to the activities performed under this Agreement, each of the Parties represents, warrants and covenants that:

11.11.1 Each Party will not, for activities under this Agreement, (i) engage in any such activities in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; or (iii) include companies, organizations, or Governmental Entities from or located in a Restricted Market. "**Restricted Market**" for purposes of this Agreement means the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria, or any other country or region sanctioned by the United States or European Union.

11.11.2 Each Party represents and warrants that it is not a Restricted Party and is not owned or controlled by a Restricted Party. With respect to activities performed under this Agreement, neither Party will engage or delegate to any Restricted Parties for any activities under this Agreement. Each Party will screen all relevant third parties involved by such Party in the activities under this Agreement under the relevant Restricted Party Lists. "**Restricted Parties**" for purposes of this Agreement means any individual or entity on any of the following "Restricted Party Lists": the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List of the U.S. Treasury Department's Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List of the U.S. Department of Commerce; entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities published by the U.S. Health and Human Services' Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of parties suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Authorities of the countries that have jurisdiction over the activities conducted under this Agreement.

11.11.3 Neither Party will knowingly transfer to the other Party any goods, software, technology or services that are (i) controlled under the U.S. International Traffic in Arms Regulations or at a level other than EAR99 under the U.S. Export Administration Regulations; or (ii) specifically identified as an E.U. Dual Use Item or on an applicable export control list of another country.

11.12 **Dispute Resolution**. If any dispute or disagreement arises between Pfizer and Valneva in respect of this Agreement, they will follow the following procedures in an attempt to resolve the dispute or disagreement:

11.12.1 The Party claiming that such a dispute exists will give notice in writing ("**Notice of Dispute**") to the other Party of the nature of the dispute.

11.12.2 Within [***] of receipt of a Notice of Dispute and in advance of any meeting pursuant to Section 11.12.3, the receiving Party will provide a written response to the other Party's claims regarding the dispute.

11.12.3 Within [***] of receipt of Notice of Dispute, the Vice President, Vaccines of Pfizer and the Chief Executive Officer of Valneva will me ta mutually agreed-upon time and location for the purpose of resolving such dispute.

Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement. The provisions of this Section 11.12 will survive for five years from the date of termination or expiration of this Agreement.

11.13 **Governing Law**. This Agreement is governed by, and all disputes arising under or in connection with this Agreement shall be resolved in accordance with, laws of the State of New York, without regard to conflict of law principles thereof.

11.14 **Consent to Jurisdiction and Venue**. Each Party to this Agreement hereby (a) irrevocably submits to the exclusive jurisdiction and venue of the state courts of the State of New York or the United States District Court for the Southern District of New York (collectively, the "**Courts**"), for the purpose of any and all actions, suits or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof or such award (other than appeals therefrom), (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of such Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Courts do not have any jurisdiction over such Party. Section 11 of this Agreement does not intend to deprive any New York court of competent jurisdiction with respect to its power to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of arbitration proceedings or the enforcement of any judgment or award. In any such action, the courts of New York shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum; and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party.

11.15 **Entire Agreement**. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof, including that certain Confidential-Disclosure Agreement between the Parties dated [***] which is hereby terminated effective as of the Execution Date, *provided that* such Confidential Disclosure Agreement will continue to govern the treatment of Confidential Information disclosed by the Parties prior to the Execution Date in accordance with its terms.

11.16 **Independent Contractors**. Both Parties are independent contractors under this Agreement. Nothing herein contained will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party intends to form a partnership for tax purposes and each Party will report all transactions in connection with this Agreement consistently with such intent and will cooperate with any reasonable request to assist the other Party with such reporting (including to respond to any tax inquiries or proceedings. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

11.17 **Counterparts**. This Agreement may be executed two (2) counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by facsimile or digital (e.g., PDF file, each of which will be binding when received by the applicable Party.

11.18 **No Third Party Rights or Obligations**. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement. However, Pfizer may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, *provided that* Pfizer will remain liable hereunder for the performance by any such Affiliates of any such obligations.

(Signature page follows.)

[***] = 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.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Execution Date to be effective as of the Effective Date.

PFIZER INC

By_____
Name:
Title:

VALNEVA GmbH

By */s/ [***]*
Name: [***]
Title: [***]

[***]

By */s/ [***]*
Name: [***]
Title: [***]

[Signature Page to Research Collaboration and License Agreement]

Exhibit A

[***]

[***] = 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 B

[***]

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Exhibit C

[***]

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Exhibit D

[***]

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Schedule 3.4.1

[***]

[***] = 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.

Schedule 8.3.1

[***]

[***] = 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.

Schedule 8.3.3

[***]

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Schedule 8.3.4

[***]

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Schedule 8.3.16

[***]

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DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT ("***Agreement***") is entered into as of December 9, 2015, between **VALNEVA AUSTRIA GMBH**, CIN: FN 389960 x, organized under the laws of Austria, with its registered office at Campus Vienna Biocenter 3, AT-1030 Vienna, Austria, hereinafter referred to as "***SUPPLIER***", and **GLAXOSMITHKLINE GMBH & CO. KG**, organized under the laws of Germany, with its registered office at Prinzregentenplatz 9, D-81675 Munich, Germany, hereinafter referred to as "***DISTRIBUTOR***," (hereinafter each referred to as a "***Party***", and collectively as the "***Parties***").

WITNESSETH:

WHEREAS, SUPPLIER is engaged in the research, development and manufacture of biopharmaceutical products, including the Product, and is the exclusive owner or licensee of proprietary rights in such Product;

WHEREAS, DISTRIBUTOR is engaged in the marketing of pharmaceutical products and has represented to SUPPLIER that it has the facilities, personnel and technical expertise to import, market, sell, promote and distribute the Product in the Territory (as defined below);

WHEREAS, the former distributor of the Product in Germany GlaxoSmithKline Vaccines Vertriebs GmbH (formerly known as Novartis Vaccines Vertriebs GmbH) is a company that now belongs, as does DISTRIBUTOR, to the GSK Group of companies. Consequently the Product has already been launched in the Territory by a GSK Group company; and

WHEREAS, SUPPLIER is willing to exclusively sell the Product in the Territory to DISTRIBUTOR, and DISTRIBUTOR is willing to acquire the Product from SUPPLIER for resale to customers in its own name and on its own account in the Territory, on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration for the premises and promises contained herein, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 "***Affiliate***" means, with respect to a Party, any entity that is controlled by, controls, or is under common control with such Party. For such purpose, the term "***control***" means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting interest in an entity, or more than fifty percent (50%) interest in the income of the entity in question, or the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity.

1.2 "***Agreement***" means this contract together with all attachments and amendments agreed upon by the Parties in writing.

1.3 "***Anti-Corruption Laws***" means any and all applicable local, European or other legislations/regulations regarding corruption that may be applicable to one or both Parties, including but not limited to the following legislations/regulations as amended from time to time: (a) the Criminal Law Convention on Corruption (Council of Europe), (b) the Organization for Economic Co-Operation and Development Convention on Combating Bribery of Foreign Officials in International Business, and (c) the United States Foreign Corrupt Practices Act of 1977.

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1.4 "***Applicable Laws***" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, and other requirements of a Governmental Authority, as may be in effect from time to time, including but not limited to the Anti-Corruption Laws.

1.5 "***Average Selling Price***" or "***ASP***" is calculated by dividing annual Sales by the number of packs of the Product sold by DISTRIBUTOR in a one (1) year's period. For the purpose of this calculation, "***Sales***" mean the sales of the Product which DISTRIBUTOR achieves by selling the Product to third parties (other than Affiliates) in the Territory after deduction of [***].

1.6 "***Change of Control***" means an acquisition by any third party, directly or indirectly, of voting securities or capital stock, or other comparable ownership interest, of or in DISTRIBUTOR, resulting in such third party, together with its Affiliates, owning, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or capital stock, or other comparable ownership interest, of or in DISTRIBUTOR.

1.7 "***Confidential Information***" means any trade secrets, confidential data or other confidential information, whether oral or written, relating to the other Party's past, present and/or future efforts in research, development, manufacturing, and business activities that is disclosed to or obtained by the receiving Party in connection with, and during the Term of, this Agreement. All such information disclosed by either Party to the other shall be marked as "confidential" or bear a similar legend. Confidential Information disclosed orally, shall at the time of disclosure be identified as Confidential Information and the disclosing Party shall confirm the same in writing no later than [***] after the information has been disclosed. Notwithstanding the foregoing, any information or material which by its nature and under the circumstances surrounding its disclosure is generally considered proprietary and confidential shall be deemed Confidential Information regardless of whether it is properly marked with legends or properly reduced to writing.

1.8 "***Dealer***" means Affiliates of DISTRIBUTOR or third parties, which Affiliates or third parties have been appointed by DISTRIBUTOR and, in the case of third parties, approved by SUPPLIER pursuant to Section 2.2.3 to promote, market and distribute the Product in the Territory. For the avoidance of doubt, Dealer does not include any entity engaged by DISTRIBUTOR for the purposes of providing logistical support of such promotion, marketing or distribution, including storage, transportation, packaging and invoicing.

1.9 "***Effective Date***" means the date of this Agreement as designated in the preamble to this Agreement on the first page.

1.10 "***FCA***" means Free Carrier SUPPLIER's or its Affiliate's warehouse or designated service provider in Continental Western Europe in accordance with the ICC Incoterms 2010, International Rules for the Interpretation of Trade Terms, ICC Publication No. 715.

1.11 "***GDP***" means, as relevant to the Product, the then-current good distribution practices and similar rules, regulations and guidelines, as amended from time to time, applicable to the proper handling, transport, storage, importation, marketing, promotion, sale and distribution of pharmaceutical products in the Territory, including but not limited to the then-current guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended) (i.e: as of the Effective Date, the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use).

1.12 "***GMP***" means, as relevant to the Product, the principles and guidelines of good manufacturing practice as contained in the Commission Directive 2003/94/EC, of 8 October 2003, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, as such principles and guidelines are interpreted and expanded in "The Rules Governing Medicinal Products in the European Community, Volume IV. Good Manufacturing Practice for Medicinal Products".

1.13 "***Governmental Authority***" means and includes all governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, having jurisdiction over the marketing authorization, pricing, reimbursement, importation, promotion, distribution and/or sale of the Product in the Territory.

1.14 "***Intellectual Property Rights***" means and includes all copyrights, designs, databases, mask works, patents, Trademarks, Confidential Information, trade names, Know How and other proprietary rights, and all registrations and applications therefor, which SUPPLIER may at any time own, control, adopt, use, license or register with respect to the Product or its business, to the extent such rights are enforceable by Applicable Laws.

1.15 "***Know How***" shall mean any and all materials, information, experience and data, formulae, procedures, results and specifications, regulatory filings and clinical and pre-clinical data, in written or electronic form, which are related to the Product, including, but not limited to the composition and chemical, structural, toxicological, physical and environmental characteristics of Product including any process information relating to the manufacturing thereof; all conclusions, opinions, advice and reports needed to comply with all appropriate laws and regulations pertaining to the Marketing Authorization, the manufacturing, the marketing and the distribution of Product, such as analytical specifications, test methods, stability test methods and the necessary reference standards and disclosed by SUPPLIER to DISTRIBUTOR in connection with this Agreement.

1.16 "***Marketing Authorization***" means the European marketing authorization referenced EU/1/08/501/002, presentation without needle, as such may be modified from time to time.

1.17 "***Person***" means and includes any agency, association, company, individual, or other entity regardless of the type or nature thereof.

1.18 "***Pricing Approval(s)***" means any approval or authorization of any Governmental Authority establishing a pricing scheme and/or health insurance reimbursement scheme for the Product or any of them in the Territory, but excluding Marketing Authorization.

1.19 "***Product***" shall mean the product manufactured by or on behalf of SUPPLIER, for the indication(s) and application(s) specified in the approved Summary of Product Characteristics, listed in ANNEX A.

1.20 "***Start Date***" means April 1, 2016 where DISTRIBUTOR will be granted exclusive rights for the commercialization of the Product in the Territory as provided for under this Agreement, including but not limited to the exclusive rights defined under Section 2.1.1 below.

1.21 "***Term***" means the term of this Agreement as determined in accordance with Section 16.1

1.22 "***Territory***" shall mean the country/countries as set forth in ANNEX B of this Agreement.

1.23 "***Trademarks***" means the word and design marks, and corresponding registrations applicable to the Territory, owned by, or licensed to SUPPLIER (with the right to sublicense), solely pertaining to the Product, which Trademarks are listed in ANNEX A.

1.24 "***Transfer Price***" means the price specified in ANNEX C for Products supplied by SUPPLIER and purchased by DISTRIBUTOR under this Agreement.

In this Agreement, unless a contrary intention appears, the singular shall include the plural, each gender shall include each other gender and the terms "include" and "including" shall be construed without limitation.

2. GRANT OF RIGHTS

2.1 Exclusive Distribution and Supply

2.1.1 Distribution Rights. Subject to the terms and conditions of this Agreement, as of the Start Date, SUPPLIER hereby grants to DISTRIBUTOR, and DISTRIBUTOR accepts, exclusive rights subject to SUPPLIER's retained rights in section 2.1.2 below to import, market, promote, distribute and sell the Product in and into the Territory under this Agreement. Such right being exclusive shall mean that SUPPLIER will not during the Term hereof (1) grant rights to distribute, market, sell and import the Product in and to the Territory to any other Person, nor (2) directly or indirectly through Affiliates distribute, market, sell and import the Product in and to the Territory except as reserved in Sections 2.1.2 and 2.1.3 below.

2.1.2 SUPPLIER's Retained Rights. SUPPLIER retains and reserves the right to deliver, distribute, market, sell, promote and import the Product to the Territory either directly or indirectly through its Affiliates and/or any third party, exclusively with respect to the National and/or International Aid Organizations and/or Supranational Organizations, *e.g.* WHO, UNICEF, PAHO, and Red Cross ("***Organizations***"). Notwithstanding the foregoing, this Section 2.1.2 shall not prevent DISTRIBUTOR to sell to such Organizations should such Organizations contact DISTRIBUTOR directly.

2.1.3 No Other Rights. Neither Party grants to the other any rights or licenses, implicit or otherwise, to any of its assets, licensable or not, including for example its products, projects or under its intellectual property rights, including but not limited to its patents, trademarks, copyrights and know how, other than those expressly set forth in this Agreement.

2.1.4 Modification or Discontinuation of Product. SUPPLIER retains and reserves the right to modify and/or discontinue the manufacture and sale of the Product, at its own discretion. In the case of discontinuation SUPPLIER's decision shall be based on [***]. In the case of discontinuation, SUPPLIER shall respect a [***] notice and shall permit the DISTRIBUTOR to sell its remaining stock of Product, or shall, at DISTRIBUTOR's option, purchase back the remaining stock at the Transfer Price initially invoiced to DISTRIBUTOR. In addition, SUPPLIER shall reimburse DISTRIBUTOR any reasonable expenses incurred by the DISTRIBUTOR for the storage and, as the case may be, transportation for Products returned to SUPPLIER for their destruction.

2.1.5 Appointment of Distributors outside the Territory. DISTRIBUTOR acknowledges that SUPPLIER may grant exclusive marketing rights for the Product to other Persons in countries outside the Territory or that SUPPLIER may retain exclusive marketing rights for itself or its Affiliates for the same purpose. SUPPLIER undertakes to impose upon such Persons restrictions on their active marketing in the Territory, to the extent that such restrictions are legally permissible. It is however understood, that by operation of law, restrictions on passive sales which includes the sale of the Product over the internet, may not be permitted and that DISTRIBUTOR shall not be entitled to receive any compensation for such sales in the Territory by such Persons.

2.1.6 Exclusive Supply. During the Term DISTRIBUTOR shall purchase all of its requirements of the Product for the Territory from SUPPLIER or any party designated by SUPPLIER for this purpose.

2.2 Sub-distribution Rights

2.2.1 Appointment. DISTRIBUTOR shall have the right to appoint Dealer(s) to market, promote and distribute Product in the countries of the Territory pursuant to the rights granted herein and in accordance with this Section 2.2.

2.2.2 Subdistribution Agreements. DISTRIBUTOR shall require that each Dealer execute a ‘ written agreement, including quality agreement and pharmacovigilance agreement with DISTRIBUTOR, which shall contain terms substantially similar to those set forth herein and shall terminate upon the expiration, non-renewal, or termination of this Agreement for any reason. No Dealer shall have a right to sublicense any rights or to appoint Dealers. Not later than [***] following written agreement with any Dealer, DISTRIBUTOR shall provide SUPPLIER with a copy of the quality agreement entered into between the DISTRIBUTOR and any of its Dealers.

2.2.3 Notification and Approval. DISTRIBUTOR shall notify SUPPLIER in writing of the identity of any Dealer, and shall request SUPPLIER’s prior written approval for any third party Dealer. SUPPLIER shall not unreasonably withhold such approval and shall either grant or deny such approval in writing within [***] from receipt of a written request from DISTRIBUTOR, which request shall include, at SUPPLIER’s request, background information on such third party Dealer. The addresses used for this communication are defined in ANNEX I.

2.2.4 Liability for performance of Dealers. DISTRIBUTOR shall remain solely responsible and liable to SUPPLIER for the performance of this Agreement by its Dealers.

2.3 Trademarks and Trade Name Use

2.3.1 Trademark Freedom to Operate. SUPPLIER agrees that neither SUPPLIER nor its Affiliates shall assert any trademarks or trade names owned or controlled by SUPPLIER or its Affiliates based on DISTRIBUTOR’s or any Dealer(s)’commercialization of the Product provided any use is compliant with the terms and conditions of this Agreement including that the use shall be consistent with standards for trademark use that are generally accepted within the pharmaceutical industry.

2.3.2 Additional Trademarks. SUPPLIER shall have the right to select additional Trademarks and register them at its expense, and such Trademarks shall be owned by SUPPLIER and added to ANNEX A, initially as secondary Trademarks. If (i) a Governmental Authority does not approve the then-current primary Trademark indicated on ANNEX A, (ii) a third party asserts that such Trademark infringes its trademarks, (iii) such Trademark is successfully opposed by a third party, (iv) a petition to cancel such Trademark is filed by a third party, (v) there is an infringement of such Trademark by any third party against which SUPPLIER does not enforce its rights pursuant to Section 11.3, or (vi) there is a bona fide issue with such Trademark which is supported by an opinion of DISTRIBUTOR’s outside trademark attorneys, then SUPPLIER shall designate one of the secondary Trademarks (as indicated on ANNEX A) as a replacement primary Trademark. If there are no remaining secondary Trademarks, DISTRIBUTOR shall have the right to select another trademark of its choosing after having received the written consent of SUPPLIER. Any such trademark selected by DISTRIBUTOR shall be registered in the name of SUPPLIER, at SUPPLIER’s expense, shall be added as a Trademark to ANNEX A and shall be owned by SUPPLIER.

2.3.3 Trademark Use in Materials. Subject to the terms and conditions of this Agreement, DISTRIBUTOR shall use or have used the Trademarks related to the Product indicated in ANNEX A, and no other trademarks or trade names, in connection with its marketing, promotion, sale and distribution of the Product in the Territory, unless otherwise agreed by the Parties and provided, however, that DISTRIBUTOR may use its own trademarks and trade names on product packaging, brochures and other promotion materials to identify itself as the distributor of the respective Product. DISTRIBUTOR agrees to provide copies of all such materials to SUPPLIER for Trademark use review and approval prior to publication and distribution. SUPPLIER agrees that its approval of such materials will not be unreasonably withheld. The Parties agree that SUPPLIER will be deemed to approve any such materials if it does not respond to DISTRIBUTOR within [***] after having received said materials. The addresses used for this communication are defined in ANNEX I.

2.3.4 Trademark Use Undertakings. DISTRIBUTOR's use of the Trademarks related to the Product in ANNEX A shall be consistent with standards for trademark use that are generally accepted within the pharmaceutical industry. DISTRIBUTOR shall in particular (1) ensure that no damaged, out-of-date and deteriorated Product shall be put on the market or otherwise disposed of in a manner which would bring into disrepute the Trademarks or the trade name of SUPPLIER; (2) avoid in any case the use of the Trademarks as generic names; and (3) report to SUPPLIER all matters which, to the best of its knowledge, may affect the validity of the Trademarks, including any imitations of Product or infringements of the Trademarks and report them without unreasonable delay to SUPPLIER.

2.3.5 Trademark Audit Right. SUPPLIER shall have the right to audit DISTRIBUTOR's use of the Trademarks related to the Product in ANNEX A. DISTRIBUTOR shall remedy any non-compliant use identified by SUPPLIER as soon as possible using commercially reasonable efforts after notification by SUPPLIER.

2.4 Wholesale License and Import License

2.4.1 Wholesale License. DISTRIBUTOR undertakes that it, or its Dealers, if applicable, holds and shall maintain, throughout the term of this Agreement and for a period of [***] thereafter, a wholesale license or adequate license issued by the respective authority of the Territory granting DISTRIBUTOR permission to import, market and sell medical products including vaccines at its own cost and expenses. A legalized copy of such license shall be attached to the Agreement as ANNEX F. Any renewal of such license will be sent to SUPPLIER at the address given in ANNEX I.

2.4.2 Loss of License. DISTRIBUTOR shall immediately inform SUPPLIER of the loss or the threat of loss of such license. The failure of DISTRIBUTOR to maintain its license, as set forth in Section 2.4.1 above, in the Territory shall give SUPPLIER the right, in its sole discretion, to terminate the Agreement, in accordance with Section 16.2, with [***] prior written notice, unless DISTRIBUTOR has cured every such diligence infringement within that [***] period.

2.4.3 Import License. DISTRIBUTOR shall obtain at its own costs any import license or other authorization and carry out under its responsibility, where applicable, all customs formalities required to import Product in the Territory and that are specific to Product.

3. NON-COMPETITION COVENANTS

3.1 No manufacturing of Product. DISTRIBUTOR covenants not to manufacture the Product or cause the Product to be manufactured directly or indirectly by third parties without the written consent of SUPPLIER.

3.2 No Active Sales in other Territories. DISTRIBUTOR covenants not to actively sell the Product or to establish or maintain branches, sales offices or distribution depots, set up subsidiaries or maintain deposits for the purpose of the sales of the Product in any countries outside the Territory allocated to another distributor, to SUPPLIER or any of its Affiliates for the exclusive distribution of the Products. The Parties understand that fulfilling orders made over the internet or unsolicited orders received from customers outside the Territory is permitted under EU competition law and is not prohibited hereunder.

3.3 No distribution of Competing Products. During the term of this Agreement, but in no event for a period of more than [***] from the Effective Date of this Agreement and to the extent permitted under European competition law, DISTRIBUTOR will not, without the written consent of SUPPLIER, manufacture, market, file applications for regulatory approval (for the sake of clarity, the restriction to not file applications for regulatory approval does not apply to, or restrict any of DISTRIBUTOR's Affiliates outside the Territory), distribute, sell or promote in the Territory any pharmaceutical products that directly compete with the Product in ANNEX A that are generically substitutional to the Product and sold for the same indications as the Product in ANNEX A.

4. MARKETING AND PROMOTION

4.1 Diligent Marketing Efforts

4.1.1 Diligent Efforts. DISTRIBUTOR shall use reasonable commercial efforts to promote, sell, and distribute the Product within the Territory, at its own expense. Such efforts shall include, but not be limited to, *e.g.* professional sales calls on target medical audiences (*e.g.* physicians, hospitals, pharmacists), advertising the Product in appropriate media and participating in trade shows, conferences, expositions, and promotional seminars, all with due consideration for the local marketing environment in the Territory.

4.1.2 Offices and Personnel. DISTRIBUTOR shall at its own expense maintain offices adequate to market and support the Product within the Territory and shall retain and have at its disposal at all times a sufficient and adequate staff of trained and qualified personnel to perform its obligations under this Agreement.

4.1.3 Compliance. DISTRIBUTOR shall conduct its marketing activities in accordance with Applicable Law and in accordance with appropriate or applicable standards of pharmaceutical product promotional practices, fair trade, fair competition, and business ethics, and shall cause its employees and Dealers to do the same.

4.1.4 Diligence Failure. Failure to meet DISTRIBUTOR's diligence obligations, as set forth in this Section 4.1 shall be considered as a breach of this Agreement and will give SUPPLIER the right, in its sole discretion, with [***] prior written notice (if DISTRIBUTOR has failed to cure either such diligence obligation within such [***] period), to either (i) terminate the Agreement, in accordance with Section 16.2; or (ii) appoint additional distributor(s) for the Territory or parts thereof, and convert the exclusive rights of Section 2.1.1 and 2.3.1 into non-exclusive rights. In such event, the Parties will agree on new applicable Minimum Annual Purchase Quantities. The remedies available to SUPPLIER under this Section 4.1.4 (i) and (ii) shall however not commence until [***] after the Effective Date.

4.2 Distribution

4.2.1 Inventory. DISTRIBUTOR shall or shall cause its nominated third parti(es) to at all times maintain a stock of Product so as to adequately serve and fulfill the normal and reasonably foreseeable sales of Product within the Territory, however such stock not to be less than [***] supply of Product. In particular, DISTRIBUTOR shall ensure that DISTRIBUTOR, its Dealers or its nominated third parti(es), if applicable, shall maintain suitable premises for the storage and handling of Product and shall assure proper storage and handling of Product in accordance with Good Distribution Practice (GDP) standards and Product requirements as set forth in the Marketing Authorization. SUPPLIER or its authorized representatives are entitled to inspect the storage and handling facilities used by DISTRIBUTOR for Product and the offices where pertinent documentation is handled during normal business hours upon reasonable prior written notice. The Parties shall bear its own costs for such inspections.

4.2.2 Distribution. DISTRIBUTOR shall be responsible for proper packing of Product for shipment and distribution within the TERRITORY. DISTRIBUTOR shall use suitable transport systems and handle Product in accordance with Good Distribution Practice (GDP) standards and Product requirements.

4.2.3 Alterations. DISTRIBUTOR shall ensure that the Product is distributed, sold, promoted, marketed and advertised in the form and with the labeling or marking designated by SUPPLIER and in accordance with the applicable regulations in the Territory and, in particular, shall not alter, remove, or deface any Trademark without the written approval of SUPPLIER.

4.3 Promotional Materials

4.3.1 Promotional Materials. DISTRIBUTOR may develop sales literature, product descriptions, sales aids and advertising and promotional materials (collectively "***Promotional Materials***") from background information and materials provided by SUPPLIER, provided however, that all costs and expenses incurred by DISTRIBUTOR in the preparation and distribution of such sales literature and promotional materials shall be borne solely by DISTRIBUTOR.

4.3.2 Provision of Promotional Materials. To the extent that it is legally and contractually permitted to do so, SUPPLIER will share with DISTRIBUTOR Promotional Materials developed and used by SUPPLIER, its other distributors or licensees in respect of each Product as soon as practicable; and hereby grants to DISTRIBUTOR a royalty free, non-exclusive license during the Term to reproduce and/or adapt the Promotional Materials only for the purpose of promoting the Product in the Territory, provided that DISTRIBUTOR shall bear all costs of reproducing and/or adapting such Promotional Materials.

4.3.3 Copyright. DISTRIBUTOR shall retain the copyright in any Promotional Material developed by DISTRIBUTOR and any adaptation of the Promotional Materials provided by SUPPLIER (the "***DISTRIBUTOR Promotional Materials***"). DISTRIBUTOR agrees to provide to SUPPLIER on request samples of the DISTRIBUTOR Promotional Materials.

4.3.4 Compliance and Approval. DISTRIBUTOR shall submit DISTRIBUTOR Promotional Materials, which DISTRIBUTOR shall ensure comply with the Marketing Authorization, Applicable Laws and/or all other applicable rules and regulations in Territory, for review and approval by SUPPLIER on a timely basis to allow SUPPLIER to verify if such Promotional Materials are in line with global branding strategies and relevant Marketing Authorization. In the event that such Promotional Materials are not in line with global branding strategies and relevant Marketing Authorization, SUPPLIER will notify DISTRIBUTOR of any discrepancies and request DISTRIBUTOR to cure such discrepancies. Upon reasonable request by SUPPLIER, and provided SUPPLIER has no internal resources to read and understand [***] text, DISTRIBUTOR shall, at its own risk, cost and expense, translate Promotional Materials into the English language or certify in writing that any Promotional Material in a local language is a correct translation of the Promotional Material provided by SUPPLIER and that the translation was made by a certified translator. SUPPLIER shall provide comments or approval within [***] from receipt of a complete submission. If SUPPLIER does not give approval or comments within that [***] period, such Promotional Material shall be deemed approved.

5. AUTHORIZATIONS, PHARMACOVIGILANCE, COMPLAINTS, FIELD ACTIONS AND ESCALATIONS

5.1 Regulatory and Pricing Approval

5.1.1 No Marketing of Product without Marketing Authorization. DISTRIBUTOR shall import, transport, store, market, promote, offer for sale or sell and distribute the Product in accordance with the Marketing Authorization.

5.1.2 Marketing Authorization. SUPPLIER shall provide DISTRIBUTOR with SUPPLIER's available information that is needed for the promotion and distribution of the Product. The SUPPLIER will be in charge of the regulatory submissions to obtain and maintain the Marketing Authorization for the Product in the Territory. Any changes and variations to the Summary of Product Characteristics of the Product and package leaflet and packaging components will only be implemented after approval of the competent Regulatory Authority. SUPPLIER will keep DISTRIBUTOR informed about Marketing Authorization or other label changes relevant for marketing and promotion.

5.1.3 Pricing Approvals. DISTRIBUTOR shall be solely responsible for obtaining and maintaining Pricing Approval(s) for the sale of Product in the Territory, unless otherwise agreed by the Parties or legally required. For this purpose, SUPPLIER shall provide DISTRIBUTOR with data and documentation required for obtaining and maintaining Pricing Approval(s). This includes timely response to requests for the submission of pricing data by the local Governmental Authorities.

5.2 Manufacturing License and Batch Release

5.2.1 Manufacturing License. SUPPLIER shall be responsible, without any additional cost to DISTRIBUTOR, for securing and maintaining all necessary governmental approvals, licenses, authorisations and permissions, which may be required for SUPPLIER to manufacture or have manufactured the Product for distribution in the Territory.

5.2.2 Batch Release and Wholesale License. SUPPLIER shall be responsible for securing batch release relating to Product with an European Official Medicinal Control Laboratory and shall provide DISTRIBUTOR with relevant information forms and certificates as further specified in ANNEX E. DISTRIBUTOR shall be entitled to rely upon such information forms and certificates without the necessity of performing additional testing. DISTRIBUTOR is responsible to obtain and hold all necessary regulatory registrations regarding distribution in the Territory. Product will be supplied with all relevant documents showing that the Product is finally released for marketing in the Territory.

5.3 Pharmacovigilance and Clinical Trials

5.3.1 Pharmacovigilance. DISTRIBUTOR shall adopt and maintain a service responsible to handle pharmacovigilance in the Territory concerning Product as detailed in the Pharmacovigilance Agreement as attached hereto as ANNEX G. The obligations of DISTRIBUTOR to forward any Safety Report to SUPPLIER, as further specified in ANNEX G, shall survive expiry or termination of this Agreement and be effective until [***] to cover a transitional period.

5.3.2 Data Collection. DISTRIBUTOR shall not initiate, sponsor or support any structured data collection schemes involving Product, including but not limited to:

(i) interventional clinical trials; and/or

(ii) non-interventional clinical studies, compassionate use/named subject use programs, or any other subject support programs.

5.4 Recalls, Technical Complaints etc.

5.4.1 DISTRIBUTOR and SUPPLIER shall accept and follow the responsibilities and processes for recalls, complaints and other quality related issues as described in the Quality Agreement attached hereto as ANNEX E.

5.5 Medical Information Services

5.5.1 DISTRIBUTOR shall provide medical information services for the Product in the Territory through qualified personnel in accordance with this Agreement and as further detailed in this Section 5.5. Medical queries from the Territory received by SUPPLIER shall be directed to DISTRIBUTOR's Address for Medical Information Purposes as further detailed in ANNEX I.

5.5.2 Product queries. DISTRIBUTOR shall perform the medical information services for the Product by using up-to-date and SUPPLIER approved resources: Summary of Product Characteristics or local equivalent and the English Product Questions & Answers (Q&A) document(s).

DISTRIBUTOR shall forward all Product medical queries outside the scope of the Summary of Product Characteristics (or local equivalent) and the English Product Q&A document(s) it receives in an anonymous form to SUPPLIER's Address for Medical Information Purposes (ANNEX I) as soon as practicable after receipt but no longer than [***]. The answer will be compiled by SUPPLIER's respective department and will be sent as soon as practicable, but no longer than [***], to DISTRIBUTOR, who shall be responsible for ensuring that answers are compliant with local laws and regulations *e.g.* by adding specific required information and for contacting and liaising with its customer.

5.5.3 Information flow between DISTRIBUTOR and SUPPLIER. SUPPLIER will provide DISTRIBUTOR with the updated English version of the Product Q&A document(s) on at least a [***] basis. The English Product Q&A document(s) can be translated by DISTRIBUTOR to the local language(s) of the Territory at its own risk and expense. Every [***] the DISTRIBUTOR shall provide—in an anonymous form and in the [***] language—SUPPLIER with all Product medical queries (without DISTRIBUTOR's reply to such queries) it has received. Such information shall be directed to the SUPPLIER's Address for Medical Information Purposes (ANNEX I). Any newly identified safety issue relating to the Product shall be communicated promptly to the other Party for review, discussion and a decision to be made on the appropriate course of action(s) to be taken, if any.

5.5.4 Training. If requested by either Party, SUPPLIER's respective department shall provide DISTRIBUTOR's qualified personnel with an annual medical information training, whose form shall be at the discretion of the SUPPLIER (*e.g.* training manual, web-based or face to face training) and it is DISTRIBUTOR's responsibility to assure that its qualified personnel attends such training. Unle4s, otherwise agreed, such training shall be conducted in the Territory.

5.5.5 Continuing Obligation. After expiry or termination of this Agreement plus [***] to cover a transitional period, DISTRIBUTOR shall continue to forward any Product related medical query it received to SUPPLIER's Global Medical Information department per fax as indicated by such department, as soon as practicable but no later than within [***] of receipt.

5.5.6 Archiving. During the term of this Agreement, DISTRIBUTOR will document and archive all Product related medical queries it received together with DISTRIBUTOR's reply to such queries, and if required by a Governmental Authority, provide them to SUPPLIER and/or Governmental Authority.

5.6 Exchange and Update of Essential Information

5.6.1 SUPPLIER shall keep DISTRIBUTOR informed about any changes regarding or having any effect on (i) the procedure according to which a Product is manufactured, (ii) the composition and/or pharmaceutical characteristics of a Product and/or (iii) the content and/or the wording of the Summary of Product Characteristics (SPC) package leaflet and packaging components for a Product. All changes will only be implemented after having received approval by the competent Regulatory Authority.

5.6.2 Whenever a change as described in Section 5.6.1 occurs or becomes foreseeable, SUPPLIER will inform DISTRIBUTOR about all necessary details without undue delay. The Parties will then initiate and carry out a change control procedure that is compliant with all applicable standards of Good Manufacturing Practice (GMP).

5.6.3 Each change control procedure according to Section 5.6.2 shall be documented by the Parties. The documentation shall be signed by the Parties and added to each Party's exemplar of the present Agreement.

6. FORECASTS AND ORDERS

6.1 Minimum Purchase Quantities and Sales Target

6.1.1 Minimum Purchase Quantities. In any full calendar year following the Start Date, where DISTRIBUTOR retains exclusive rights, and where applicable Pricing Approval of a Product in the Territory, DISTRIBUTOR shall purchase the minimum annual purchase quantities set forth in ANNEX D.

6.1.2 Failure to fulfill Minimum Purchase Quantities. If, at the end of any full calendar year, DISTRIBUTOR has failed to purchase the minimum annual purchase quantity of Product, DISTRIBUTOR shall pay to SUPPLIER an amount equivalent to [***] of the Transfer Price, reference to ANNEX C, then in effect per Product dose not purchased by the DISTRIBUTOR for such calendar year equal to such shortfall. Should DISTRIBUTOR fail to purchase the minimum annual purchase quantity of Product for [***], SUPPLIER may, at its option and upon [***] prior written notice (1) appoint additional distributor(s) for the Territory and DISTRIBUTOR'S rights hereunder will automatically be converted to non-exclusive, or (2) terminate this Agreement in accordance with Section 16.3 below. For the avoidance of doubt: despite the Start Date April 1st, 2016, the minimum annual purchase quantity refers to the full calendar year 2016 as the GSK Group company GlaxoSmithKline Vaccines Vertriebs GmbH (formerly known as Novartis Vaccines Vertriebs GmbH) has already been distributing the Product under a previous and now terminated distribution agreement.

6.1.3 Sales Target. In any full calendar year following the Start Date, and where applicable Pricing Approval of a Product in the Territory, DISTRIBUTOR shall use reasonable commercial efforts to reach the sales targets set forth in ANNEX D. For the avoidance of doubt: despite the Start Date April 1st, 2016, the sales target refers to the full calendar year 2016 as one of the GSK Group companies, GlaxoSmithKline Vaccines Vertriebs GmbH, (formerly known as Novartis Vaccines Vertriebs GmbH) has already been distributing the Product under a previous and now terminated distribution agreement.

6.2 Forecasts and Orders

6.2.1 Forecasts. DISTRIBUTOR shall provide, or ensure that its nominated Affiliates provide SUPPLIER with its best estimate of anticipated orders of Product on a rolling, [***] basis in accordance with ANNEX C hereto. DISTRIBUTOR shall be entitled to increase or decrease the quantities of Product required, and to amend any forecast accordingly, to the extent necessary to take into account (i) any shortfall in supply of, or (ii) any defect, in the Product, or any of them, whether or not such shortfall or defect is due to the default of SUPPLIER. For the avoidance of doubt, a forecast, shall have no bearing on the minimum purchase quantities referred to in Section 6.1 above.

6.2.2 Firm Purchase Orders. DISTRIBUTOR shall place orders with the lead-time defined in ANNEX C and in line with DISTRIBUTOR's forecast requirements for the Territory ("***Firm Orders***"). All Firm Orders will be delivered to SUPPLIER via DISTRIBUTOR's electronic global trading platform (or such similar system as DISTRIBUTOR may deploy from time to time provided SUPPLIER has the necessary resources and ability to receive such electronical orders). SUPPLIER shall use reasonable commercial efforts to work with DISTRIBUTOR, or DISTRIBUTOR's nominated Representative, to ensure that SUPPLIER is able to accept purchase orders via such global trading platform. Cost for implementation necessary for adapting SUPPLIER's systems to DISTRIBUTOR's will be split equally between the Parties. Each order shall contain a valid purchase order number, shall separately specify the labeling requirements in the Territory to allow SUPPLIER to label those products before shipment, and shall be duly signed by DISTRIBUTOR or its nominated Representative. The terms and conditions of this Agreement shall apply to all orders placed by DISTRIBUTOR or its nominated Representative and shall override and supersede any different or additional terms on orders from, or any general conditions maintained by DISTRIBUTOR or its nominated Representative. All orders are subject to written acceptance by SUPPLIER and will not be binding on SUPPLIER until the order has been accepted in writing as set out in Section 6.5.

6.3 Minimum Orders. Any single order placed by DISTRIBUTOR shall amount to not less than [***] doses of Product. Moreover, for any calendar year, DISTRIBUTOR shall not place more than [***] purchase orders. In the event that DISTRIBUTOR does place more than [***] orders, SUPPLIER will use its reasonable commercial efforts to comply with such additional orders.

6.4 Problem Notification. SUPPLIER shall, as soon as practicable after receipt of each quarterly rolling forecast, notify DISTRIBUTOR of any prospective problems it then knows it will have with respect to meeting DISTRIBUTOR's forecasted order quantities or estimated shipment dates. SUPPLIER will use its reasonable commercial efforts to deliver to DISTRIBUTOR the Product in the quantities and at the dates specified on the purchase orders submitted by DISTRIBUTOR and as accepted in writing by SUPPLIER. If a purchase order cannot be (fully) shipped, SUPPLIER will notify DISTRIBUTOR after receipt of the purchase order, and the Parties will jointly determine an appropriate new shipment schedule.

6.5 Order confirmation and Rescheduling

6.5.1 Acceptance of Orders. No Firm Order shall be binding upon SUPPLIER until accepted by SUPPLIER in writing and SUPPLIER reserves the right to accept or reject any such order, offer or request for Product; rejection of Firm Orders may only be declared by SUPPLIER for comprehensible reasons which have to be substantiated in writing to DISTRIBUTOR. SUPPLIER shall review DISTRIBUTOR's submitted Firm Orders and respond with a written order acceptance confirming the quantity, delivery date, price and payment terms, or a written order rejection indicating the reason for rejection.

6.5.2 Rescheduling. SUPPLIER will use its reasonable best commercial efforts to honor any request of DISTRIBUTOR to reschedule shipment of any order accepted by SUPPLIER.

7. SHIPMENT AND DELIVERY

7.1 Shipment. The Product shall be shipped FCA and title and risk shall pass upon delivery.

7.2 Packaging for Shipment. The Product shall be delivered to DISTRIBUTOR or its nominated third parti(es) in suitable packaging, so as to permit safe storage and transport.

7.3 Shelf-Life. The Product shall have not less than [***] of the total shelf-life at the requested delivery date indicated on any accepted Purchase Order, unless otherwise agreed upon, in writing, between the Parties.

7.4 Quantities. DISTRIBUTOR agrees and accepts that due to the particularity of the Product, the quantity of Product supplied to DISTRIBUTOR may differ by plus/minus [***] from the ordered and confirmed quantity and that the actual delivered quantity of Product will be invoiced.

7.5 Delivery Delay and Failure. SUPPLIER will use reasonable commercial efforts to supply and deliver ordered and confirmed quantity of Product, however, due to the particularities of the manufacturing processes used, and provided SUPPLIER has used reasonable commercial efforts, SUPPLIER shall not be liable for any failure, shortfall or delay in delivery of such ordered and confirmed Product. In case of failure, shortfall or delay, the Parties will jointly determine an appropriate new shipment schedule for such ordered and confirmed Product. For the avoidance of doubt, in the event of delay, shortfall or failure to supply the minimum purchase quantities requirements referred to in Section 6.1 above, shall be adjusted on a pro rata basis.

8. PRODUCT WARRANTY

8.1 Product Supply Warranties. SUPPLIER represents and warrants, each time SUPPLIER supplies Product to DISTRIBUTOR under this Agreement, that each Product supplied hereunder shall:

(1) conform in all material aspects to the Product specifications consistent with the data contained in the Marketing Authorizations;

(2) be manufactured in accordance with current Good Manufacturing Practice ("***GMP***"), as amended from time to time, and

(3) not be adulterated or misbranded.

8.2 Audit/Inspection Right. SUPPLIER or its authorized representatives are entitled to audit/inspect the DISTRIBUTOR regarding handling of Product and activities according to this Agreement as provided for in ANNEX E. Such audits/inspections are aimed to ensure compliance with this Agreement and all Applicable Laws and regulations, including but not limited to GMP and shall be carried out during normal business hours and upon reasonable prior written notice.

8.3 Inspection. DISTRIBUTOR shall inspect or shall ensure that its nominated third party(ies) inspect each shipment of Product visually promptly upon receipt. If the Product supplied fails to meet the Product specifications and standards set forth or referenced herein or otherwise fail to comply with the terms and conditions of this Agreement, DISTRIBUTOR shall within [***] from receipt of the Product notify SUPPLIER (to the attention of its Quality Assurance Department) of such non-compliance, including a description thereof in accordance with the provisions set forth in ANNEX E. Failures to give such notice within the aforesaid time period shall constitute acceptance of the Product by DISTRIBUTOR as to defects reasonably discoverable upon visual inspection. Warranty claims for hidden defects, shall be made promptly after discovery of the hidden defect, but may only be made [***]. Any Product found to be non-compliant in line with this Section 8.3, shall be put into quarantine and kept there until SUPPLIER has decided upon its further disposition. After such disposition it shall be dealt with as decided by SUPPLIER.

8.4 Non-Conforming Product. Where DISTRIBUTOR alleges that any delivered Product is non-conforming, DISTRIBUTOR shall or shall ensure that its nominated third parti(es), on request, provide SUPPLIER or SUPPLIER's designee with a sample of such allegedly non-conforming Product, within [***] after the detection of such defects. SUPPLIER or such designee will examine such allegedly non-conforming Product as soon as reasonably practicable.

8.5 Remedy. If SUPPLIER agrees that the Product is non-conforming or if such non-conformance has been established by an independent laboratory in accordance with Section 8.7 below, SUPPLIER shall use its reasonable commercial efforts to dispatch to DISTRIBUTOR or its nominated third parti(es) replacement Product as soon as is reasonably practicable. All shipment costs in respect of replacement Product shall be borne by SUPPLIER.

8.6 Return of defective Product. DISTRIBUTOR agrees, if so requested by SUPPLIER, to return to SUPPLIER at SUPPLIER's expense, such Product that does not meet the Product specifications therefor, or otherwise dispose such Product, at SUPPLIER's expense and in compliance with all applicable rules and regulations, as SUPPLIER may direct. If SUPPLIER does not so direct, within [***] following DISTRIBUTOR's notification of non-conformity, DISTRIBUTOR may dispose of such Product at SUPPLIER's expense as DISTRIBUTOR may deem reasonably appropriate and shall certify to SUPPLIER in writing that such Product has been destroyed.

8.7 Independent Testing. If the Parties disagree as to whether any delivered Product meets the applicable Product specifications, or SUPPLIER alleges that the defects are not attributable to the manufacture of the Product, the Parties will submit representative samples of the shipment to a mutually acceptable independent testing laboratory and the results of said laboratory shall be binding on the Parties. The costs associated with submission will be paid by the Party, whose position is not substantiated by the independent laboratory.

9. PRICES AND PAYMENTS

9.1 Transfer Prices. SUPPLIER shall sell Product to DISTRIBUTOR at the Transfer Prices and in accordance with the terms set forth in ANNEX C hereto. Payment terms are [***] from date of invoice and any and all payments shall be made to an account designated by SUPPLIER. SUPPLIER shall send invoices to the designated Affiliate as per DISTRIBUTOR's instructions and DISTIBUTOR shall ensure that its designated Affiliate pay the invoice in accordance with this Agreement. Upon request by SUPPLIER or SUPPLIER's representative, DISTRIBUTOR shall represent to SUPPLIER or to third parties named by SUPPLIER that all payments will be made to such designated account. Upon shipment of Product ordered, SUPPLIER shall invoice prices in Euro (EUR). Any stamp duty, document tax, filing fee, or other similar amount due under the laws and regulations of the Territory in connection with the execution or entry into force of this Agreement shall be borne by DISTRIBUTOR. Further, should this Agreement be required to be registered with any Governmental Authority in the Territory, DISTRIBUTOR shall cause such registration to be made and shall bear any expense or tax payable in respect thereof.

9.2 Pricing Modifications. The payment terms as specified in ANNEX C can be reviewed annually and adjusted if the Parties so agree in writing. In case of modifications, ANNEX C shall be amended accordingly. Either Party may initiate pricing discussions [***] based on substantial increase of labor or material cost or significant changes in the relevant Product markets in the Territory, as described in ANNEX C. In such a case, the Parties shall negotiate in good faith upon a mutual acceptable pricing modification. Such changes shall take effect immediately after the Parties have mutually agreed in writing upon the modifications. If the Parties fail to reach agreement within a reasonable time, such time being within [***] following year end the following calendar year, the Transfer Price then in effect may be increased by an amount equal to [***].

9.3 Pricing of Orders in Progress. Firm purchase orders placed with SUPPLIER before written agreement for a pricing modification is reached shall be carried out at previous pricing conditions and payment terms.

9.4 Late Payment. If any payment under this Agreement is not made by the date on which the same becomes due and payable, DISTRIBUTOR shall automatically, without any further notification being given by SUPPLIER, owe SUPPLIER interest calculated at a rate of [***] on the invoiced amount [***].

9.5 Non-Creditable Payments. All payments to be made by DISTRIBUTOR hereunder are non-creditable and refundable under any circumstances, including but not limited to the termination of this Agreement for whatever reason, except as otherwise provided in this Agreement.

9.6 Selling Prices. Supplier acknowledges that DISTRIBUTOR has the sole right to establish selling prices for Product in the Territory, and nothing in this Agreement will be construed as giving SUPPLIER any right or authority to determine or influence such selling prices.

10. SALES RECORDS AND REPORTING OBLIGATIONS

10.1 Sales Records. DISTRIBUTOR shall, or ensure that its Affiliates maintain and retain all records relating to Product sales, contracts, invoices, customers, accounts, complaints and other transactions concerning Product for the period required by Applicable Laws, but in no case less than [***] from the date on which such records arose.

10.2 Reports. To the extent permitted by EU competition law, DISTRIBUTOR shall keep SUPPLIER informed of significant market developments in the Territory especially in the field of the vaccination policy. DISTRIBUTOR shall provide SUPPLIER with [***] reports on sales figures of the Product in the Territory as well as [***] reports including, to the extent applicable, updates of DISTRIBUTOR'S activities to develop and market the Product in the Territory, and any competitive product intelligence, including market share information that DISTRIBUTOR may have received. The report on the [***] shall cover in addition the full calendar year and serve as an annual report. Each such report shall comply with the format provided by SUPPLIER in ANNEX J and shall be due on the [***] of the following [***]. Each such [***] report shall additionally include for the Product (1) the amount of inventory of Product held at the end of each [***], and (2) the [***] volume sold both on doses and in net value in the Territory. DISTRIBUTOR

shall cause its Dealers, if any, to prepare and submit to DISTRIBUTOR, on a timely basis, similar reports and shall include information from such reports in the reports provided by DISTRIBUTOR hereunder. In case of major volume shortfalls, DISTRIBUTOR will immediately inform SUPPLIER about the reasons of such deviation and propose corrective actions. Commencing on [***], and every [***] thereafter, the Parties shall meet and discuss DISTRIBUTOR's marketing efforts performed during the preceding [***] period including DISTRIBUTOR's planned marketing activities in the Territory.

10.3 Tenders. DISTRIBUTOR shall duly inform SUPPLIER about any and all tenders concerning the Product issued by any Governmental Authority or any relevant public institution in the Territory, where DISTRIBUTOR intends to participate and quote, and upon DISTRIBUTOR's reasonable request, SUPPLIER shall supply DISTRIBUTOR with all information and documents required by DISTRIBUTOR to submit a valid offer. DISTRIBUTOR shall consult and provide SUPPLIER with all relevant information with respect to the tender offer prior to submission of such tender offer in order to receive SUPPLIER's written approval by SUPPLIER to the extent permitted under EU competition law.

11. INTELLECTUAL PROPERTY RIGHTS

11.1 Intellectual Property Rights

11.1.1 Acknowledgment. DISTRIBUTOR acknowledges that, prior to entering into this Agreement, it has no right, title or interest in and to any and all Intellectual Property Rights pertaining to the Product. DISTRIBUTOR shall not at any time during or after the Term of this Agreement take any act or step impairing the Intellectual Property Rights or do anything that may otherwise adversely affect the Intellectual Property Rights, provided that any legal proceedings or oppositions shall not be deemed to be such an act or step.

11.1.2 Preservation of Trademarks. DISTRIBUTOR agrees to take any action, at SUPPLIER's expense, which SUPPLIER reasonably deems necessary to establish and preserve SUPPLIER's exclusive rights in and to the relevant Trademarks, including but not limited to cooperating in the registration of the Trademarks on the trademark registry or other appropriate registration procedure within the Territory. DISTRIBUTOR shall not adopt, use, or register any acronym, trademark, trade names, service mark or other marketing name that is confusingly similar to the SUPPLIER's Trademarks or the SUPPLIER name.

11.1.3 Benefit. DISTRIBUTOR agrees that all its use of SUPPLIER's Trademarks shall be for the sole and exclusive benefit of SUPPLIER and the goodwill and reputation accrued in connection with DISTRIBUTOR's use of those Trademarks shall accrue to SUPPLIER.

11.2 Third Party Claims

11.2.1 SUPPLIER Third Party Claims. DISTRIBUTOR shall promptly notify SUPPLIER of any claims or objections that claims that SUPPLIER's use of the Intellectual Property Rights in connection with the distribution, sale, marketing, promotion, and importation of the Product infringe the copyrights, patents, design rights, trademarks or other proprietary rights of another Person, provided DISTRIBUTOR's use of the Intellectual Property Rights is in accordance with the terms and conditions of this Agreement ("***SUPPLIER Third Party Claim***"). If DISTRIBUTOR is served with a legal action or otherwise forced to respond in a legal proceeding due to a SUPPLIER Third Party Claim, SUPPLIER shall conduct the defense of such SUPPLIER Third Party Claim at its own cost. SUPPLIER shall have the sole control over the defense and settlement of any SUPPLIER Third Party Claims. For that purpose, DISTRIBUTOR shall (1) without delay, tender the defense of such SUPPLIER Third Party Claim to SUPPLIER; and (2) render SUPPLIER all reasonable assistance, at SUPPLIER's expense, in connection with the defense of any such SUPPLIER Third Party Claim or objection, whether in the courts, before administrative agencies, or otherwise. DISTRIBUTOR shall not, except as required by law, knowingly make any admission to jeopardize, compromise or otherwise limit the validity of Intellectual Property Rights.

11.2.2 DISTRIBUTOR Third Party Claims. SUPPLIER shall promptly notify DISTRIBUTOR of any claims or objections of which it receives in written notice, that its use of the DISTRIBUTOR Promotional Materials in connection with the distribution, sale, marketing, promotion, and importation of the Product may or will infringe the copyrights, patents, trademarks, design rights or other proprietary rights of another Person, provided SUPPLIER's use of the Intellectual Property Rights is in accordance with the terms and conditions of this Agreement ("***DISTRIBUTOR Third Party Claim***"). If SUPPLIER is served with a legal action or otherwise forced to respond in a legal proceeding due to a DISTRIBUTOR Third Party Claim, DISTRIBUTOR shall have the initial right, but not the obligation, to conduct the defense of such DISTRIBUTOR Third Party Claim at its own cost. DISTRIBUTOR shall have the sole control over the defense and settlement of any DISTRIBUTOR Third Party Claims. For that purpose, SUPPLIER shall (1) without delay, tender the defense of such DISTRIBUTOR Third Party Claim to DISTRIBUTOR; and (2) render DISTRIBUTOR all reasonable assistance, at DISTRIBUTOR's expense, in connection with the defense of any such DISTRIBUTOR Third Party Claim or objection, whether in the courts, before administrative agencies, or otherwise. SUPPLIER shall not, except as required by law, knowingly make any admission to jeopardize, compromise or otherwise limit the validity of intellectual property rights related to the DISTRIBUTOR Promotional Materials. If DISTRIBUTOR declines to defend a DISTRIBUTOR Third Party Claim, SUPPLIER may do so at its own expense.

11.3 Infringement of Intellectual Property Rights

11.3.1 Notification. DISTRIBUTOR shall promptly notify SUPPLIER of any infringement or suspected infringement of Intellectual Property Rights in the Territory, of which infringement DISTRIBUTOR becomes aware, and provide SUPPLIER with any available evidence of such infringement or suspected infringement.

11.3.2 Enforcement. SUPPLIER may at its own discretion, institute enforcement proceedings ("***Enforcement Proceedings***") in respect of an infringement or unauthorized use of Intellectual Property Rights in the Territory.

11.3.3 Assistance. DISTRIBUTOR agrees to provide all reasonable co-operation and assistance to SUPPLIER in relation to any such Enforcement Proceedings (and agrees to be named as a party if legally required). Any reasonable fees and costs related to DISTRIBUTOR's assistance, which were borne by DISTRIBUTOR, shall be reimbursed by SUPPLIER. SUPPLIER shall be entitled to any recovery in damages.

12. NON-DISCLOSURE AND NON-USE OBLIGATIONS

12.1 Non-disclosure of Agreement

12.1.1 Non-disclosure of Agreement. Neither Party shall disclose any information about this Agreement without the prior written consent of the other.

12.1.2 Exceptions. Consent shall not be required, however, for (1) disclosures to tax authorities or to bona fide potential Dealers, to the extent required or contemplated by this Agreement, provided, that in connection with such disclosure, each Party agrees to use its reasonable commercial efforts to secure confidential treatment of such information; (2) disclosures of information for which written consent has previously been obtained, or (3) information which had previously been publicly disclosed. Each Party shall have the further right to disclose the terms of this Agreement as required by Applicable Law, including the rules and regulations promulgated by the Securities and Exchange Commission and/or the regulatory bodies/authorities governing securities issues in foreign jurisdictions and to disclose such information to stockholders or potential investors as is customary for publicly-held companies (as the case may be at the time of disclosure), provided the disclosing Party provides to the other Party, to the extent practicable, a copy of the information to be disclosed and an opportunity to comment thereon prior to such disclosure, and, to the extent practicable, consults within a reasonable time in advance of the proposed disclosure with the other on the necessity for the disclosure and the text of the proposed release.

12.2 Non-disclosure and non-use of Confidential Information

12.2.1 Non-disclosure and non-use of Confidential Information. SUPPLIER and DISTRIBUTOR hereby agree to hold in strictest confidence and not to disclose to any third party or itself use (except to enable each Party to perform its obligations in connection with this Agreement) any Confidential Information of the other Party without the prior written consent of the other Party. This confidentiality obligation shall remain in effect for Confidential Information with the exception of trade secrets, which confidentiality obligation shall survive Termination, for a period of (i) [***] after termination of the Marketing and Distribution Agreement between SUPPLIER's Affiliate and DISTRIBUTOR's Affiliate dated [***] or (ii) [***] from the earlier or normal termination or expiration of this Agreement, whichever is later.

12.2.2 Exceptions. The confidentiality obligations under this Agreement shall not apply to the extent that (1) the Party who has received the Confidential Information ("***Recipient***") is required to disclose Confidential Information by order or regulation of a governmental agency or court of competent jurisdiction subject to the provisions below, or (2) the Recipient can demonstrate that (i) the disclosed Confidential Information was at the time of such disclosure to Recipient already in the public domain, or falls into the public domain, other than as a result of actions of Recipient, its Dealers, its Affiliates, agents, direct employees, consultants or representatives, in violation hereof; (ii) the disclosed Confidential Information was known by Recipient (as shown by its written records) prior to the date of disclosure to Recipient from sources legally entitled to disclose the same or is independently developed without regard to the Confidential Information (as shown by its written records); or (iii) the disclosed Confidential Information was received by Recipient (as shown by its written records) on an unrestricted basis from a source unrelated to any Party to this Agreement and not under a duty of confidentiality to the other Party.

12.2.3 Confidentiality Agreements. Both Parties shall ensure that each of their directors, officers and employees and the directors, officers and employees of its Affiliates respectively, Dealers and SUPPLIER's assignees, who will receive Confidential Information, shall at all material times be bound by appropriate undertakings as to the confidentiality of such information. DISTRIBUTOR and SUPPLIER, respectively, shall at their own expense undertake the enforcement of any such obligations of confidentiality in the event of any breach thereof.

12.2.4 Ownership of other Party's Materials. All files, lists, records, documents, drawings, specifications and records provided by a Party, whether in written or electronic form, which incorporate or refer to all or a portion of a Party's Confidential Information, shall remain the sole property of that Party. Such materials shall be promptly destroyed or returned (1) upon that Party's reasonable request, or (2) in accordance with Section 17.3 of this Agreement upon termination of this Agreement, whichever is earlier. The decision whether such material shall be destroyed or returned is taken by the Party owning the Confidential Information.

13. REPRESENTATIONS AND WARRANTIES

13.1 SUPPLIER Representations and Warranties. SUPPLIER represents, and warrants, as of the Start Date, the following:

(1) SUPPLIER is not in any material breach of any agreement with third parties relating to the Product or the Intellectual Property Rights which would or might prejudice the rights of DISTRIBUTOR in the Territory (the "***Third Party Agreements***");

(2) to SUPPLIER's knowledge, there are no actions, suits or claims pending against SUPPLIER with respect to the Product or the Intellectual Property Rights in the Territory;

(3) to SUPPLIER's knowledge, the sale and use of the Product in accordance with and as further outlined in this Agreement, in the Territory, does not infringe the proprietary rights of any third party in the Territory; and

(4) to SUPPLIER's knowledge, it has disclosed appropriately and has not misrepresented to DISTRIBUTOR, any material matters relating to the Intellectual Property Rights, marketing, adverse events, supply, clinical and regulatory information pertaining to the Product in the Territory.

13.2 DISTRIBUTOR'S Representations and Warranties. DISTRIBUTOR represents, and warrants, as of the Start Date, the following:

(1) DISTRIBUTOR has disclosed appropriately and has not misrepresented, to SUPPLIER any material matters relating to DISTRIBUTOR's promotion, marketing and distribution capabilities in the Territory, and

(2) DISTRIBUTOR and/or its Dealers holds a wholesale license or adequate license issued by the respective authority in each country of the Territory granting DISTRIBUTOR permission to import, market and sell medical products and vaccines, as further specified in 2.4.

13.3 DISCLAIMERS. To the full extent permitted by law, apart from the warranties stated in this Agreement and indemnities below, SUPPLIER makes no additional representations or warranties and hereby disclaims all warranties, representations, and liabilities, whether express or implied, arising from contract or tort (except fraud), imposed by statute or otherwise, relating to the products and/or any patents or technology used or included in the products, including any warranties as to merchantability, fitness for purpose, correspondence with description, or non-infringement.

14. INDEMNITIES AND LIMITATIONS OF LIABILITY

14.1 SUPPLIER's Indemnity

14.1.1 SUPPLIER's Indemnity. SUPPLIER shall defend, indemnify and hold DISTRIBUTOR and its shareholders, managers, officers, directors, agents and employees (the "***DISTRIBUTOR Indemnitees***") harmless against any and all third party losses, damages, claims, liabilities, costs and expenses including reasonable attorney's fees ("***Claim***") resulting from the following:

(1) the personal injury to or death of any person or any property damage caused by the defective design and/or manufacture of the Product or inadequate warnings or instructions, or the failure of any Product to meet their Product specification; any act or omission of SUPPLIER or any of its shareholders, managers, officers, directors, agents or employees contrary to Applicable Law and so declared by a court of competent jurisdiction or as agreed by the Parties.

(2) SUPPLIER's transportation, storage, use and handling of the Product in compliance with this Agreement; or

(3) a negligent act or omission of SUPPLIER contrary to the law and is so declared by a court of competent jurisdiction or as agreed by the Parties any material breach by SUPPLIER of any of SUPPLIER's representations and warranties set forth in this Agreement or a negligent or willful breach of any term of this Agreement, so declared by a court of competent jurisdiction or as agreed by the Parties.

14.1.2 Limitation of SUPPLIER's Indemnity. SUPPLIER will not be liable for any indirect or consequential damages, including any loss of profits or opportunity, caused by any of its auxiliary persons or caused by the slight negligence of its employees, directors and officers. Further, SUPPLIER's indemnification under Section 14.1 shall not apply to any Claim to the extent that it is directly and/or indirectly related to the negligent activities, reckless misconduct or intentional misconduct attributable to DISTRIBUTOR.

14.2 DISTRIBUTOR's Indemnity

14.2.1 DISTRIBUTOR's Indemnity. DISTRIBUTOR shall indemnify and hold SUPPLIER and its shareholders, managers, officers, directors, agents and employees (the "***SUPPLIER Indemnitees***") harmless against any and all losses, damages, claims, liabilities, costs and expenses including reasonable attorneys' fees ("***SUPPLIER'S Claim***") resulting from the following:

(1) DISTRIBUTOR's importation, transportation, storage, use, promotion, marketing, sales, distribution and handling of the Product; any act or omission of DISTRIBUTOR or any of its shareholders, managers, officers, directors, Dealers, agents or employees contrary to Applicable Law and so declared by a court of competent jurisdiction or as agreed by the Parties,

(2) any breach by DISTRIBUTOR of any of DISTRIBUTOR's representations and warranties set forth in this Agreement or of negligent or willful breach of any term of this Agreement, so declared by a court of competent jurisdiction or as agreed by the Parties,

(3) any act or omission by DISTRIBUTOR and/or any Dealer which would constitute a violation of ANNEX H (Anti-Corruption Laws), or

(4) any breach due to negligent or willful misconduct of any term of a subdistribution agreement of any Dealer.

14.2.2 Limitation of Liability. DISTRIBUTOR shall not be liable for any indirect or consequential damages, including any loss of profits, caused by any of its auxiliary persons or caused by the slight negligence of its directors and officers. Further, DISTRIBUTOR's indemnification under Section 14.2 shall not apply to any SUPPLIER Claim to the extent that it is directly related to the negligent activities, reckless misconduct or intentional misconduct attributable to SUPPLIER.

14.3 Indirect damages. In no event shall any Party be liable to the other for indirect, special or consequential damages or losses suffered, including but not limited to loss of use, loss of profits and/or punitive damages, provided, that this exclusion of liability does not apply in cases of gross negligence or intentional misconduct.

14.4 Indemnification procedure

14.4.1 Notification. Each Party shall promptly notify the other in writing of any claim, action or suit potentially giving rise to an indemnification obligation hereunder.

14.4.2 Indemnification Procedure. The indemnifying Party shall have the sole and absolute control of, and discretion in, the handling of the defense and/or settlement of any such claim, action or suit, including, without limitation, the selection of defense counsel, and the other Party shall fully cooperate with the indemnifying Party in the defense and settlement of all such claims, actions or suits, provided, however, that the other Party may take any appropriate action necessary to preserve or avoid prejudice to its interests, or the interests of the indemnifying Party, in the event that:

(1) notice to the indemnifying Party cannot be given in sufficient time for the indemnifying Party to take action, or

(2) the indemnifying Party, after prompt notice and inquiry from the other Party, fails to acknowledge its obligation to indemnify the other Party under this clause.

15. GOOD ETHICAL BUSINESS PRACTICES, ANTI-CORRUPTION LAWS AND HUMAN RIGHTS

15.1 Good Ethical Business Practice. DISTRIBUTOR shall in connection with its activities under this Agreement or otherwise relating to Product:

(i) conduct business in a manner that reflects favorably on Product;

(ii) not disparage the name, good will, or reputation of SUPPLIER;

(iii) not engage in deceptive, misleading, or unethical practices;

(iv) not make any false or misleading representations or other statements with regard to SUPPLIER or Product;

(v) represent only such facts about Product as are in accordance with the Market Authorization, the Summary of Product Characteristics or otherwise expressly approved by SUPPLIER in writing, and

(vi) in no event make any representations, warranties, guarantees or other statements in SUPPLIER's name or on SUPPIER's behalf, except as approved in advance in writing by SUPPLIER.

15.2 Conflict of Interest. In order to avoid a conflict of interest between SUPPLIER and DISTRIBUTOR or an adverse effect on SUPPLIER, DISTRIBUTOR represents and warrants that, prior to the execution of this Agreement, it has disclosed to SUPPLIER all information with respect to DISTRIBUTOR's prior business and other activities that may reasonably support a belief that DISTRIBUTOR's appointment under this Agreement may result in a conflict of interest or may adversely affect the sale of Product. DISTRIBUTOR will disclose to SUPPLIER any future circumstances that could create possible conflicts of interest or adversely affect the sale of Product as soon as DISTRIBUTOR knows or becomes aware of them. Without limiting the generality of the foregoing, DISTRIBUTOR will inform SUPPLIER of any business relationship, circumstance or situation that could prejudice in any way the conduct of SUPPLIER's marketing activities according to the highest ethical standards or place DISTRIBUTOR or SUPPLIER in a disreputable situation.

15.3 Anti-corruption Laws. DISTRIBUTOR understands and shall comply with the U.S. Foreign Corrupt Practices Act, any applicable local anti-corruption laws and in accordance with ANNEX H attached to this Agreement.

15.4 Non-Compliance. DISTRIBUTOR's failure to abide by the provisions of Section 15.1, 15.2 and/or 15.3 shall be deemed a material breach of this Agreement, allowing SUPPLIER to immediately terminate this Agreement at its sole discretion without any notice to DISTRIBUTOR. DISTRIBUTOR shall indemnify and hold SUPPLIER and any of its Affiliates harmless from and against any and all liabilities that may arise by reason of its acts or the acts of third parties acting on its behalf, which would constitute a violation of Section 15.1, 15.2 and/or Section 15.3.

15.5 Human Rights. SUPPLIER represents that, with respect rift employment and manufacturing the Product under this Agreement, SUPPOR wile

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if housing is provided by SUPPLIER to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage, where applicable, and provide any legally mandated benefits;

(g) comply with laws on working hours and employment rights;

(h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;

(j) maintain a complaints process to address any breach of these standards.

16. TERM AND TERMINATION

16.1 Term and Extensions. The Term of this Agreement shall commence on the Effective Date and shall continue until December 31, 2018 (hereinafter the "***Initial Term***"). Notwithstanding the foregoing, any rights of exclusivity under this Agreement, including but not limited to the rights granted and obligations defined under Sections 2.1.1., 4.1.1 and 5.1.1, shall commence on April 1, 2016, unless otherwise agreed in writing. For the avoidance of doubt: despite the Start Date April 15t, 2016, the sales target and the minimum purchase quantities refer to the full calendar year 2016 as the Group company GlaxoSmithKline Vaccines Vertriebs GmbH (formerly known as Novartis Vaccines Vertriebs GmbH) has already been distributing the Product under a previous and now terminated distribution agreement. Either Party may initiate in [***] negotiations for the prolongation of this Agreement. In such case, the Parties shall negotiate in good faith whether and for how long this Agreement shall be extended. The Initial Term may be extended for an agreed period of time ("***Subsequent Terms***") by mutual written agreement of the Parties at any time prior to the expiry of the Initial Term of Subsequent Term, as the case may be.

16.2 Termination Events. This Agreement may forthwith be terminated by either Party by giving written notice of termination in the event that:

(1) the other Party breaches any of its material obligations under this Agreement, and fails to cure such breach within [***] of receiving a written notice specifying such breach and requiring it to be cured; provided that such termination shall not be effective where such breach is incapable of cure within such [***] period and where the Party being asked to cure such breach has commenced good faith and commercially reasonable efforts to cure such breach within such [***] period and cures such breach within [***] after the receipt of notice of material breach;

(2) the other Party enters into insolvency or bankruptcy or is unable to pay its debts as they fall due, or a trustee or receiver or the equivalent is appointed to the other Party, or proceedings are instituted against the other Party relating to dissolution, liquidation, winding up other than on a reconstruction, bankruptcy, insolvency or the relief of creditors, if such proceedings are not terminated or discharged within [***];

(3) in the event of a Change of Control of the other Party; or

(4) withdrawal of the Marketing Authorization in the Territory.

16.3 Termination by SUPPLIER. This Agreement may forthwith immediately be terminated by SUPPLIER, at its sole discretion, by giving written notice of termination, in the event that:

(1) DISTRIBUTOR ceases to carry on business in the marketing of pharmaceutical products in the Territory;

(2) DISTRIBUTOR is in breach of any provision of ANNEX H of this Agreement; and

(3) DISTRIBUTOR fails to achieve the minimum purchase quantities as required by Section 6.1.2 above;

(4) DISTRIBUTOR breaches its obligation to use reasonable commercial efforts to promote, sell and distribute the product DUKORAL° in the Territory according to a Distribution Agreement for DUKORAL° entered into between the Parties in parallel to this Agreement and in the event that SUPPLIER terminates the Distribution Agreement for DUKORAL° for this reason.

16.4 Termination by DISTRIBUTOR. This Agreement may forthwith be terminated upon [***] prior written notice by DISTRIBUTOR in the event that SUPPLIER fails in supplying Product under any Firm Purchase Order for a consequitive Period of [***].

17. EFFECTS OF TERMINATION OR EXPIRATION

17.1 Cessation of Rights. Upon expiration or termination of this Agreement (collectively "***Termination***") for any reason whatsoever as provided herein, all rights and obligations of the Parties hereunder shall cease, except as provided in Section 17.2 of this Agreement; provided, however, that Termination of this Agreement shall not relieve the Parties hereto of any obligations accrued prior to said Termination.

17.2 Survival of Terms. Termination of this Agreement shall not release either Party from any liabilities or obligations set forth in this Agreement which (i) the Parties have expressly agreed shall survive any such Termination, or (ii) remain to be performed or by their nature would be intended to be applicable following any such Termination.

17.3 Return of Confidential Information. Upon Termination, each Party shall promptly return to the other Party or destroy, or deliver to a third party designated by that other Party, and shall cause employees and Dealers, in the case of DISTRIBUTOR, to return or destroy or deliver as appropriate and indicated by the other Party, all of the other Party's Confidential Information in written, recorded or other tangible form. DISTRIBUTOR shall further return or deliver to SUPPLIER or destroy any other items in DISTRIBUTOR's possession, which SUPPLIER has furnished or supplied to DISTRIBUTOR, and which DISTRIBUTOR has passed on to its Dealers and employees, including customer lists for the Product provided by SUPPLIER.

17.4 Trademarks. Upon Termination of this Agreement, neither DISTRIBUTOR nor any third party Dealer or Affiliate, shall use or permit the use of any of the Intellectual Property Rights, Trademarks and trade names of SUPPLIER or similar trademarks, denominations, label designs or package presentations. If DISTRIBUTOR acquires any right, title or interest in or to or relating to the Intellectual Property Rights, Trademarks for any reason, effective immediately upon the expiration or termination of this Agreement, DISTRIBUTOR hereby assigns, at no cost, all such right, title and interest, together with any related goodwill or reputation, to SUPPLIER. DISTRIBUTOR agrees to promptly execute all documents reasonably requested by SUPPLIER in connection with such assignment.

17.5 Pricing Approvals, Trademarks and other Product Rights. Upon Termination of this Agreement as provided herein for any reason whatsoever, DISTRIBUTOR shall immediately take all steps necessary to transfer to SUPPLIER, or to SUPPLIER's designee, any and all rights DISTRIBUTOR may have to Pricing Approvals and/or SUPPLIER's Trademarks including any related documents and any other rights associated with the Product including Product-specific approvals necessary for SUPPLIER or its designee to commercialize the Product in the Territory, to the extent permitted by Applicable Law and at DISTRIBUTOR's cost. DISTRIBUTOR shall, at the time for application for Pricing Approvals, take all reasonable steps to ensure that such transfers may later be completed. If such transfer is not possible, DISTRIBUTOR shall use its best efforts to arrange for SUPPLIER or its designee to rely upon such Pricing Approvals and shall permit SUPPLIER or its designee to use and reference such Pricing Approvals in its own applications. DISTRIBUTOR shall assign (1) any clinical trial documentation, if any, and administrative files, such as, but not limited to, price certificates, authorization and reimbursement authorizations to SUPPLIER or to any party appointed by the latter, or, as directed by SUPPLIER, to cancel said certificates and authorizations, provided that such administrative files are directly relating to the Product; and (2) transfer the contracts entered into with authorized representatives to SUPPLAR as ar as possible, or any party appointed by the SUPPLIER, if the latter so requests.

17.6 Orders upon Termination. DISTRIBUTOR shall be entitled to purchase under the terms and conditions of this Agreement, any Product ordered for which the orders were accepted by SUPPLIER prior to the effective date of Termination, even though shipment of the Product may be made subsequent to the date of Termination. SUPPLIER may only refuse to accept firm purchase orders placed by DISTRIBUTOR in deviation of the rolling purchase forecast and/or firm purchase orders placed by DISTRIBUTOR upon notice of termination being given by either Party, if the refusal does not interfere with already existing non-cancelable contractual obligations to third parties.

17.7 Repurchase of Inventory. SUPPLIER shall have the option, exercisable at its sole discretion by written notice to DISTRIBUTOR within [***] after Termination, but subject to DISTRIBUTOR's non-cancelable contractual obligations existing as of the Termination, to repurchase all or part of DISTRIBUTOR's remaining inventory of Product. The price payable by SUPPLIER upon the exercise of the option shall be [***]. Upon receipt of SUPPLIER's notice of exercise of its option pursuant to this clause, DISTRIBUTOR shall let ship its inventory of Product on hand to such location as SUPPLIER may designate at SUPPLIERS own cost. If SUPPLIER does not exercise its rights under this clause, DISTRIBUTOR shall have the right to sell its existing inventory for a period of [***] following the date of Termination. Thereafter, DISTRIBUTOR shall no more be allowed to sell the Product, and stock still held by DISTRIBUTOR will have to be destroyed or otherwise disposed of. At that point accounts receivables between the Parties will be netted out and the balance shall be settled within the payment terms specified in ANNEX C.

17.8 No Compensation. No indemnity whatsoever shall be due by reason of expiration or ordinary termination of this Agreement by either Party to the other. Neither Party shall be entitled to compensation, reimbursement or damage on account of the loss of prospective profits on anticipated sales or on account of marketing investments in connection with the business or goodwill of SUPPLIER or DISTRIBUTOR.

18. GENERAL PROVISIONS

18.1 Mutual Material Information Disclosure Obligation. Each Party shall inform, within due course, the other Party of any material information regarding the Product or the subject matter of this Agreement, which information could impede or assist the other Party's performance under this Agreement.

18.2 Independent Contractors. The relationship of SUPPLIER and DISTRIBUTOR established by this Agreement is of seller and buyer, or independent contractors, and nothing in this Agreement shall be construed:

(1) to give either Party the power to direct or control the daily activities of the other Party, or

(2) to constitute the Parties as principal and agent, partners, or otherwise as participants in a joint undertaking, or to provide a Party with the power or authority to make or give any representation or warranty or to incur any liability or obligation, or to waive any right, on the other Party's behalf, except as may be specifically provided for herein. SUPPLIER shall have no obligation or authority, express or implied, to exercise any control whatsoever over the employees or the business affairs of DISTRIBUTOR.

18.3 Insurance. Both Parties shall obtain and at all times during the term of this Agreement maintain, and bear the cost of, adequate and appropriate insurance including comprehensive general liability insurance which is adequate to cover their respective activities under this Agreement. A certificate of insurance and any other documentation necessary to prove compliance with this provision will be provided to the other Party upon request. Each Party shall notify the other not less than [***] prior to the termination or reduction of such coverage.

18.4 Assignments. This Agreement is entered into by SUPPLIER in reliance upon the facilities, personnel and technical expertise of DISTRIBUTOR, and DISTRIBUTOR may only transfer or delegate the performance of the Agreement or any part thereof to a Dealer pursuant to the terms and conditions of Section 2.2. In all other cases, DISTRIBUTOR may not assign this Agreement or its respective rights, duties and obligations thereunder to any third party or parties without having previously secured the written consent of the SUPPLIER, and any assignment or transfer in violation of this Section shall, at the option of SUPPLIER, be null and void and shall have no force or effect. SUPPLIER may assign or transfer this Agreement, or any of its rights or obligations under this Agreement, in whole or in part, without DISTRIBUTOR's consent (i) to an Affiliate, (ii) in connection with the transfer or sale of all or substantially all of the assets and/or business to which the Agreement pertains, or (iii) in connection with its merger or consolidation with another company.

18.5 Waivers. The waiver by either Party of a breach or default in any of the provisions of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions.

18.6 Entire Agreement and Amendments. This Agreement including the attachments hereto constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements between the Parties, whether written or oral, relating to the same subject matter. No modification, amendments or supplements to this Agreement shall be effective for any purpose unless in writing and signed by each Party.

18.7 Contract Formation. This document is not an offer unless signed by a Party and shall not constitute or reflect a legally binding contract unless signed by both Parties.

18.8 Annexes. The following documents are understood to be an integral part of this Agreement:

Description of Product	ANNEX A
Description of Territory and Trademarks	ANNEX B
Price Schedule; Payment Terms; Forecasts and Orders	ANNEX C
Minimum Purchase Quantities and Iles targets	ANNEX D
Quality Agreement	ANNEX E

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Wholesale License	ANNEX F
Pharmacovigilance Agreement	ANNEX G
Compliance with anti-corruption laws	ANNEX H
Contact Address List	ANNEX I
Reporting Format (Section 10.1 of the Agreement)	ANNEX J

18.9 Language. All written correspondence between the Parties shall be in the English language.

18.10 Further Assurances. Each Party agrees to do such acts and execute such further documents as may be necessary or desirable to enable the performance of and to fulfill the provisions and intent of this Agreement.

18.11 Force Majeure. Neither Party shall be liable to the other Party for any delay or omission in the performance of any obligation under this Agreement, other than the obligation to pay monies, where the delay or omission is due to any cause or condition beyond the reasonable control of the Party obliged to perform, including acts of God, acts of government (in particular with respect to the refusal to issue necessary import or export licenses), inability of SUPPLIER to obtain sufficient raw materials, fire, flood, earthquake, war, riots or embargoes, but excluding strikes or other labor difficulties affecting SUPPLIER ("***Force Majeure***"). If Force Majeure prevents or delays the performance by a Party of any obligation under this Agreement, then the Party claiming Force Majeure shall promptly notify the other Party thereof in writing. This Agreement shall be deemed suspended as long as, and to the extent that any such event prevents its performance. If the Force Majeure situation exceeds [***], Parties shall meet to determine whether they wish to terminate or adapt the Agreement and agree on how to proceed.

18.12 Notices. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and in English, effective upon receipt, and may be delivered personally, or may be sent by registered letter or facsimile, addressed as defined in ANNEX I.

In addition, the Parties shall notify each other of the names of the respective contacts in the important areas, including sales, shipping, marketing, pharmacovigilance, and regulatory. For the avoidance of doubt, all information and/or notices pursuant this Agreement, such as but not limited to, restricted and highly restricted business and personal information, shall be exchanged and/or sent by one Party to the other Party via secure channels, such as but not limited to encrypted e-mails and/or facsimile.

18.13 Severability. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

18.14 No Third Party Rights. A Person, including a Dealer, that is not a party to this Agreement, may not enforce any of the terms of this Agreement. Where any clause of this Agreement anyhow entitles any Person to enforce any term of the Agreement, the Parties reserves the right to vary that term or any other term of this Agreement without the consent of that Person.

18.15 Authorized Signatories. The persons signing below certify in their personal capacity that they have all required authority to execute this Agreement on behalf of the entity they are acting for.

19. CHOICE OF LAW AND DISPUTE RESOLUTION

19.1 Choice of Law. Notwithstanding its place of performance or execution, this Agreement is governed by, and shall be construed in accordance with, the laws of Austria without regard to its conflict of laws rules. It is understood that the application of the United Nations Convention on Contracts for the International Sales of Goods (CISG, Vienna 1980) shall be excluded.

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19.2 Disputes. The Parties shall endeavour to resolve amicably any and all disputes arising under or in connection with this Agreement, including but not limited to the interpretation of this Agreement, its validity and the performance hereunder. Notwithstanding the foregoing, either Party may initiate court proceedings seeking urgent provisional remedies prior to, or during such amicable settlement discussions.

19.3 Jurisdiction. The courts of Vienna, Austria, shall have the exclusive jurisdiction over any dispute arising from or relating to this Agreement or the performance thereof. Notwithstanding the foregoing, provisional remedies may be applied for in any court having jurisdiction by law.

[(Signature page follows)]

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IN WITNESS WHEREOF, each Party has caused its duly authorized representative to execute and deliver this Agreement in reliance on the due authority of the representative of the other Party, to be effective as of the date written on the first page above.

VALNEVA AUSTRIA GMBH	**GLAXOSMITHKLINE GMBH & CO. KG**
By: *[***]*	By: *[***]*
Name: [***]	Name: [***]
Title: [***]	Title: [***]
Date: 09 Dec 2015	Date: 20-12-2015
By: *[***]*	By: *[***]*
Name: [***]	Name: [***]
Title: [***]	Title: [***]
DATE: 09 Dec 2015	DATE: 20-12-2015

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ANNEX A

[***]

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ANNEX B

DESCRIPTION OF TERRITORY

Territory

Germany

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ANNEX C

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ANNEX D

[***]

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ANNEX E

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ANNEX F

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ANNEX G

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ANNEX H

[***]

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ANNEX I

[***]

36

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ANNEX J

[***]

37

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Exhibit 10.6

ORIGINAL

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SUBLICENSE AGREEMENT

This **SUBLICENSE AGREEMENT** (the "***Agreement***") is made and executed as of April 14, 2003 (the "***Effective Date***") by and between InterCell Biomedical Research and Development AG, having its principal place of business at Campus Vienna Biocenter 6, A-1030, Vienna, Austria (hereinafter "***InterCell***") and VaccGen International, LLC, having its principal place of business at 8 Cambridge Court, Larchmont, New York 10538, U.S.A. (hereinafter "***VaccGen***").

RECITALS

WHEREAS, Cheil (as defined hereinafter) and WRAIR (as defined hereinafter) are joint owners of the right, title, and interest in and to certain inventions and patent applications related to the Vaccine (as defined hereinafter).

WHEREAS, under the terms and conditions of the Cheil License Agreement (as defined hereinafter), VaccGen acquired an exclusive, worldwide (excluding Korea) license to the Vaccine from Cheil in order for VaccGen (either directly and/or via sublicense arrangements) to develop, gain regulatory approval, market, manufacture, distribute, use, import, offer for sale, sell, and otherwise commercially exploit the Vaccine.

WHEREAS, under the terms and conditions of the Cheil License Agreement, VaccGen has the right to sublicense its rights in the Vaccine to third parties such as InterCell.

WHEREAS, InterCell obtain a sublicense to the Vaccine from VaccGen in order for InterCell to develop gain regulatory approval, market, manufacture, have manufactured, distribute, use, import, offer for sale, sell and otherwise commercially exploit the Vaccine exclusively in the Territory (as defined hereinafter) and VaccGen is willing to provide such a sublicense to InterCell, subject to the terms: and conditions set forth in this Agreement.

NOW, THEREFORE, and of the foregoing premises and the mutual covenants and agreements hereinafter .4 forth, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

ARTICLE I

DEFINITIONS

1.1 "***Affiliate(s)***" shall mean, when used with reference to any Person (as defined hereinafter), any other Person controlling, controlled by, or under common control with such Person. For purposes of the above definition, the term "control" (including with correlative meaning, the terms "controlling," "controlled by," and "under common control with") as used with respect to any Person, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, occupation of board, officer, or management positions, by contract, or otherwise.

1.2 [***].

1.3 "***Bridging Study***" shall mean a human clinical trial in any country acceptable to FDA approval using the Vaccine, that is designed so that the results can be used to support initiation of the Definitive Clinical Trial (as defined hereinafter) with the Vaccine as the next step in the clinical program under the Development Plan and to support the acceptance by FDA of prior relevant preclinical and clinical study results in the further course of the Vaccine development.

1.4 "***Cheil***" shall collectively mean Cheil Jedang Corporation, having its principal place of business at Dokpyong-Ri, Majang-Myon, Ichon-Si, Kyonggi-Do, 467-810, Republic of Korea and its Affiliate, CJ America, Inc.

1.5 "***Cheil License Agreement***" shall mean that certain license agreement dated September 24, 1998 between Cheil and VaccGen pursuant to which VaccGen acquired an exclusive, worldwide (excluding Korea) license to the Vaccine from Cheil in order for VaccGen (either directly and/or via sublicense arrangements) to develop, gain regulatory approval, market, manufacture, distribute, use, sell, and otherwise commercially exploit the Vaccine.

1.6 "***Confidential Information***" is defined in Section 8.1(vi).

1.7 "***Definitive Clinical Trial***" shall mean a human clinical Phase III trial or equivalent trial using the Vaccine that is designed so that the results can be used in the submission of a PLA (as defined hereinafter) to the FDA and/or non-USA regulatory agencies in order to gain regulatory approval for the Vaccine.

1.8 "***Development Plan***" shall mean the document, as shown on **Exhibit A** hereto, which outlines the anticipated activities, budget, costs, and timelines related to development and regulatory approval of the Vaccine as of the Effective Date, as may be updated from time to time in accordance with Section 4.1(vi).

1.9 "***Development Program***" shall mean any and all efforts and activities necessary to gain regulatory approval for the Vaccine in the Territory, including, but not limited to, preclinical studies, formulation development, human clinical testing, laboratory studies, regulatory activities, and manufacturing.

1.10 "***Effective Date***" shall mean the date first specified in the introduction to the Agreement.

1.11 "***FDA***" shall mean the United States Food and Drug Administration or any successor agency thereto.

1.12 "***Improvements***" shall mean VaccGen Improvements and InterCell Improvements.

1.13 "***InterCell Improvements***" shall mean any and all new or useful processes, formulations, manufacturing processes, or methods of use of the Vaccine, which are first conceived, reduced to practice or developed by InterCell, the Sublicensee(s), or by InterCell and/or the Sublicensee(s) in collaboration with any other Person other than VaccGen during the term of this Agreement.

1.14 "***JDMC***" shall mean the Joint Development and Marketing Committee as further defined in Section 4.1.

1.15 "***Marketing Partner(s)***" shall mean a Person(s) who is appointed and actually paid by InterCell to market, sell, and distribute the Vaccine in an entire country within the Territory. For purposes of clarification: a) a Marketing Partner(s) is not considered a Sublicensee(s) and b) a Marketing Partner(s) is not a vaccine wholesalers (like GIV), a drugstore, a distributor, a salesforce organization, or other like entities that are generally used by companies to market and sell their vaccines.

1.16 "***Milestone Payments***" is defined in Section 3.2.

1.17 "***Net Sales***" shall mean the gross amount received by InterCell and/or its Affiliates and Marketing Partners for the sale or other disposition of the Vaccine (including Improvements) (as determined by generally accepted accounting principles consistently applied) to any party, less the following (and only the following) documented deductions [***]:

[***]

Net Sales shall not include [***].

1.18 "***Person(s)***" shall mean an individual, a partnership, a corporation, a trust, a joint venture, an unincorporated organization, or a government or any department or agency thereof.

1.19 "***Phase I***" shall mean a human clinical trial which is designed for first safety data and/or covering a broader range of doses of the Vaccine produced by BioReliance.

1.20 "***PLA***"' shall mean a Product License Application or equivalent document (Biologics License Application ("BLA") or other application) filed with the FDA or any other non-USA regulatory agencies for approval of the Vaccine.

1.21 "***Royalty***" is defined in Section 3.3.

1.22 "***Sublicensee(s)***" shall mean any Person(s) to whom InterCell issues a sublicense of any or all of the rights granted to InterCell under Section 2.1 to the Vaccine in accordance with the provisions of Sections 2A and 2.5 of this Agreement.

1.23 "***Sublicense Revenue***" shall mean any combination of prepaid royalties, profit-sharing or revenue-sharing income, license fees, milestone payments, royalties, and/or any other consideration in the form of cash or any other consideration (including, but not limited to, private or publicly traded securities or other assets) actually received by InterCell from a Sublicensee(s) for the Vaccine or the sublicense of rights granted to InterCell under Section 2.1 (as determined by generally accepted accounting principles consistently applied). It is at InterCell's sole decision in which form any payments will be made, but InterCell will use commercially reasonable efforts to cause all Sublicense Revenue to be in the form of cash if possible.

Excluded from Sublicense Revenue are amounts received by InterCell (as determined by generally accepted accounting principles consistently applied):

[***]

In the event that InterCell sublicenses the Vaccine and other InterCell products or technologies to the same Sublicensee, InterCell will use commercially reasonable efforts to insure that the Sublicense Revenue received by InterCell under the sublicense agreement for the Vaccine reflects the relative commercial value of the Vaccine.

1.24 "***Territory***" shall mean the entire world, except for Korea and the Caribbean (Aruba, Antigua, Bahamas, Barbados, Bermuda, Cayman Islands, Curacao, Dominican Republic, Jamaica, Puerto Rico, St. Croix, St. Lucia, St. Martin, St. Thomas, and Turks and Calicos).

1.25 "***VaccGen Improvements***" shall mean any and all new or useful processes, formulations, manufacturing processes, compositions of matter or methods of use of the Vaccine, which are first conceived, reduced to practice or developed by VaccGen, Cheil, WRAIR or by VaccGen in collaboration with any other Person other than InterCell, including without limitation Cheil or WRAIR, during the term of this Agreement.

1.26 "***Vaccine***" shall mean that certain prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine developed by Cheil, VaccGen, and WRAIR, whose manufacture, use or sale is covered by a Valid Claim.

1.27 "***Vaccine Information***" shall mean any information developed with respect to the Vaccine or Improvements, whether prior to Of during the term of the Agreement. By way of illustration, but not limitation, Vaccine Information may include know how, preclinical data, clinical data, laboratory data, manufacturing processes, manufacturing data, methods, techniques, projects, development plans, suppliers, etc.

1.28 "***Vaccine Patents***" shall mean United States patent #6,309,650 as well as any other patents or patent applications owned or controlled by Cheil, WRAIR or VaccGen which cover the prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine developed by Cheil, VaccGen and WRAIR, as shown on Exhibit B hereto, and all continuations, continuation-in-part, additions, divisions, renewals, extensions, re-examinations, substitutions, confirmations, registrations, revalidations, revisions, additions and reissues of the foregoing and all non-USA counterparts of any of the foregoing.

1.29 Valid Claim shall mean any claim of an issued and unexpired patent within the Vaccine Patents or patents assigned to Cheil covering Improvements which has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in an =appealed or unappealable decision, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise.

1.30 "***WRAIR***" shall mean the Walter Reed Army Institute of Research, with a principal place of business at 503 Robert Grant Avenue, Silver Spring, MD 20910-7500.

ARTICLE II

GRANT OF SUBLICENSE

2.1 License Grant

Subject to the terms and conditions hereinafter set forth, VaccGen hereby grants to InterCell and InterCell's Affiliates, and InterCell hereby accepts, an exclusive, sublicensable (in accordance with Sections 2.1(ii) and 25) sublicense to the Vaccine and under the Vaccine Patents, including without limitation all intellectual property rights relating to Improvements as specified herein, in order for InterCell and InterCell's Affiliates to:

(i) develop, gain regulatory approval, manufacture, have manufactured, distribute, use, offer for sale, import, sell, market, and otherwise commercially exploit the Vaccine in the Territory, and

(ii) sublicense rights in, to and under the Vaccine and any or all of the Vaccine Patents to Persons other than Affiliates in order that the Sublicensee(s) can develop, gain regulatory approval, manufacture, have manufactured, use, offer for sale, import, sell, market, and otherwise commercially exploit the Vaccine in the Territory.

2.2 License Scope

For the avoidance of doubt, InterCell's sublicense pursuant to Section 2.1 shall be exclusive in the Territory.

2.3 Rights Retained by VaccGen in the Territory

(i) VaccGen shall retain the right to co-promote the Vaccine in the United States of America. For the purposes of clarification, co-promote will mean that VaccGen will market and engage in promotional activities for the Vaccine, such as detailing, with InterCell as mutually agreed by the parties in good faith. The parties agree to co-promote the Vaccine in harmony with each other, always with the objective of maximizing Net Sales in the Territory. Both parties acknowledge that VaccGen will not itself sell any Vaccine as part of its co-promotional activities, as sales generated from such co-promotional efforts by VaccGen shall be made and received by, paid directly to and recognized by InterCell and will be considered Net Sales and subject to Royalty payments in accordance with Section 3.3. Upon submission of the PLA in the United States, the parties will negotiate in good faith the cost, expense, and other details of such co-promotional efforts by VaccGen.

(ii) VaccGen will participate with InterCell in all discussions regarding a federal government contract for the Vaccine with the United States military.

(iii) VaccGen will retain the exclusive rights to the Vaccine in the Caribbean.

(iv) VaccGen will have the right to participate with InterCell in the Development Program in accordance with Section 4.1.

(v) Upon approval of the PLA by the FDA, the parties will discuss in good faith whether VaccGen will be appointed as InterCell's co-marketing partner in the United States and provided that any of VaccGen's co-marketing activities for the Vaccine shall be subject to and conditioned upon a written agreement by the parties.

(vi) VaccGen shall retain certain additional rights expressly set forth in this Agreement, including such rights expressly stated in Article V and Article VI herein.

2.4 No Other Rights

Nothing in this Agreement shall be construed to constitute a grant to InterCell and/or the Sublicensees of any rights other than those expressly granted herein.

InterCell shall sell the Vaccine in the Territory only and shall use its reasonable best efforts not to directly or indirectly sell, transfer, or in any way deliver the Vaccine to Korea, as exclusive rights to the Vaccine in Korea are retained by Cheil in accordance with the Cheil License Agreement.

Nothing in this Agreement shall be construed to constitute a grant to VaccGen, Cheil or WRAIR of any rights other than those expressly granted herein.

2.5 InterCell's Sublicense Obligations

InterCell will be responsible for negotiating and executing sublicense agreements with potential Sublicensees regarding the Vaccine, if any, according to the following guidelines:

(i) InterCell will advise VaccGen of a potential Sublicensee(s) and will keep VaccGen routinely updated on progress of discussions and negotiations with a potential Sublicensee(s).

(ii) Subject to reasonable redaction rights, InterCell will send reasonably complete drafts of all sublicense agreements to VaccGen for review and comments prior to execution. VaccGen shall diligently review such sublicense agreements by providing InterCell with comments, if any, as soon as possible, but in no event to exceed [***] from VaccGen's receipt of such draft sublicense agreements. InterCell will give reasonable consideration to VaccGen's comments; however, all final decisions regarding such sublicense agreements will be the sole responsibility of InterCell as long as the sublicense agreements are materially consistent with the terms and conditions of this Agreement.

(iii) Subject to reasonable redaction rights, InterCell will send VaccGen a copy of all final executed sublicense agreements for the Vaccine (as well as all other associated agreements, side letters, and/or the like related to the Vaccine executed by InterCell and the Sublicensee(s), if any) with Sublicensees within [***] after execution of such sublicense agreement.

As VaccGen has a right to verify its share of Sublicense Revenue owed under sublicense agreements in accordance with Section 3.4, InterCell's shall not use its redaction rights above to redact any sections of sublicense agreements that pertain to Sublicense Revenue owed by Sublicensees to InterCell.

2.6 Maintenance of the Cheil License Agreement

VaccGen shall comply with all of the terms and conditions of, and shall maintain in full force and effect, the Cheil License Agreement. VaccGen shall use its best efforts to allow InterCell to exercise all of the rights provided to it hereunder and represents and warrants that it has obtained all necessary consents to enter into this Agreement, including without limitation from Cheil and WRAIR, to the extent such consents are required. VaccGen acknowledges and agrees that Section 7.4(v) of the Cheil License Agreement provides for the continuation of VaccGen's sublicenses thereunder in the event of termination of the Cheil License Agreement under certain conditions, and VaccGen in its reasonable best efforts to secure the continuation of this Agreement in the event of such determination, VaccGen shall promptly notify InterCell in writing if Cheil or any third party alleges any breach by VaccGen of the Cheil License Agreement, the rights under which have been granted to lnterCell, and VaccGen shall use its reasonable best efforts to cure any such breach. Notwithstanding the foregoing, InterCell shall be entitled, but not obligated, to cure any alleged breach by VaccGen of the Cheil License Agreement and set-off the cost of such cure against amounts otherwise owed to VaccGen hereunder.

2.7 Combination Vaccine and Adjuvanted Vaccine

(i) In the event the parties identify opportunities to develop a combination vaccine by formulating the antigen component of the Vaccine with another antigen(s), InterCell shall have the right, but not the obligation, to pursue such a combination vaccine if, in good faith, it is in the economic interest of both InterCell and VaccGen. In the event InterCell decides to pursue such a combination vaccine, the parties agree to negotiate in good faith appropriate adjustments to the Royalties owed to VaccGen under Section 3.3.

(ii) In the event the parties identify opportunities to develop an improved Japanese encephalitis vaccine (single shot, more potent, etc.) by formulating the antigen component of the Vaccine with an adjuvant other than alum, InterCell shall have the right, but not the obligation, to pursue such an adjuvanted vaccine if, in good faith, it is in the economic interest of both InterCell and VaccGen. In the event InterCell decides to pursue such an adjuvanted vaccine, the parties agree to negotiate in good faith appropriate adjustments to the Royalties owed to VaccGen under Section 3.3.

2.8 [***]

ARTICLE III

PAYMENTS

3.1 License Fees

(i) In consideration of this grant of sublicense to InterCell hereunder, InterCell shall pay VaccGen a non-creditable, non-refundable initial license fee of three hundred fifty thousand United States dollars (USD$350,000), which shall be payable within five (5) days upon execution of this Agreement.

(ii) In consideration of this grant of sublicense to InterCell hereunder, InterCell shall pay VaccGen a non-creditable, non-refundable second license fee of four hundred fifty thousand United States dollars (USDS450,000), which shall be payable upon the first human subject being enrolled in the Bridging Study.

3.2 Milestone Payments

InterCell shall make non-creditable, non-refundable milestone payments ("***Milestone Payments***") to VaccGen upon InterCell's, an InterCell Affiliate's or a Sublicensee's achievement of the following milestones in accordance with the following schedule:

(i) InterCell shall make a Milestone Payment of five hundred thousand United States dollars (USD$500,000) to VaccGen upon the first human subject being enrolled in the Definitive Clinical Trial.

(ii) InterCell shall make a Milestone Payment of nine hundred thousand United States dollars (USD$900,000) to VaccGen upon the first PLA being filed for the Vaccine anywhere in the Territory.

(iii) InterCell shall make a Milestone Payment of two million United States dollars (USD$2,000,000) to VaccGen upon the first regulatory approval of the Vaccine anywhere in the Territory.

After the second license fee is paid by InterCell in accordance with Section 3.1(ii), VaccGen and InterCell will discuss in good faith whether portions of the Milestone Payments owed under Section 3.2 will be replaced by transfer of InterCell stock options to VaccGen.

3.3 Royalty Payments

(i) For Vaccine marketed, sold and distributed directly by InterCell and/or its Affiliates (other than to or through Marketing Partners), InterCell shall pay VaccGen a royalty ("***Royalty***") upon commercialization of the Vaccine equal to [***] percent ([***]%) of Net Sales.

(ii) For Vaccine marketed, sold, and distributed by InterCell's Marketing Partners, InterCell shall pay VaccGen a Royalty upon commercialization of the Vaccine equal to [***] percent ([***]%) of Net Sales.

(iii) InterCell shall make a minimum Royalty payment to VaccGen during each and every calendar year (January 1 — December 31) after the first commercial launch of the Vaccine during the term of this Agreement as follows. [***]. In the event that, during the applicable calendar year for as long as royalty obligations exist, InterCell's total annual Royalty payments to VaccGen pursuant to Section 3.3 and/or Sublicense Revenue sharing under Section 3.4 are less than the annual minimum amounts set forth above ("***Minimum Royalty***"), InterCell shall make a payment to VaccGen together with the Royalty report for the fourth quarter of such year required in Section 3.6 equal to the difference between such Minimum Royalty and the Royalties paid to VaccGen for such year pursuant to Section 3.3 above.

3.4 Revenue Sharing if InterCell Sublicenses the Vaccine

Under all sublicensing agreements executed by InterCell for the Vaccine, InterCell shall pay VaccGen [***] of any and all Sublicense Revenue actually received by InterCell from Sublicensees; provided, however, that with respect to all Sublicense Revenue received by InterCell from Sublicensees for achievement of milestones set forth in Section 3.2, or substantially similar milestones, InterCell shall only pay VaccGen [***] of that portion of such Sublicense Revenue which is in excess of the applicable milestone amount set forth in Section 3.2.

3.5 Payments

(i) The license fee owed to VaccGen under Section 3.1(ii) due for the first human subject being enrolled in the Bridging Study shall be payable by InterCell within [***] after the achievement of such event.

(ii) Any Milestone Payments owed to VaccGen under Section 3.2 shall be payable by InterCell to VaccGen within [***] after the achievement of the applicable milestone.

(iii) Any Royalty owed to VaccGen pursuant to Section 3.3 shall be due [***] after the end of each calendar quarter (March 31, June 30, September 30, and December 31) beginning with the first calendar quarter in which Net Sales occur and shall be payable by InterCell to VaccGen within [***] following the last day of the applicable calendar quarter.

(iv) Payments owed to VaccGen pursuant to Section 3.4 shall be payable by InterCell to VaccGen within [***] after the end of the calendar quarter in which such Sublicense Revenue is actually received by InterCell from the Sublicensee(s).

3.6 Reports

For each payment made pursuant to Sections 3.1-3.4, InterCell shall also deliver to VaccGen an accompanying report setting forth in reasonable detail the calculation of the accompanying VaccGen payments (e.g., license fee, Royalty, Sublicensing Revenue, and Milestone Payments).

3.7 Currency and Place of Payment

(i) All payments from InterCell to VaccGen under this Agreement shall be made in the legal currency of the United States of America by either a) corporate check to VaccGen at the address specified in Section 12.7 or an address designated in writing by VaccGen from time to time or b) wire transfer to a bank account designated in writing by VaccGen from time to time and provided to InterCell in accordance with Section 12.7.

(ii) With respect to Net Sales or Sublicense Revenue made in currency other than United States dollars, payments shall be computed based upon the conversion rate of the currencies of Net Sales or Sublicense Revenue into United States dollars as is published in The Wall Street Journal (Eastern Edition) as of the last business day of the calendar quarter covered by the report submitted to VaccGen pursuant to Section 3.6.

3.8 Late Payment

Payments to VaccGen hereunder shall be deemed paid as of the day on which they are received pursuant to Section 3.7(i). Any payment or part of a payment which is not paid on or before the date when due shall accrue interest thereon from such date until the date of its payment in full at [***].

3.9 Records

InterCell agrees to maintain for [***] after the submission of each report under Section 3.6 hereof full and accurate books and records in sufficient detail to enable the amounts due to VaccGen under this Agreement to be verified.

3.10 Taxes

Subject to applicable law, InterCell will use its reasonable best efforts to insure that Austrian taxes are not withheld from any payments owed to VaccGen under this Agreement. Notwithstanding the foregoing, InterCell may withhold from any Royalty or payment to VaccGen under this Agreement any taxes required to be withheld by InterCell under the applicable laws of the United States or any other country, state, territory or jurisdiction and if such taxes are required to be withheld by InterCell, they will be deducted from such payments due to VaccGen and will be paid by InterCell for the account of VaccGen, a receipt thereof secured, if available, and sent to VaccGen.

3.11 Audit Rights

InterCell shall maintain appropriate books and records in such a manner as to clearly and accurately show Net Sales and Sublicense Revenue as defined herein. InterCell shall permit an independent public accountant designated by VaccGen and reasonably acceptable to InterCell, to have access, no more than [***] in each calendar year during the term of this Agreement and for the [***] following the expiration or termination of InterCell's royalty obligations hereunder, during regular business hours and upon at least [***] prior written notice, to InterCell's records and books relating to amounts payable hereunder, for the purpose of determining the accuracy of Net Sales and Sublicense Revenue reported, and Royalty payments made, by InterCell to VaccGen within the [***] immediately preceding such an audit. The independent public accountant shall be under a confidentiality obligation to InterCell to disclose to VaccGen only (a) the accuracy of Net Sales and Sublicense Revenue reported and the basis for Royalty payments made to VaccGen under this Agreement, and (b) the difference, if any, such reported and paid amounts vary from amounts determined as a result of the audit. InterCell shall cooperate reasonably with the parties making such examination or audit on behalf of VaccGen. InterCell shall promptly pay to VaccGen or VaccGen shall promptly refund to InterCell, as the case may be, any underpayment or overpayment revealed by the examination or audit. If an examination or audit is performed due to InterCell's failure to submit any reports pursuant to Section 3.6 when such reports are due under this Agreement or its failure to reasonably maintain books and records as provided herein, or in the event such examination or audit shows an underpayment to VaccGen of more than [***] or [***] for any calendar quarter, [***], then InterCell shall within [***] following written notice pay to VaccGen the reasonable and customary cost of such an examination or audit as well as all amounts shown to be due under this Agreement.

3.12 Payments to WRAIR, Cheil, and Barr

VaccGen shall be responsible for third party royalties or other forms of consideration, if any, which are owed to WRAIR, Cheil, and Barr Laboratories, Inc. as a result of development or commercialization of the Vaccine. In the event that such third party royalties or other consideration are not paid, VaccGen shall immediately provide lnterCell written notice of such failure and InterCell shall haver; the right to make such payment on VaccGen's behalf. InterCell shall then be entitled to deduct any such payment made by InterCell under this Section 3.12 from any amounts due to VaccGen under this Agreement.

3.13 Royalty Stacking

If InterCell is required to make any payment (including, but not limited to, royalties or other license fees) to one or more third parties to obtain a license or similar right in the absence of which, based on convincing written evidence, InterCell could not legally make, import, use, sell, or offer for sale the Vaccine, such third-party payments shall be [***] creditable against all amounts otherwise owed to VaccGen hereunder.

3.14 No Multiple Royalties

No multiple Royalties shall be due or payable because the manufacture, use, offer for sale, sale or import of a Vaccine is or shall be covered by more than one Valid Claim.

3.15 Royalty and Payment Term

InterCell's obligation to pay Royalties and other amounts to VaccGen under Sections 3.3 and 3.4 shall continue until the expiration or final determination of invalidity of the last Valid Claim. Upon the expiration or final determination of invalidity of the last Valid Claim, InterCell will pay for a period of 7 years the following reduced Royalties and other amounts to VaccGen:

(i) [***] under Section 3.3(i),

(ii) [***] under Section 3.3(ii), and

(iii) [***] under Section 3.4.

Upon expiration of this 7 year period, InterCell shall have no further obligation to pay any Royalties or other amounts due under Article 3. Notwithstanding the above, InterCell shall be obligated after expiration of the royalty term to pay any Royalty amounts that accrued under Article 3 prior to such expiration.

ARTICLE IV

RESPONSIBILITIES OF THE PARTIES

4.1 Joint Development and Marketing Committee

(i) The Development Program for the Vaccine shall be designed, directed, implemented, and monitored by the JDMC. The goal and spirit of the JDMC during the Development Program is to develop and gain regulatory approval for the Vaccine as promptly as practical, consistent with reasonable commercial and scientific practices.

(ii) After commercialization of the Vaccine, the JDMC will advise InterCell on the marketing and sale of the Vaccine is the Territory. The goal and spirit of the JDMC after commercialization is to maximize salts of the Vaccine in the Territory, consistent with reasonable business practices.

(iii) The JDMC will be composed of two (2) representatives appointed by each of InterCell and VaccGen. Initially, such representatives shall be [***] from VaccGen and [***] from InterCell. The JDMC will be chaired by InterCell. Initially, the chairperson shall be [***]. The representatives of the JDMC shall be the primary contacts between the parties with respect to the Development Program. Each party may replace its representative at any time upon written notice to the other party and InterCell may replace the chairperson at any time, as long as the replacement representative and/or chairperson, as the case may be, are adequately qualified and empowered to make decisions regarding the Development Program. Other persons from VaccGen and InterCell may be invited to attend meetings of the JDMC on an as needed basis. The JDMC shall meet on an as needed basis; however, unless unanimously agreed to by the JDMC, the JDMC will at minimum:

(a) prior to commercialization of the Vaccine, conduct a conference call to review the Development Program on a monthly basis and, after commercialization of the Vaccine, conduct a conference call to review the marketing and sales of the Vaccine on a quarterly basis (every [***]); and

(b) prior to commercialization of the Vaccine, hold a meeting to review the Development Program on a quarterly basis (every [***]) and, after commercialization of the Vaccine, hold a meeting to review the marketing and sales of the Vaccine on a twice annual basis.

The times and/or locations of such conference calls and meetings will be determined by the JDMC representatives. The reasonable cost and expense of the JDMC (meetings, travel, etc.), which have been pre-approved in writing by InterCell, will be borne by InterCell.

(iv) The JDMC will use its best efforts to resolve any disagreements among the parties. However, if the JDMC representatives cannot resolve such disagreements, the chairperson shall have a casting and deciding vote (which such vote shall thereupon be the decision of the JDMC with respect thereto). All final decisions by the JDMC, including the chairperson, shall be consistent with the terms, conditions and spirit of this Agreement; provided however that in no event shall InterCell as chair of the JDMC be required to approve any amendments or changes to the Development Plan which would substantially increase its obligation to fund Development Plan beyond the projected cost of such plan as of the Effective Date.

(v) At meetings and conference calls of the JDMC, the parties will share with each other all Vaccine Information generated during the Development Program and all marketing information (sales, manufacturing, distribution, etc.) alter commercialization of the Vaccine.

(vi) The Development Plan, as shown on **Exhibit A** hereto, details the activities, budget, costs, and timelines related to development and commercialization of the Vaccine after the Effective Date. Either party may submit proposed amendments or updates to the Development Plan for the JDMC's consideration and approval and the JDMC will update the Development Plan on an as needed basis during the term of the Agreement, so that the Development Plan remains up-to-date and accurate.

4.2 Sharing of Vaccine Information

(i) Promptly following the Effective Date, VaccGen shall transfer all Vaccine Information developed prior to the Effective Date to InterCell.

(ii) During the term of this Agreement and pursuant to Section 4.1(v), both parties shall share with the other party all Vaccine Information generated by the disclosing party or other Persons working in collaboration with such disclosing party, including Sublicensees.

(iii) With respect to Vaccine Information disclosed hereunder by VaccGen to InterCell, VaccGen hereby grants to InterCell a royalty-free, transferable, sublicensable, exclusive, worldwide (except for Korea and the Caribbean) right and license, under VaccGen's rights and interests in, under and to Vaccine Information (including without limitation any copyright or trade secret interests), disclosed either before or after the Effective Date, to use, reproduce, distribute, display, prepare derivative works of and otherwise modify, make, sell, offer to sell, import and otherwise use and exploit (and have others exercise such rights on behalf of InterCell) all or any portion of such Vaccine Information in connection with InterCell's exercise of the license grant set forth in Section 2.1.

(iv) With respect to Vaccine Information disclosed hereunder by InterCell to VaccGen, InterCell hereby grants to VaccGen a royalty-free, transferable, sublicensable, non-exclusive right and license, under InterCell's rights and interests in, under and to such Vaccine Information (including without limitation any copyright or trade secret interests), disclosed after the Effective Date, to use, reproduce, distribute, display, prepare derivative works of and otherwise modify, make, sell, offer to sell, import and otherwise use and exploit (and have others exercise such rights on behalf of VaccGen) all or any portion of such Vaccine Information in the Caribbean and in Korea solely in connection with VaccGen's satisfaction of its contractual obligations with Cheil which exist as of the Effective Date and are set forth in the Cheil License Agreement.

4.3 Responsibility for the Development Program

(i) The cost and expense of the Development Program pursuant to and expressly set forth in the Development Plan shall be solely borne by InterCell, it's Sublicensees (if any), and their Affiliates.

(ii) InterCell and/or its Sublicensee(s) shall be responsible, at their cost and expense, for any and all activities performed by InterCell and/or its Sublicensees(s) pursuant to and expressly set forth in the Development Plan.

(iii) InterCell and/or its Sublicensee(s) shall fund their activities performed pursuant to the Development Program in a reasonable and timely manner according to the Development Plan (Exhibit A). InterCell and/or its Sublicensees will fund activities performed by others (including without limitation VaccGen, Cheil, [***] and WRAIR) performed in accordance with the terms of the Development Plan, including without limitation the budgets and costs. InterCell and/or its Sublicensees will fund activities performed by others which costs exceed the budget provided for in the Development Plan only to the extent such activities and costs have received InterCell's prior written approval.

(iv) InterCell will share with VaccGen all plans and results from activities under the Development Program pursuant to and in accordance with Section 4.2(ii), such plans and results to be included within the license grant set forth in Section 4.2(iv).

(v) InterCell acknowledges that development and regulatory approval of the Vaccine is a high priority project for InterCell. Consequently, InterCell and/or its Sublicensee(s) shall use commercially reasonable efforts to develop, manufacture, gain regulatory approval and reasonably promptly launch the Vaccine, consistent with reasonable commercial and scientific practices and in accordance with the Development Plan (Exhibit A).

4.4 Government Approvals for the Vaccine

(i) InterCell and/or its Sublicensee(s) shall be responsible, at their cost and expense, for obtaining and maintaining all approvals, licenses, permits, registrations or authorizations, including pricing and reimbursement approvals, of any U.S. or non-U.S. national, state or local regulatory agency, department, bureau or other government entity, necessary for the manufacture, use, storage, transport or sale of the Vaccine sold by or on behalf of InterCell, the Sublicensee(s) or their Affiliates in the Territory obtained or maintained after the Effective Date. All such approvals, registrations and authorizations shall be in the name of InterCell and/or the Sublicensee(s). If requested by InterCell in writing, VaccGen will reasonably cooperate, and will request that Cheil reasonably cooperates, with InterCell to satisfy InterCell's obligations under this Section 4.4 at InterCell's cost and expense.

(ii) The parties acknowledge and agree that (a) all regulatory filings for the Vaccine, including without limitation the Investigational New Drug application originally filed by WRAIR and transferred to VaccGen during the fourth quarter 2002, shall be transferred to InterCell, (b) InterCell shall receive full rights of reference to any regulatory filings for the Vaccine which have not been transferred, if any, in accordance with the foregoing and (c) VaccGen will assist in effectuating all of InterCell's rights in connection with the foregoing, including arrangements that need to be addressed with WRAIR, if any.

4.5 Responsibility for Commercialization

(i) Subject to the parties' agreement with respect to VaccGen's co-promotional and co-marketing efforts pursuant to Section 2.3, InterCell and/or its Sublicensee(s) and Marketing Partner(s) shall be responsible, at their cost and expense, for commercialization of the Vaccine in the Territory, including, but not limited to, sales, marketing, manufacturing, and distribution.

(ii) InterCell acknowledges that commercialization of the Vaccine is a high priority project for InterCell. Consequently, InterCell and/or its Sublicensee(s) and Marketing Partner(s) shall use commercially reasonable efforts to maximize Net Sales of the Vaccine in the entire Territory, consistent with commercially reasonable business practices.

(iii) VaccGen acknowledges that InterCell has the right at its own and sole discretion to appoint Marketing Partners to market, sell, find distribute the Vaccine in the Territory. InterCell is responsible for the cost and expense of such Marketing Partners, if any.

(iv) InterCell will share with VaccGen reasonable marketing and sales information on the Vaccine in the entire Territory after commercialization of the Vaccine pursuant to and in accordance with Section 4.2(ii), such information to be included within the license grant set forth in Section 4.2(iv).

4.6 Manufacture and Supply of the Vaccine

InterCell and/or its Sublicensee(s) shall be responsible, at their cost and expense, to manufacture or have manufactured at a third party the Vaccine according to the Development Plan and for commercial purposes. InterCell will share with VaccGen reasonable manufacturing information on the Vaccine pursuant to and in accordance with Section 4.2(ii), such information to be included within the license grant set forth in Section 4.2(iv).

4.7 Assistance by VaccGen

VaccGen and InterCell have entered into a consulting agreement (the "***Consulting Agreement***") as of even date herein. Under the terms and conditions of the Consulting Agreement, VaccGen will reasonably assist, and request Cheil and WRAIR to reasonably assist, if applicable, InterCell with reasonable best efforts in the development, regulatory approval, manufacture, marketing and selling of the Vaccine in the Territory; provided, however, that such assistance by VaccGen shall in no way relieve InterCell of its responsibility for implementing those aspects of the Development Program assigned to it according to the Development Plan and commercialization of the Vaccine.

4.8 Notification

Each party shall notify the other immediately in writing of any adverse or unexpected results, or any potential government action relevant to the Vaccine of which such party is aware, either directly or as result of notice from a Sublicensee(s) or otherwise. Following such notification, the parties shall confer to determine in good faith an appropriate course of action, if any, subject to applicable national, state and local laws, rules, regulations and statutes, with InterCell having final decision-making authority as to the appropriate course of action, if any.

ARTICLE V

OWNERSHIP OF VACCINE AND IMPROVEMENTS

5.1 Ownership of Vaccine

Nothing contained herein shall confer upon either InterCell or VaccGen ownership rights in and to the Vaccine and the Vaccine Patents; it being understood that the ability of InterCell and VaccGen to have access to the Vaccine, Vaccine Patents, and Improvements (if any) in accordance with the terms of the Agreement shall not be impaired by the foregoing.

5.2 Improvements

(i) During the term of this Agreement, VaccGen shall disclose to InterCell, in writing, all VaccGen Improvements, whether patentable or not, if any. With respect to all VaccGen Improvements disclosed under this Section 5.2(1), such VaccGen Improvements shall be automatically included under the terms and conditions of this Agreement, including without limitation the license grant to InterCell in Section 2.1.

(ii) During the term of this Agreement, InterCell shall disclose to VaccGen, in writing, all InterCell Improvements, whether patentable or not, if any. With respect to all InterCell Improvements disclosed under this Section 5.2(ii), when InterCell has so promptly disclosed, InterCell will assign its rights in, to and under any such InterCell Improvements to Cheil and such InterCell Improvements shall be included under the terms and conditions of this Agreement, including without limitation the license grant to InterCell in Section 2.1.

(iii) In accordance with the Cheil License Agreement, Cheil and VaccGen shall have the first and second options, respectively, of filing, prosecuting and maintaining any patent applications, at their cost and expense, regarding Improvements disclosed under Section 5.2(i) and (ii). VaccGen shall provide InterCell with all material documentation and correspondence from, sent to or filed with patent offices regarding such patent applications and with a reasonable opportunity to review and comment upon all filings with such patent offices in advance. VaccGen shall reasonably consult with InterCell with respect thereto and raise InterCell's comments and concerns thereto with Cheil. Title to any such patent applications and any patents issuing therefrom on such Improvements shall be in Cheil's name in accordance with the Cheil License Agreement, but such patents shall be exclusively licensed to InterCell in the Territory under the terms and conditions of this Agreement, including without limitation the license grant in Section 2.1.

(iv) If VaccGen and Cheil elect not to file, prosecute or maintain any such patent applications or patents on such Improvements, then InterCell shall have the right, but not the obligation, to file, prosecute and maintain any such patent applications or patents on such Improvements at its own expense. Title to any such patents on such Improvements shall be in Cheil's name in accordance with the Cheil License Agreement, but such patents shall be exclusively sublicensed to InterCell in the Territory under the terms and conditions of this Agreement. InterCell shall be entitled to deduct any amounts it incurs as a result of its filing, prosecution or maintenance of any patent applications or patents under this Section 5.2(iv) from any amounts due to VaccGen under this Agreement.

5.3 Joint Improvements

In the event that Improvements are jointly invented, as determined under United States patent law, by at least one (1) VaccGen employee or person contractually required to assign or license patent rights covering such inventions to VaccGen and at least one (1) InterCell employee or person contractually required to assign or license patent rights covering such inventions to InterCell ("***Joint Improvements***") during the term of this Agreement, such Joint Improvements and any patent rights based thereon shall be owned by Cheil in accordance with the Cheil License Agreement, and the parties will assign their rights in, to and under any such Joint Improvements to Cheil and such Joint Improvements shall be included under the terms and conditions of this Agreement, including without limitation the license grant to InterCell in Section 2.1.

ARTICLE VI

PATENTS

6.1 Prosecution of Vaccine Patents

(i) The parties acknowledge that, during the term of this Agreement, Cheil, in accordance with the Cheil License Agreement, shall be responsible, at Cheil's cost and expense, for prosecuting to issuance and maintaining all Vaccine Patents, for filing and prosecuting all patent reissues and re-examinations, for applying for and obtaining any patent term extensions, and for paying all maintenance fees, on all Vaccine Patents and all patent applications and patents claiming Improvements.

(ii) VaccGen shall cooperate with Cheil including, without limitation, executing all lawful papers and instruments and making all rightful oaths and declarations, as may be necessary, in the preparation and prosecution of all such Vaccine Patents. If necessary, InterCell will reasonably assist VaccGen in such efforts at VaccGen's cost and expense.

(iii) VaccGen shall provide InterCell with draft copies of all correspondence and filings on the Vaccine Patents and related prosecution documents in the Territory, and InterCell shall have, to the extent reasonably possible, [***] from receipt of such documents, to provide comments to VaccGen. VaccGen shall confer with InterCell and make reasonable efforts to adopt InterCell's suggestions regarding prosecution of the Vaccine Patents. Notwithstanding the foregoing, VaccGen and/or Cheil shall have the right to take such actions as are reasonably necessary, in their good faith judgment, to preserve all rights under the Vaccine Patents throughout the Territory. As soon as practical subsequent to the filing of any prosecution document on the Vaccine Patents, VaccGen shall provide InterCell with a copy of such document. In addition, VaccGen shall copy InterCell on any official office action and submissions with respect to the Vaccine Patents in the Territory.

(iv) If Cheil does not diligently file, prosecute and/or maintain Vaccine Patents in the Territory, then VaccGen shall have the right, but not the obligation, to prosecute and/or maintain such Vaccine Patents at VaccGen's cost and expense.

(v) If both Cheil and VaccGen do not diligently file, prosecute and/or maintain such Vaccine Patents in the Territory, then VaccGen shall immediately provide written notice to InterCell of such failure and InterCell shall have the right, but not the obligation, to file, prosecute and/or maintain such Vaccine Patents at InterCell's cost and expense. In the event that InterCell assumes responsibility for the cost of prosecution and/or maintenance of the Vaccine Patents in the Territory, at InterCell's choice and discretion, the actual out-of-pocket costs of filing, prosecution and/or maintenance of such Vaccine Patents shall be deducted against the next Milestone Payment or the Royalty payments owed by InterCell to VaccGen under Section 3.3(i) shall be reduced from [***] percent ([***]%) to [***] percent ([***]%) and under Section 3.3(ii) shall be reduced from [***] percent ([***]%) to [***] percent ([***]%) in the country or countries where InterCell is assuming responsibility for the cost of prosecuting and maintaining such Vaccine Patents. InterCell will make its decision within [***] after any prosecution and/or maintenance of such Vaccine Patents.

6.2 Infringement of Vaccine Patents

(i) In the event either party becomes aware of a suspected infringement of any Vaccine Patents or patents assigned to Cheil covering Improvements in the Territory, such party shall immediately notify the other party in writing, and following such notification, the parties shall confer as to the handling of such suspected infringement. For suspected infringement claims in the Territory, InterCell shall have the exclusive right, but not the obligation, at its own cost and expense, to: (a) prosecute such suspected infringement by bringing an infringement claim in a court of competent jurisdiction or (b) in its sole good faith discretion, settle such infringement dispute with such third party. All such actions prosecuted or settled pursuant to this Section 6.2(i) shall be in InterCell's own name and entirely under its own direction and control. At InterCell's expense, VaccGen will, and will request Cheil to, reasonably assist InterCell in such actions or settlements if so requested by InterCell, and will lend its name, and request Cheil to lend its name, to such actions or settlements if requested by InterCell or required by law. Notwithstanding the foregoing, VaccGen and Cheil shall have the right to participate and be represented in any such actions or settlements by their own counsel at their own expense.

(ii) If InterCell elects not to prosecute or settle any infringement dispute described in Section 6.2(i) within [***] after receiving written notice of the suspected infringement, then VaccGen shall have the right, but not the obligation, to bring such action at its own expense and entirely under its own direction and control. At VaccGen's expense, InterCell will reasonably assist VaccGen in such actions if so requested by VaccGen or required by law. Notwithstanding the foregoing, InterCell shall have the right to participate and be represented in any such actions or settlements by its own counsel at its own expense.

(iii) Any amounts paid by third parties to InterCell pursuant to Section 6.2(i), whether by settlement or otherwise, shall first be applied toward reimbursement for reasonable expenses incurred and paid for (by both InterCell and VaccGen), and then, amounts received In excess of such expenses, if any, shall be considered Net Sales and subject to Royalty payments in accordance with Section 3.3.

(iv) Any amounts paid by third parties to VaccGen pursuant to Section 6.2(11), whether by settlement or otherwise, shall first be applied toward reimbursement for reasonable expenses incurred and paid for (by both InterCell and VaccGen), and then, amounts received in excess of such expenses, if any, shall be split [***] to VaccGen and [***] to InterCell.

(v) No settlement of any infringement action under this Section 6.2 that: (a) restricts the scope or affects the enforceability of the Vaccine Patents, (b) imposes any liability on InterCell, VaccGen, Cheil, or the Sublicensee(s) or (c) does not provide InterCell, VaccGen, Cheil, and the Sublicensee(s) with a full release from all claims and liability with respect to claims made in litigation, if applicable, may be entered into under this Section 6.2 without the prior written consent of the other party.

6.3 Revocation Proceedings

(i) In the event either party becomes aware of the institution by a third party of any proceedings for the revocation of the Vaccine Patents or any patents assigned to Cheil covering Improvements in the Territory, such party shall immediately notify the other party in writing, and following such notification, the parties shall confer on bow to handle such third party proceeding. The parties acknowledge that for revocation proceedings, Cheil, in accordance with the Cheil License Agreement, shall have the first right, but not the obligation, at Cheil's cost and expense, to: (a) defend such revocation proceedings or (b) in Cheil's sole good faith discretion, settle such revocation proceedings with such third party. All such actions defended pursuant to this Section 6.3(i) shall be in Cheil's own name and entirely under its own direction and control. At Cheil's cost and expense, InterCell and VaccGen will reasonably assist Cheil in such proceedings if so requested by Chet!, and will lend its name to such proceedings if requested by Cheil or required by law. Notwithstanding the foregoing, InterCell and VaccGen shall have the right to participate and be represented in any such proceedings by their own counsel at their own cost and expense.

(ii) If Cheil elects :lot to defend or settle any proceedings for revocation described in Section 6.3(i) within [***] after becoming aware of the proceeding, then VaccGen shall have the right, but not the obligation, to defend or settle such proceedings at its own cost and expense and entirely under its own direction and control. At VaccGen's cost and expense, InterCell will reasonably assist VaccGen in such proceedings if so requested by VaccGen or required by law. Notwithstanding the foregoing, InterCell shall have the right to participate and be represented in any such proceedings by its own counsel at its own expense.

(iii) If both VaccGen and Cheil elect not to defend or settle any proceedings for revocation described in Section 6.3(i) and (ii) within [***] after becoming aware of the revocation, then VaccGen shall immediately provide InterCell with written notice of such election and InterCell shall have the right, but not the obligation, to defend or settle such proceedings at its own cost and expense and entirely under its own direction and control. At InterCell's cost and expense, VaccGen and/or Cheil will reasonably assist InterCell in such proceedings if so requested by InterCell or required by law. Notwithstanding the foregoing, VaccGen and/or Cheil shall have the right to participate and be represented in any such proceedings by their own counsel at their own cost and expense.

In the event both VaccGen and Cheil decide not to participate in such revocation proceedings and InterCell assumes the responsibility for such proceedings in accordance with Section 6.3(iii), then the Royalty payments owed by InterCell to VaccGen under Section 3.3(i) shall be reduced from [***] to [***] and under Section 3.3(ii) shall be reduced from [***] to [***] in the country or countries where InterCell is defending such revocation proceedings.

(iv) Any amounts paid by third parties to InterCell, Cheil and/or VaccGen as a result of such proceedings, whether by settlement or otherwise, shall first be applied toward reimbursement for reasonable expenses incurred and paid for (by InterCell, Cheil, and VaccGen), and then, amounts received in excess of such expenses, if any, shall be provided to InterCell and considered Net Sales and subject to Royalty payments in accordance with Section 3.3.

(v) No settlement of any defense that: (a) restricts the scope or affects the enforceability of the Vaccine Patents, (b) imposes any liability on InterCell, Cheil, VaccGen, or the Sublicensee(s) or (c) does not provide InterCell, Cheil, VaccGen, and the Sublicensee(s) with a full release from all claims and liability with respect to claims made in the revocation proceeding, if applicable, may be entered into under this Section 6.3 without the prior written consent of the other party

6.4 Responsibility for Defense

(i) In the event that a third party at any time threatens or brings suit against either party, their Affiliates, or the Sublicensee(s) alleging infringement of any third party patent on account of the development, manufacture, marketing, use, or sale of the Vaccine (each a "***Third Party Claim***") in the Territory, the party receiving notification of the Third Party Claim shall immediately notify the other party in writing, enclosing a copy of all pleadings served, if any. Following such notification, the parties shall confer to determine whether either or both parties shall control the defense of the Third Party Claim. If both parties have been named in the Third Party Claim, then, unless otherwise agreed between them in writing, each party shall have the right, but not the obligation, to defend such Third Party Claim in its own name and under its own direction and control. If only one party has been named or if the parties agree in writing that only one party shall defend such Third Party Claim, then the defending party shall have the right, but not the obligation, to defend such Third Party Claim in its own name (and the other party's name, if so agreed by the parties in writing) and under its own direction and control. The other party will reasonably assist the party defending such Third Party Claim if so requested in writing. In addition, the other party shall have the right to participate and be represented in any such Third Party Claim by its own counsel at its own expense. No settlement of any action or defense that: (a) restricts the scope or affects the enforceability of the Vaccine Patents, (b) imposes any liability on InterCell, Cheil, VaccGen, or the Sublicensee(s) or (c) does not provide InterCell, Cheil, VaccGen, and the Sublicensee(s) with a full release from all claims and liability with respect to claims made in litigation, if applicable, may be entered into under this Section 6.4 without the prior written consent of the other party.

(ii) In the event that InterCell, VaccGen, or the Sublicensee(s), as the case may be, incurs any costs or expenses in connection with the defense of any Third Party Claim, such costs or expenses shall be borne by the party that incurs them.

(iii) In the event that, by way of counterclaim or otherwise, either party or both parties recovers any damages or other sums in any action, suit, or proceeding involving a Third Party Claim, or in settlement thereof, such recoveries shall be applied and shared follows:

(iv) if both parties defend such Third Party Claim, such recoveries shall be split [***] to InterCell and [***] to VaccGen.

(v) if only one party defends such Third Party Claim, such party shall be entitled to all such recoveries.

ARTICLE VII

TERM & TERMINATION

7.1 Term of the Agreement

This Agreement shall become effective on the Effective Date and, unless sooner terminated under this Article VII, shall expire upon the earlier of (1) the expiration or termination of InterCell's Royalty and payment obligations as set forth in Section 3.15 or (ii) when InterCell and/or its Sublicensees and Marketing Partners are no longer developing, marketing or selling the Vaccine anywhere in the Territory for a period of at least twelve consecutive months.

7.2 Termination

(i) In the event that InterCell or VaccGen shall be in material default of, or materially breaches any material conditions or covenants of this Agreement, the non-breaching party may, at its election, serve notice in writing upon the breaching party of its intention to terminate this Agreement on the expiration of ninety (90) days after the date of such notice, such notice to describe the alleged breach or default in reasonable detail; provided, however, that if the breaching party cures such default or breach within such ninety (90) day period, termination of this Agreement shall be avoided.

(ii) VaccGen may, at its election, terminate this Agreement forthwith upon written notice thereof to InterCell in the event that InterCell: (a) shall make an assignment for the benefit of creditors; (b) applies for or consents to the appointment of a trustee, receiver, or liquidator of all or substantially all of the assets of InterCell; (c) shall file a voluntary petition for liquidation in bankruptcy; or (d) be declared bankrupt by reason of a voluntary or involuntary bankruptcy proceeding, which proceeding, if involuntary and contested in good faith by InterCell, shall not have been dismissed within [***] after the date of filing.

(iii) VaccGen may, at its election, terminate this Agreement upon [***] written notice to InterCell in the event that InterCell a) does not substantially fund the Development Plan in accordance with the terms of the Development Plan as described more specifically in Section 4.3 or b) acquires rights to a Japanese encephalitis vaccine competitive to the Vaccine, unless InterCell has refuted VaccGen's claim or cured such breach during such [***].

(iv) In the event that InterCell decides, in good faith, not to develop, market, and sell the Vaccine in any country(ies) in the Territory, then InterCell will provide written notice to VaccGen of such decision and in such country(ies) the rights granted to InterCell in Section 2.1 to the Vaccine will automatically return to VaccGen at no cost to VaccGen. In such event, InterCell's rights to the Vaccine in the remaining countries in the Territory will not be affected.

(v) InterCell shall have the right, but not the obligation, to terminate this Agreement after giving [***] written notice to VaccGen if the FDA requires InterCell to repeat a Phase 1 human clinical trial with the Vaccine because of changes in the manufacturing process at [***] versus Vaccine previously produced at WRAIR. Such termination shall be supported by InterCell with appropriate written documents.

(vi) VaccGen shall have the right, but not the obligation, to terminate this Agreement after giving [***] written notice to InterCell if InterCell has not enrolled the first subject in the Bridging Study within [***] after the Effective Date, unless such delay in initiating the Bridging Study is caused by, based on convincing evidence, a) the FDA requiring InterCell to repeat a Phase 1 human clinical trial with the Vaccine because of changes in the manufacturing process at BioReliance versus Vaccine previously produced at WRAIR, b) unavoidable delays in producing the Vaccine at BioReliance for the Bridging Study, c) data showing that the safety and/or immunogenicity of Vaccine produced by BioReliance does not justify initiation of the Bridging Study, and/or d) the failure of cooperation on the part of WRAIR or VaccGen to assist InterCell with its obligations hereunder and such failure causes unavoidable delays in the Development Plan, unless InterCell has cured such breach during such [***] period.

(vii) The parties acknowledge that certain Vaccine Information, including without limitation know-how relating to the manufacture, use or development of the Vaccine in WRAIR's possession or control, is critical to InterCell's successful development and commercialization of the Vaccine and will be disclosed to InterCell pursuant to Section 4.2. If InterCell does not receive such information in accordance with the provisions of Section 4.2, InterCell shall have the right, but not the obligation, to terminate this Agreement upon thirty (30) days written notice to VaccGen, unless such information is provided to InterCell within such thirty (30) day period.

(viii) In the event of any good faith dispute as to a party's grounds for termination under this Agreement or whether a party has cured an identified breach under Section 72(i), 7.2(iii), 7.2(v), 7.2(vi), or 7.2(vii), this Agreement shall not be terminated pending resolution of such dispute pursuant to the alternative dispute resolution described in Section 12.11.

7.3 No Other Events of Termination

This Agreement shall terminate or otherwise be deemed to end if and only if the termination is effected pursuant to Section 7.1 or 7.2.

7.4 Rights and Duties Upon Termination

(i) No exercise by either party of any right of termination will constitute a waiver of any right of either party for recovery of any moneys owned to it hereunder or any other right or remedy either party may have by law or by this Agreement.

(ii) Upon termination of the Agreement (but not expiration in accordance with Section 7.1(i)), all rights and ownership granted by VaccGen to InterCell under this Agreement, with the exception of the right to sell off inventory pursuant to Section 7.4(iv), shall immediately and completely terminate and such rights and ownership shall revert completely back to VaccGen, without any limitations on VaccGen whatsoever and at no cost to VaccGen.

(iii) Within [***] after termination of this Agreement (but not expiration in accordance with Section 7.1(i)):

(iv) Each party shall return to the other party all Confidential Information (as defined hereinafter) of the other party received pursuant to this Agreement or otherwise, and

(v) InterCell will transfer to VaccGen at no cost to VaccGen 1) all Vaccine Information developed during the term of this Agreement (including, but not limited to, all marketing, sales, clinical, manufacturing, and other information on the Vaccine in InterCell's possession) and 2) all Vaccine Information provided to InterCell by VaccGen pursuant to Section 4.2 and VaccGen is free to use such Vaccine Information in order to commercially exploit the Vaccine in the Territory, without any limitations on VaccGen whatsoever.

(vi) All non-commercial inventories of Vaccine, including clinical supplies, in InterCell's possession shall be provided to VaccGen or destroyed, at VaccGen's sole option. All disposals of such inventories shall be performed in compliance with applicable law.

(vii) In the event of termination of this Agreement, InterCell's sublicense agreements with Sublicensees shall remain in effect and be assigned, along with all rights and obligations thereunder, to VaccGen, at no assignment cost to VaccGen.

(viii) Commercial inventories of the Vaccine, if any, may be sold by InterCell and/or its Sublicensee(s) and Marketing Partner(s) for [***] after the date of termination consistent with the terms and conditions of this Agreement At the end of the [***] period, any remaining commercial inventories of Vaccine may be sold by InterCell and/or its Sublicensee(s) and Marketing Partner(s) consistent with the terms and conditions of this Agreement or destroyed (in compliance with applicable law), at the sole option of the terminating Party.

(ix) Upon expiration of the Agreement under Section 7.1, the licenses granted to InterCell pursuant to Section 2.1 and 4.2(ii) shall become paid-up and royalty-free.

7.5 Survival of Contents

Notwithstanding anything else in this Agreement to the contrary, the parties agree that either party's obligation to pay the other party any consideration accrued but unpaid prior to such termination shall survive the termination of this Agreement. In addition, Sections 2.4, 3.9, 3.11, 6.2 (only to the extent such Third Party Claim arose prior to termination or expiration of this Agreement), 6.4 (only to the extent such Third Party Claim arose prior to termination or expiration of this Agreement), 7.4, 7.5, 8.1, 8.4, and Articles IX, X (only to the extent such claim or action arose prior to termination or expiration of this Agreement), XI and XII, as well as any other provisions to the extent required for the full observation and performance of the foregoing Sections and Articles or which by their nature are intended to survive such termination, shall survive the termination of this Agreement and continue to be enforceable.

ARTICLE VIII

CERTAIN COVENANTS

8.1 Proprietary Information

(i) Non-Disclosure Covenant

Trade Secrets (as defined hereinafter) and Confidential information (as defined hereinafter) and all physical embodiments thereof received by one party (the "***Receiving Party***") from the other (the "***Disclosing Party***") during the term of this Agreement are confidential to and are and will remain the sole and exclusive property of the Disclosing Party. At all times both during the term of this Agreement and for the longer of (a) [***] after the date of termination or (b) expiration of the last to expire Valid Claim, a

Receiving Party shall hold all Trade Secrets of a Disclosing Party in confidence, and will not (except as needed to exercise the rights granted or to perform obligations hereunder or as otherwise permitted by this Agreement) use, copy or disclose such Trade Secrets, or any physical embodiments thereof, or cause any of such Trade Secrets to lose their character as Trade Secrets. At all times both during the term of this Agreement and for the longer of (c) [***] after the date of termination or (d) expiration of the last to expire Valid Claim, a Receiving Party shall hold the Confidential Information of a Disclosing Party in confidence, and will not (except as needed to exercise the rights granted or to perform obligations hereunder or as otherwise permitted by this Agreement) use, copy or disclose such Confidential Information, or any physical embodiments thereof, or cause any of such Confidential Information to lose its character or cease to qualify as Confidential Information.

(ii) Security Measures

Trade Secrets and Confidential Information shall be maintained under secure conditions by a Receiving Party, using reasonable security measures and in any event not less than the same security measures used by the Receiving Party for the protection of its trade secrets and confidential information of a similar kind. A Receiving Party shall not remove, obscure, or deface any proprietary legend relating to a Disclosing Party's rights, on or from any tangible embodiment of any Trade Secrets or Confidential Information without the Disclosing Party's prior written consent.

(iii) Disclosure Ordered by Government Bodies

If a Receiving Party is ordered by a court, administrative agency, or other governmental body of competent jurisdiction to disclose Trade Secrets or Confidential Information, or if required by applicable law to disclose (e.g., for tax or compliance with United States securities laws), then a Receiving Party will not be liable to a Disclosing Party for disclosure of Trade Secrets or Confidential Information required by such order if a Receiving Party complies with the following requirements: (a) if an already-issued order calls for immediate disclosure, then the Receiving Party shall immediately move for or otherwise request a stay of such order to permit the Disclosing Party to respond as set forth in this Article 8.1(iii); (b) the Receiving Party shall immediately notify the Disclosing Party of the motion or order both in writing and by the most expeditious possible means; and (c) the Receiving Party shall join or agree to (or at minimum shall not oppose) a motion or similar request by the Disclosing Party for an order protecting the secrecy of the Trade Secrets and Confidential Information subject to disclosure including joining or agreeing to (or non-opposition to) a motion for leave to intervene by the Disclosing Party.

(iv) Reports of Misappropriation by Others

The Receiving Party shall immediately report to the Disclosing Party in writing any action by any Person of which the Receiving Party has knowledge to use, copy, or disclose any portion of the Trade Secrets or Confidential Information without authorization from the Disclosing Party.

(v) Trade Secrets Defined

"***Trade Secrets***" shall mean information related to the Disclosing Party which: (a) derives economic value, actual or potential, from not being generally known to or readily ascertainable by other persons who can obtain economic value from its disclosure or use; (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy; and (e) is not generally known or readily ascertainable by other persons.

(vi) Confidential Information Defined

"***Confidential Information***" shall mean information that is: (a) confidential to the business of the Disclosing Party; (b) is designated and identified in writing as such by the Disclosing Party and (c) is not a Trade Secret. Confidential Information does not include:

(a) any information that is at the time of receipt by the Receiving Party or thereafter becomes part of the public domain other than as a result of the unauthorized actions of the Receiving Party (through publication or otherwise);

(b) any information that was independently known to the Receiving Party prior to receipt thereof from the Disclosing Party, as evidenced by written records of the Receiving Party;

(c) any information that was disclosed to the Receiving Party by a third party having the right to disclose such information without an obligation of confidentiality owned to the Disclosing Party; and

(d) information that is subsequently developed independently by the Receiving Party without any knowledge or use of or access to the Confidential Information of the Disclosing Party.

Notwithstanding the foregoing, it is understood that a Receiving Party may disclose Trade Secrets and Confidential Information to its consultants, outside contractors, clinical investigators, Sublicensees, potential Sublicensees, and agents if such persons sign a written agreement to keep such information secret to the same extent the Receiving Party is so obligated hereunder, and agree to use such information only for such purposes as the Receiving Party is authorized to use such information under this Agreement.

8.2 Compliance with Law

InterCell shall comply with, and shall obligate its Sublicensee(s) and Marketing Partners to comply with, all applicable laws, rules, and regulations in the Territory pertaining to the use of the Vaccine and the development, clinical testing, manufacturing, marketing, advertising, sale, use, and distribution of the Vaccine. VaccGen shall comply with all applicable laws, rules and regulations in the Territory in connection with its activities under this Agreement.

8.3 Press Releases and Securities Laws

Each party shall provide the other party with the prior opportunity to review and approve any press releases or similar public announcements concerning this Agreement or the Vaccine as soon as practicable, but in no event later than [***] before an announcement is made. Both parties acknowledge that its opportunity to review and approve press releases is subject to and may be limited by any securities laws to which the parties may be subject that require immediate disclosure. Nothing in this Agreement shall limit the ability of either party to take any action that it deems necessary or advisable to comply with the securities laws.

8.4 Publication and Presentation

(i) If either party desires to publish or present the results of the Development Program, the publishing / presenting party shall provide the non-publishing / non-presenting party with a copy of the manuscript of the proposed publication or presentation at least [***] prior to such publication or presentation. The non-publishing / non-presenting party shall then review such manuscript or presentation by providing the publishing / presenting party with comments, if any, as soon as possible, but in no event to exceed [***] after receipt of such manuscript or presentation. The publishing / presenting party agrees to delete any information identified by the non-publishing / non-presenting party as its Trade Secrets or Confidential Information.

(ii) In the event the non-publishing / non-presenting party determines that a patent application covering the information contained in the proposed publication or presentation should be filed, the party proposing the publication or presentation shall delay such publication or presentation to allow a reasonable amount of time for such filing to be made.

8.5 Trademarks

InterCell shall have the right, at its cost and expense, to select, register, prosecute, maintain, and defend all trademarks used with the Vaccine in the Territory. In the event of termination of this Agreement, InterCell shall license VaccGen's or VaccGen's designee, at no cost to VaccGen or VaccGen's designee, to use in connection with the Vaccine in the Territory any such trademarks used by InterCell in connection with the Vaccine in the Territory.

ARTICLE IX

DISCLAIMER

EXCEPT AS EXPRESSLY SET FORTH IN ARTICLE XI HEREINAFTER, NEITHER PARTY MAKES ANY EXPRESS OR IMPLIED WARRANTIES, STATUTORY OR OTHERWISE, CONCERNING THE VACCINE, ANY VACCINE INFORMATION, TRADE SECRETS OR ANY CONFIDENTIAL INFORMATION COMMUNICATED TO THE OTHER PARTY. SPECIFICALLY, BUT WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKE ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS (FOR A PARTICULAR PURPOSE OR OTHERWISE), QUALITY OR USEFULNESS OF THE VACCINE, ANY VACCINE INFORMATION, TRADE SECRETS OR ANY CONFIDENTIAL INFORMATION COMMUNICATED TO THE OTHER PARTY. ALL MATERIALS PROVIDED HEREUNDER ARE PROVIDED ON AN "***AS IS***" BASIS. NEITHER PARTY WARRANTS THE ACCURACY OF ANY INFORMATION INCLUDED WITHIN THE VACCINE INFORMATION OR CONFIDENTIAL INFORMATION NOR DOES ANY PARTY WARRANT THAT ANY SUCH INFORMATION CONSTITUTES TRADE SECRETS OR. CONFIDENTIAL INFORMATION OR THAT THE VACCINE PATENTS OR PATENTS COVERING IMPROVEMENTS WILL BE FREE FROM CLAIMS OF INFRINGEMENT BY THIRD PARTIES OR ANY OTHER RIGHTS OF THIRD PARTIES.

UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES IN TORT, CONTRACT, STRICT LIABILITY OR OTHERWISE INCURRED BY THE OTHER PARTY OR ANY THIRD PARTY.

ARTICLE X

INDEMNITY

10.1 Indemnification by InterCell and Sublicensees

InterCell will indemnify and hold harmless VaccGen, Cheil, and their Affiliates, employees, officers, directors, stockholders, and agents (a "***VaccGen Indemnified Party***") from and against any and all liability (out-of-pocket costs, including reasonable attorneys' fees) to third parties which the VaccGen Indemnified Party will incur or be required to pay resulting from third party claims arising from or in connection with: (i) the breach by InterCell of any of its representations or warranties contained in this Agreement or the Consulting Agreement; (ii) the development, clinical testing, manufacturing, marketing, sale, or distribution of the Vaccine by InterCell or the Sublicensee(s) or any Person acting on behalf of InterCell or the Sublicensee(s) in the Territory, including VaccGen's co-promotional efforts, but excluding possible co-marketing efforts pursuant to Section 2.3; (iii) the use in the Territory by any person of the Vaccine that was manufactured, marketed, sold, or distributed by InterCell, the Sublicensee(s), their Affiliates or any Person acting on behalf of InterCell, the Sublicensee(s), or their Affiliate; or (iv) the use by InterCell, the Sublicensee(s), their Affiliates or any Person acting on behalf of InterCell, the Sublicensee(s), or their Affiliate of the Vaccine, except that neither InterCell nor the Sublicensee(s) shall have any obligation to so indemnify or hold harmless a VaccGen Indemnified Party for any such liability from third parties (out-of-pocket costs, including reasonable attorneys' fees) resulting from or arising in connection with the gross negligence or willful misconduct of such VaccGen Indemnified Party.

10.2 Indemnification by VaccGen

VaccGen will indemnify and hold harmless InterCell, the Sublicensee(s) and their Affiliates, employees, officers, directors, stockholders, and agents (an "***InterCell Indemnified Party***") from and against any and all liability (out-of-pocket costs, including reasonable attorneys' fees) which the InterCell Indemnified Party may incur or be required to pay resulting from third party claims arising from or in connection with: (i) the breach by VaccGen of any of its representations or warranties contained in this Agreement or the Consulting Agreement or (ii) the use, development, clinical testing, manufacturing, marketing, sale, or distribution of the Vaccine by or on behalf of VaccGen prior to the Effective Date or pursuant to Section 2.3 after the Effective Date, except that VaccGen shall have no obligation to indemnify or hold harmless an InterCell Indemnified Party for any such liability from third parties (out-of-pocket costs, including reasonable attorneys' fees) resulting from or arising in connection with the gross negligence or willful misconduct of such InterCell Indemnified Party.

10.3 Conditions to Indemnification

The obligations of the indemnifying party under Sections 10.1 and 10.2 are conditioned upon the prompt notification to the indemnifying party of any of the aforementioned suits or claims in writing as promptly as reasonably possible, but in no event to exceed thirty (30) days, after receipt of notice by the indemnified party of such suit or claim. The indemnifying party shall have the right to assume the defense of any such suit or claim. If the indemnifying party defends the claim, the indemnified party may participate in the defense of such suit or claim at its sole cost and expense. Neither the indemnifying party nor the indemnified party shall settle or dispose of any such matter in any manner which would adversely affect the rights or interests of the other party (including the obligation to indemnify hereunder) without the prior written consent of the other party, which shall not be unreasonably withheld or delayed. This provision for indemnification shall be void and there shall be no liability against a party as to any suit or claim for which settlement or compromise or an offer of settlement or compromise is made without the prior written consent of the indemnifying party. Each party shall cooperate with the other party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses.

10.4 Indemnification by Cheil

VaccGen shall take or cause to be taken all such other actions, as InterCell may reasonably deem necessary or desirable, in order for InterCell to obtain the full benefit of Cheil's agreement to indemnify InterCell, as VaccGen's sublicensee, pursuant to Section 10.2 of the Cheil License Agreement.

ARTICLE XI

REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties of VaccGen

VaccGen represents and warrants to InterCell as follows:

(i) The execution and delivery of this Agreement have been duly and validly authorized, and all necessary actions have been taken to make this Agreement a legal, valid, and binding obligation of VaccGen enforceable in accordance with its terms and conditions.

(ii) The execution and delivery of this Agreement and the performance by VaccGen of its obligations hereunder will not contravene or result in any breach of the Operating Agreement of VaccGen or bylaws of VaccGen or result in any material breach or violation of or material default under any material agreement, indenture, license, instrument, or understanding or, to the best of its knowledge, result in any violation of any agreement, order or decree to which VaccGen is a party or by which any of it or any of its property is subject.

(iii) As of the Effective Date, VaccGen has not received any notice nor is VaccGen aware of any claim that the manufacture, use or sale of the Vaccine or the exercise of rights under the Vaccine Patents infringes upon any third party's know-how, patent, or intellectual property rights, except those patents and patent applications that were discussed between InterCell and VaccGen prior to the Effective Date (Exhibit C).

(iv) VaccGen possesses, pursuant to the Cheil License Agreement, all rights and interest, as the exclusive worldwide (excluding Korea) licensee of the Vaccine, in and to the Vaccine and Vaccine Patents necessary to grant the sublicense granted to InterCell hereunder without restriction or limitation except as expressly provided herein.

(v) VaccGen has no contractual obligations to any third party that preclude, conflict with, or in any way encumber VaccGen's right to grant to InterCell the rights and sublicense granted under this Agreement. In addition, during the term of this Agreement, VaccGen shall not enter into any agreement in the future, either written or oral, that conflicts with the rights and/or sublicense granted to InterCell under this Agreement.

(vi) As of the Effective Date, VaccGen is in full compliance with the Cheil License Agreement and the Cheil License Agreement is in full force and effect between VaccGen and Cheil, and VaccGen has not failed to take any action or committed any breach of the Cheil License Agreement which would give Cheil the right to terminate the Cheil License Agreement.

(vii) The Vaccine Patents constitute all of the patents and patent applications owned or controlled by Cheil, WRAIR or VaccGen which cover the prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine developed by Cheil, VaccGen and WRAIR.

11.2 Representations and Warranties of InterCell

InterCell represents and warrants to VaccGen as follows:

(i) The execution and delivery of this Agreement have been duly and validly authorized, and all necessary actions have been taken to make this Agreement a legal, valid, and binding obligation of InterCell enforceable in accordance with its terms and conditions;

(ii) The execution and delivery of this Agreement and the performance by InterCell of its obligations hereunder will not contravene or result in any breach of InterCell's certificate of incorporation or bylaws or result in any material breach or violation of or material default under any material agreement, indenture, license, instrument, or understanding or, to the best of its knowledge, result in any violation of any agreement, order or decree to which InterCell is a party or by which any of it or any of its property is subject.

(iii) InterCell has no contractual obligations to any third party that preclude, conflict with, or in any way encumber InterCell's right to accept the rights and sublicense granted by VaccGen to InterCell under this Agreement. In addition, during the term of this Agreement, InterCell shall not enter into any agreement, either written or oral, that conflicts with the rights and/or sublicense granted to InterCell under this Agreement.

ARTICLE XII

MISCELLANEOUS

12.1 Entire Agreement

This Agreement, together with Exhibits A, B and C attached hereto which are hereby incorporated by reference, and any other written agreements entered into by the parties dated the Effective Date, sets forth and constitutes the final and entire agreement between the parties hereto with respect to the subject matter hereof, and supersedes any and all prior or contemporaneous agreements, understandings, promises, and representations made by either party to the other concerning the subject matter hereof and the terms applicable hereto. This Agreement may not be released, discharged, amended, or modified in any manner except by an instrument in writing signed by duly authorized representatives of VaccGen and InterCell.

12.2 Parties Independent

In making and performing this Agreement, the parties act and shall act at all times as independent contractors and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, or employer and employee relationship between VaccGen and InterCell. Except as specifically provided herein, at no time shall either party make commitments or incur charges or expenses for or in the name of the other party.

12.3 Effect of Invalidity of Certain Provisions

Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement.

12.4 Governing Law

The validity of this Agreement and the interpretation and performance of all its terms shall be governed by the substantive laws of the State of New York, United States of America, without regard to conflict of law principles.

12.5 Waivers

The failure of either party to insist, in any one or more instances, upon the performance of any of the terms, covenants, or conditions of this Agreement and to exercise any rights hereunder, shall not be construed as a waiver or relinquishment of the future performance of any such term, covenant, or condition or the future exercise of such right, but the obligations of the other party with respect to such future performance shall continue in full force and effect. No waiver shall be effective unless made in writing and signed by the waiving party.

12.6 Headings

The headings of the articles, sections, and paragraphs used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.

12.7 Notice

Any notice or other communication required or permitted to be made or given to either party hereto pursuant to this Agreement shall be sufficiently made or given if sent to such party by either certified or registered mail, postage prepaid, return receipt requested addressed to it as follows:

If to VaccGen:

VaccGen International, LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Attention: [***]

If to InterCell:

InterCell Biomedical Research & Development
Campus Vienna Biocenter 6
A-1030
Vienna, Austria
Attention: [***]

or to such other address as either party shall designate by written notice, provided in accordance with this Section 12.7, to the other party. Any notice if given or made by certified or registered first class mail letter, return receipt requested, shall be deemed to have been received on the date of receipt as proven by signature of acceptance.

12.8 Successors and Assigns

(i) This Agreement shall not be assignable by either party (excludes sublicense agreements by Inter-Cell) without the prior written consent of the other party (such consent shall not be unreasonably withheld), except that such consent is not required in connection with the assignment of either party's rights or obligations hereunder to a) an Affiliate thereof or b) to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise.

(ii) Any assignment of this Agreement shall provide that the assignee shall be bound by the terms and conditions of this Agreement. Unless otherwise agreed between InterCell and VaccGen, any party who assigns to a third party it obligations to perform under this Agreement shall be liable to the other party for the third party's failure to perform those obligations.

(iii) Any assignment not in conformance with this Section 12.8 shall be null, void and of no legal effect.

(iv) Subject to the foregoing, this Agreement, and each and every provision hereof, shall be binding upon and shall inure to the benefit of the parties, their respective successors, successors-in-title, heirs and assigns, permitted assigns, and each and every successor-in-interest to any party, whether such successor acquires such interest by way of gift, purchase, foreclosure, or by any other method, shall hold such interest subject to all the terms and provisions of this Agreement.

12.9 Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be an original as against either party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.

12.10 Force Majeure

The parties shall not be responsible for their failure to perform any of the obligations imposed by this Agreement (except an obligation to pay money), provided such failure is cause by fire, storms, flood, strikes, lockouts, accidents, war, riots or civil commotions, inability to obtain raw materials, embargoes, any State or Federal regulation, law, or restriction, seizure or acquisition of the Vaccine by the

government of the United States or of any state, or of any agency thereof or by reason of any compliance with a demand or request for such product for any purpose for national defense, or any other cause or contingency beyond the reasonable control of said Part), (whether or not of the same kind or nature as the causes or contingencies above enumerated) and any such event shall not subject the party so failing to any liability to the other.

12.11 Dispute Resolution

(i) Good Faith Discussions

The parties will attempt to resolve through good faith discussions any dispute between the parties which arises under or as a result of this Agreement (a "***Dispute***"). Any Dispute shall first be raised with the JDMC for good faith discussions and resolution. If the JDMC is unable to resolve such Dispute, either party may refer such Dispute to the then current chief executive officers of each patty by written notice identifying the dispute and the parties' attempted resolution efforts and proposals in reasonable detail. If the chief executive officers are unable to resolve such Dispute within [***] after receipt of such written notice, either party may seek to resolve such Dispute by initiating an Alternative Dispute Resolution ("***ADR***") in which the Judicial Arbitration and Mediation Services ("***JAMS***"), through a panel of [***] arbitrators (the "***Arbitrators***"), shall control the proceedings as provided herein. If JAMS is not in existence at the time of such Dispute, the American Arbitration Association (AAA) shall be substituted. The location of the ADR shall be New York, New York if the arbitration is initiated (as set forth below) by InterCell, and Vienna, Austria if initiated by VaccGen.

(ii) Selection of Arbitrators

An ADR shall lx initiated by a party by sending written notice thereof to the other party and JAMS, which shall state the issue(s) to be resolved and describe the Dispute in reasonable detail. Within [***] after receipt of such notice, the other party may, by sending written notice to the initiating party and JAMS, add information and issues to be resolved. Within [***] after the date of the original ADR notice, JAMS shall nominate to the parties at least [***] qualified nominees [as set forth in Article 12.11(iii)] from JAMS panel. Each party shall have [***] after the receipt of such nominations to select [***] Arbitrator. The [***] Arbitrators will then mutually agree on [***] Arbitrator to complete the panel.

(iii) Arbitrators with Special Expertise

Each Arbitrator shall have experience in the subject matter at hand and with intellectual property law matters, In the event of a Dispute between the parties relating to the calculation of any royalties or the amount of other consideration payable under this Agreement (including, without limitation, the results of any audit conducted pursuant to Article 3.11), then, in addition to the qualifications set forth in this Section 12.11(iii), the Arbitrators shall be active or retired partners or full members of internationally recognized certified public accounting firms which are not auditing firms for either party and have not provided material services to either party during the last [***] period prior to the date of ADR initiation.

(iv) ADR Hearing

Except as otherwise provided in this Article 12.11, such healing shall be conducted pursuant to the then current JAMS Rules or the Commercial Arbitration Rules of the AAA, as applicable.

(v) ADR Ruling; Tees and Expenses

The Arbitrators shall render a final disposition of the Dispute (including an award of monetary damages, if applicable) as expeditiously as possible after the hearing, but no later than [***] after the conclusion of the hearing. The Arbitrators' disposition shall be final and not appealable, except that either party shall have the right to appeal such disposition on the basis that it was obtained through fraud or bad faith in connection with the ADR proceeding. A judgment on the Arbitrators' disposition may be entered in any court having jurisdiction over the parties. The reasonable fees and expenses of the Arbitrators, as well as the standard charges of JAMS for its assistance, shall be borne equally by the parties or as they may otherwise agree in writing.

(vi) Waiver

A party shall not be prohibited from bringing a claim for resolution under this Article 12.11 on the ground that the claim could have been brought during an earlier proceeding under this Article 12.11

(vii) No **Dispute Resolution**

The following disputes, causes of action, or claims shall not be subject to the dispute resolution process set forth in this Article 12,11:

(a) a claim arising from a suit, action, or proceeding brought by a third party not subject to ADR;

(b) a claim relating to undisputed amounts owed by either party to the other under this Agreement;

(c) a suit, action, or proceeding to compel either party to comply with the dispute resolution procedures set forth in this Article 12.11;

(d) a dispute, controversy, or claim relating to the scope, enforceability, infringement, or validity of a patent or trademark of either party; and

(e) a cause of action seeking temporary or preliminary injunction or other equitable relief.

12.12 Further Assurances

From time to time on and after the Effective Date, each party shall at the reasonable written request of the other party (a) deliver to such other party such records, data or other documents consistent with the provisions of this Agreement, (b) execute, and deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and (c) take or cause to be taken all such other actions, as such other party may reasonably deem necessary or desirable in order for such party to obtain the full benefits of this Agreement and the transactions contemplated thereby.

12.13 Rights in Bankruptcy

The parties agree that the rights granted to InterCell hereunder, including, without limitation, those rights granted in Sections 2.1 and 4.2 are rights in "intellectual property" within the scope of Section 101 (or its successors) of the United States Bankruptcy Code (the "Code"). InterCell shall have the rights set forth herein with respect to the Vaccine Patents and Vaccine Information when and as developed or created. In addition, InterCell, as a licensee of intellectual property rights hereunder, shall have and may fully exercise all rights available to a licensee under the Code, including, without limitation, under Section 365(n) or its successors. In the event of a case under the Code involving VaccGen, InterCell shall have the right to obtain (and VaccGen or any trustee for VaccGen or its assets shall, at InterCell's written request, deliver to InterCell) a copy of all embodiments (including, without limitation, any work in progress) of any intellectual property rights granted hereunder, including, without limitation, embodiments of any Vaccine, Vaccine Patents or Vaccine Information, and any VaccGen confidential information or any

other intellectual property necessary or desirable for InterCell to use or exploit the Vaccine or any Vaccine Patents or any Vaccine Information or to exercise its rights hereunder. In addition VaccGen shall take all steps reasonably requested by InterCell to perfect, exercise and enforce its rights hereunder, including, without limitation, filings in the U.S. Copyright Office and U.S. Patent and Trademark Office; and under the Uniform Commercial Code.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first above written.

VaccGen International, LLC

Signature:	*[***]*
Name:	[***]
Title:	[***]
Date:	April 11, 2003

InterCell Biomedical Research and Development AG

Signature:	[***]	[***]
Name:	[***]	[***]
Title:	[***]	[***]
Date:	April 14, 2003	April 14, 2003

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1 TO THE SUBLICENSE AGREEMENT

THIS **AMENDMENT NO. 1 TO THE SUBLICENSE AGREEMENT** ("Amendment No. 1") is made and executed as of _____, 2003 (the "Effective Date") by and between **InterCell A**G, having its principal place of business at Campus Vienna Biocenter 6, A-1030, Vienna, Austria (hereinafter "InterCell") and **VaccGen International, LLC**, having its principal place of business at 8 Cambridge Court, Larchmont, New York 10538, U.S.A. (hereinafter "VaccGen").

Capitalized terms used but not otherwise defined in this Amendment No. 1 shall have the respective meanings assigned to such terms in that certain Sublicense Agreement entered into by and between InterCell and VaccGen on April 14, 2003 (the "Sublicense Agreement").

WHEREAS, InterCell wishes VaccGen to amend that certain Cooperative Research and Development Agreement between VaccGen and WRAIR, last signed April 27, 2000, as amended ("CRADA"), to cover certain studies relating to the Vaccine; and

WHEREAS, VaccGen is willing to amend such CRADA with WRAIR at the request of InterCell.

WHEREAS, in connection with such CRADA amendment, VaccGen and InterCell desire to make certain modifications to the Sublicense Agreement as set forth in this Amendment No. 1;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements hereinafter set forth, the parties hereto, intending to be legally bound hereby, agree as follows:

1. All studies and other activities relating to the Vaccine under the CRADA between VaccGen and WRAIR shall be done, and all rights of VaccGen under the CRADA shall be exercised, at InterCell's direction and with InterCell's prior written approval. VaccGen shall (i) keep InterCell informed at all times with respect to the progress and any and all other issues relating to the CRADA and the performance thereof, (ii) timely seek InterCell's direction and approval with respect to any action VaccGen must or is permitted to take, and any other decision of VaccGen, in connection with the CRADA, (iii) not take any action or make any decision in connection with the CRADA absent InterCell's prior written approval, (iv) not act in any way inconsistent with InterCell's directions relating to the CRADA, and (v) properly and promptly pass along any notice, communication, information or materials provided to VaccGen by WRAIR under the CRADA.

2. Without limiting the generality of the foregoing, VaccGen shall use its reasonable best efforts to do any of the following if and as, and only if and as, specifically directed by InterCell in writing. (a) provide any notice relating to the CRADA to WRAIR, (b) terminate the CRADA or agree to amend the CRADA, (c) inspect accounts and records of WRAIR, (d) provide any reports to WRAIR, (e) exercise, or fail to exercise in due time, any option under the CRADA, including, without limitation, the option to retain title in any Subject Inventions (as defined in the CRADA), (f) agree to or elect, or fail to elect in due time, to file or maintain any patent rights, (g) elect, or fail to elect in due time, or decline, to exercise a right to acquire a license to any Subject Invention (as defined in the CRADA) or otherwise in connection with the CRADA and negotiate and enter into license agreements relating thereto, (h) require WRAIR to assist and cooperate in accordance with the CRADA in connection with any regulatory filings or other communications with regulatory authorities as InterCell shall be the sole holder and beneficiary of any regulatory applications and approvals relating to the Vaccine in accordance with the terms and conditions of the Sublicense Agreement, (i) settle any disputes or bring any enforcement action relating to the CRADA, and (j) exercise, or fail to exercise in due time, any other rights under the CRADA.

3. VaccGen shall submit to InterCell for review and approval any proposed amendments to the CRADA, including any and all funding commitments and budgets relating to the CRADA, prior to VaccGen agreeing to any such amendments. In no event shall InterCell incur any obligation to reimburse VaccGen for any expenditures, or make any other payments to VaccGen, in excess of amounts approved by InterCell in advance in writing.

4. VaccGen shall promptly disclose, provide, transfer and deliver to InterCell any and all data (including any pre-clinical, clinical, laboratory and testing data), studies, reports, materials, documents, processes, methods, know-how and other information delivered or to be delivered to VaccGen in connection with the CRADA or otherwise developed or created under the CRADA (the "CRADA Information"). All CRADA Information shall be deemed InterCell Improvements and Vaccine Information for all purposes of the Sublicense Agreement.

5. VaccGen shall promptly disclose, provide, transfer and deliver to InterCell copies of any and all financial reports and accounting records related to the CRADA. All of the foregoing shall be deemed Vaccine Information for all purposes of the Sublicense Agreement. InterCell shall have the right to audit VaccGen's books and records to verify its compliance with its obligations under this Amendment No. 1 and the CRADA. Upon request, VaccGen shall use its reasonable best efforts to designate InterCell as its authorized representative for purposes of inspection of any accounts and records of WRAIR under the CRADA.

6. VaccGen shall invite InterCell to participate in all meetings, conferences, conference calls and other discussions related to the CRADA ("Meetings"). Mr. Paul Wilson and/or Dr. Andrew Towle will act as VaccGen's representative(s) in all such Meetings and they shall use their reasonable best efforts to act in accordance with InterCell's directions in all such Meetings.

7. VaccGen shall be solely responsible to WRAIR for all payments required to be made to WRAIR in connection with the CRADA, including both: (a) payments as set forth in Appendix B thereto entitled Costs and Schedule of Payments and (b) royalty payments under license agreements relating to Subject Inventions (as defined in the (CRADA), if any. InterCell shall advance VaccGen sufficient funds in a timely manner to allow VaccGen to make these required CRADA payments on schedule to WRAIR, provided that (i) such amounts have been approved in advance in writing by InterCell as set forth in Section 2 above, (ii) VaccGen is not in breach of any of its obligations under this Amendment I or the Sublicense Agreement, and (ii) VaccGen provides acceptable proof to InterCell of its payment to WRAIR.

As of the Effective Date of Amendment No. 1, no royalty or other payments are owed by VaccGen to WRAIR with respect to the CRADA or any license agreement related to Subject Inventions (as defined in the CRADA) under the CRADA. InterCell shall be responsible (either directly to WRAIR or indirectly via an obligation to reimburse VaccGen) for any royalty or other payments owed to WRAIR under licensing agreements for Subject Inventions that arise after the Effective Date of Amendment No. 1, if any.

The foregoing sets forth InterCell's sole and entire liability to VaccGen in connection with the CRADA.

[***] = 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.

8. All CRADA Information and any rights that are assigned to or licensed to VaccGen under the CRADA or any license agreement relating to Subject Inventions (as defined in the CRADA) executed pursuant to the CRADA, if any, shall be deemed InterCell Improvements and shall be treated, as between VaccGen and InterCell, as set forth in the Sublicense Agreement.

9. VaccGen shall use its reasonable best efforts to comply with all the terms and conditions of the CRADA and shall use its reasonable best efforts not breach the CRADA. VaccGen will promptly notify InterCell upon receipt of any notice of breach. VaccGen shall terminate the CRADA, according to its terms, if directed to do so in writing by InterCell. VaccGen shall not terminate the CRADA without InterCell's prior written consent. In the event the CRADA is terminated and there are excess funds remaining from funds advanced to VaccGen by InterCell for performance of the CRADA, after all termination costs have been covered, VaccGen shall return such excess funds to InterCell. Except in the event the CRADA is terminated as a result of a breach by VaccGen, InterCell shall reimburse to VaccGen any termination costs actually incurred by VaccGen in accordance with Section 8.4 of the CRADA, provided VaccGen is not in breach of any of its obligations under this Amendment No. 1 or the Sublicense Agreement.

10. Except as expressly modified by this Amendment No. 1, all terms, conditions and provisions of the Sublicense Agreement shall continue in full force and effect as set forth in the Sublicense Agreement. In the event of a conflict between the terms and conditions of the Sublicense Agreement and the terms and conditions of this Amendment No. 1, the terms and conditions of this Amendment No. 1 shall prevail. The Sublicense Agreement, as amended by this Amendment No. 1, constitutes the complete and exclusive statement of the agreement between the parties, and supersedes all prior proposals and understandings, oral and written, relating to the subject matter contained herein. This Amendment No. 1 shall not be modified or rescinded except in a writing signed by the parties.

VaccGen International, LLC	InterCell AG
By: */s/ [***]*	By: */s/ [***]*
Name: [***]	Name: [***]
Title: Member / Manager	Title: CFO
By: */s/ [***]*	By: */s/ [***]*
Name: [***]	Name: [***]
Title: Member	Title: COO

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VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA

Vienna, June 28, 2004

Dear [***],

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") entered into that certain Sublicense Agreement, effective April 14, 2003 (the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine as further described in the Sublicense Agreement (the "Vaccine").

Pursuant to the Sublicense Agreement, VaccGen is obligated, among other things, to transfer to Intercell all regulatory filings for the Vaccine, including, without limitation, the Investigational New Drug (the "IND") application originally filed by WRAIR (Walter Reed Army Institute of Research) and transferred to VaccGen during the fourth quarter 2002.

The parties are initiating such transfer of the IND from VaccGen to Intercell on or about the date hereof (the "IND Transfer Date"). In connection with such transfer, Intercell and VaccGen wish to clarify certain rights and obligations under the Sublicense Agreement.

1. Section 11.1 of the Sublicense Agreement is hereby amended by adding a new subclause (viii) as follows:

   "(viii) As of the IND Transfer Date, VaccGen has not received any notice nor is VaccGen aware of any instance of non-compliance regarding the regulatory management of the IND for the Vaccine (official FDA contacts, submissions, and/or other responsibilities of the IND holder)."

2. Section 4.4 of the Sublicense Agreement is hereby amended by adding a new subclause (iii) as follows:

   "(iii) As of the IND Transfer Date, all sponsor's responsibility for the IND (official FDA contacts, submissions, and/or other responsibilities of the IND holder) shall be transferred from VaccGen to Intercell. As Intercell's request, VaccGen will assist Intercell with such IND sponsor's responsibilities."

campus vienna BIOCENTER
INTERCELL AG, CAMPUS VIENNA BIOCENTER 6, A-1030 VIENNA, AUSTRIA, PHONE +43-1-20620-100, FAX +43-1-20620-800, WWW.INTERCELL.COM
BA-CA AG, BLZ 12000, ACC.NR. 00607177102, UID-NR. ATU 44511104, FB-NR. 166438 M / HG WIEN

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This letter, the Sublicense Agreement, Amendment No. 1 to the Sublicense Agreement, and such other agreements as are referenced in Section 12.1 of the Sublicense Agreement constitute the entire agreement between the parties relating to the subject matter thereof. Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement and Amendment No. 1 to the Sublicense Agreement shall remain in full force and effect as set forth therein. Each party represents and warrants to the other party that this Amendment has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

By signing this letter below the parties agree as set forth herein.

/s/ [***]	*/s/ [***]*
For VaccGen International LLC	For Intercell AG
[***]	[***], COO
By (name and title)	[***], CMO
	By (name and title)
June 29, 2004	19 June, 2004
Date	Date

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March 15, 2005

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:,

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14, 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine as further described in the Sublicense Agreement (the "Vaccine").

Intercell intends to enter into a collaborative development and commercialization arrangement, and certain related agreements, with Biological E Limited, a company established under the laws of India, currently having a place of business at 18/1&3, Azamabad, Hyderabad—500 020, A.P., India ("BE") relating to the development, manufacture, and commercialization of a prophylactic vero cell-derived inactivated Japanese encephalitis vaccine in certain territories (the "Project").

1. Intercell and VaccGen hereby acknowledge and agree that, with respect to the Project and all agreements (including sublicenses) relating thereto ("Project Agreements"), (i) BE shall be deemed to be, and shall be treated as, a "Marketing Partner" (as such term is defined and used in the Sublicense Agreement) for all purposes of the Sublicense Agreement, and (ii) neither BE nor BE's or Intercell's respective resellers, distributors, sublicensees, and other marketing partners or collaborators engaged in the Project, shall be deemed to be, nor be treated as, "Sublicensees" (as such term is defined and used in the Sublicense Agreement) for any purposes of the Sublicense Agreement. Consequently, no consideration (whether royalties, profit-sharing or revenue-sharing income, license fees, or otherwise) received by Intercell under Project Agreements or otherwise in connection with the Project shall be deemed to constitute, nor be treated as, "Sublicense Revenue" (as such term is defined and used in the Sublicense Agreement) for any purposes of the Sublicense Agreement.

2. Intercell represents and warrants that the Projects Agreements, including any future amendments, shall be consistent with the terms and conditions of the Sublicense Agreement.

3. Intercell will send VaccGen a copy of all final executed Project Agreements within ten (10) days of execution of such Project Agreements. Intercell will also send VaccGen all future executed amendments to the Projects Agreements, if any.

4. Nothing herein shall affect Intercell's obligation to pay "Royalties" (as such term is defined and used in the Sublicense Agreement) under Section 3.3 of the Sublicense Agreement when and if owed pursuant to the terms and conditions of the Sublicense Agreement as amended pursuant to this letter.

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5. For the avoidance of doubt, with respect to BE's activities under the Project and the Project Agreements, BE shall be deemed a Person acting on behalf of InterCell for purposes of Section 10.1 of the Sublicense Agreement.

6. The following provisions of the Sublicense Agreement are hereby amended as follows:

(a) Section 3.3(i) is hereby amended to read in its entirety as follows: "For Vaccine marketed, sold, and distributed directly by InterCell and/or its Affiliates (other than to or through Marketing Partners) in a country where such sale would infringe a Valid Claim issued in such country absent this Agreement, InterCell shall pay VaccGen a Royalty upon commercialization of the Vaccine equal to [***] percent ([***]%) of applicable Net Sales. InterCell's obligation to pay such [***] percent ([***]%) Royalty to VaccGen under this Section 3.3(i) shall continue until the expiration or final determination of invalidity of the last Valid Claim that would be infringed by the sale of the Vaccine in such country, and upon such expiration or final determination of invalidity of such last Valid Claim, InterCell shall thereafter pay VaccGen a Royalty of [***] percent ([***]%) for a period of seven (7) years from such expiration."

(b) Section 3.3(ii) is hereby amended to read in its entirety as follows: "For Vaccine marketed, sold, and distributed by InterCell's Marketing Partners in a country where such sale would infringe a Valid Claim issued in such country absent this Agreement, InterCell shall pay VaccGen a Royalty upon commercialization of the Vaccine equal to [***] percent ([***]%) of applicable Net Sales. InterCell's obligation to pay such [***] percent ([***]%) Royalty to VaccGen under this Section 3.3(ii) shall continue until the expiration or final determination of invalidity of the last Valid Claim that would be infringed by the sale of the Vaccine in such country, and upon such expiration or final determination of invalidity of such last Valid Claim, InterCell shall thereafter pay VaccGen a Royalty of [***] percent ([***]%) for a period of seven (7) years from such expiration."

(c) The following Section 3.3(iv) is hereby added: "During the period set forth in Section 3.15, for Vaccine marketed, sold, and distributed directly by InterCell and/or its Affiliates (other than to or through Marketing Partners) in a country where such sale does not infringe a Valid Claim issued in such country, InterCell shall pay VaccGen a Royalty upon commercialization of the Vaccine equal to [***] percent ([***]%) of applicable Net Sales. For the avoidance of doubt, this Section 3.3(iv) only applies with respect to countries where a Valid Claim never existed at some point in time."

(d) The following Section 3.3(v) is hereby added: "During the period set forth in Section 3.15, for Vaccine marketed, sold, and distributed by InterCell's Marketing Partners in a country where such sale does not infringe a Valid Claim issued in such country, InterCell shall pay VaccGen a Royalty upon commercialization of the Vaccine equal to [***] percent ([***]%) of applicable Net Sales. For the avoidance of doubt, this Section 3.3(v) only applies with respect to countries where a Valid Claim never existed at some point in time."

(e) Section 3.15 is hereby amended and replaced in its entirety by the following:

(i) The following Section 3.15(i) is hereby added: "InterCell's obligation to pay Royalties under Sections 3.3(iv) and 3.3(v) with respect to Net Sales in any particular country shall continue for a period of seven (7) years from the first commercial sale of Vaccine by InterCell or its Marketing Partners in such country. InterCell's obligation to pay Royalties under Sections 3.3(i) and 3.3(ii) shall continue as, and only as, provided therein."

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(ii) The following Section 3.15(ii) is hereby added: "InterCell's obligation to pay Royalties and other amounts to VaccGen under Section 3.4 shall continue until the expiration or final determination of invalidity of the last sublicensed Valid Claim, and upon such expiration or final determination of invalidity of the last sublicensed Valid Claim, InterCell will thereafter pay for a period of seven (7) years a reduced Royalties amount under Section 3.4 of [***]."

(iii) The following Section 3.15(iii) is hereby added: "Upon expiration of the applicable seven (7) year periods set forth in Sections 3.3(i) and 3.3(ii) and Sections 3.15(i) and 3.15(ii), InterCell shall have no further obligation to pay any Royalties (with respect to the applicable country) or other amounts pursuant to Article 3. Notwithstanding the above, InterCell shall be obligated after expiration of the royalty term to pay any Royalty amounts that accrued under Article 3 prior to such expiration."

This letter, the Sublicense Agreement (as amended), and such other agreements as are referenced in Section 12.1 of the Sublicense Agreement constitute the entire agreement between the parties relating to the subject matter hereof. Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement (as amended) shall remain in full force and effect as set forth therein. Each party represents and warrants to the other party that this Amendment has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

By signing this letter below the parties agree as set forth herein.

/s/ [***]	*/s/ [***]*
For VaccGen International LLC	For Intercell AG
[***], Member / Manager	[***] CEO
By (name and title)	By (name and title)
3 15 05	3-21-05
Date	Date
	/s/ [***]
	[***]
	3-24-05
	Date

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October 24, 2005

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:

Intercell AG ("Intermit") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14, 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine as further described in the Sublicense Agreement (the "Vaccine").

Intercell and VaccGen agree that Section 3.2(i) of the Sublicense Agreement is hereby amended to read in its entirety as follows: "InterCell shall make a Milestone Payment of five hundred thousand United States dollars (USD$500,000) to VaccGen upon complete recruitment of subjects in the Phase 3 non-inferiority clinical trial designated as IC51-301."

This letter, the Sublicense Agreement (as amended), and such other agreements as are referenced in Section 12.1 of the Sublicense Agreement, constitute the entire agreement between the Parties relating to the subject matter hereof. Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement (as amended) shall remain in full force and effect as set forth therein. Each Party represents and warrants to the other Party that this Amendment has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

By signing this letter below, the parties agree as set forth herein.

/s/ [***]	*/s/ [***]*
For: VaccGen International LLC	For: Intercell AG
[***] Member/Manager	[***], CEO [***], CFO
By: (name and title)	By: (name and title)
10/20/05	10/24/05
Date	Date

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April 12, 2006

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14, 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine.

1. Intercell and VaccGen hereby amend the Sublicense Agreement as follows:

(a) Sections 2.3(i) and 2.3(v) are hereby deleted in their entirety.

(b) A comma and the following phrase is hereby added at the end of Section 2.3(iv): "subject, however, to Section 4.5, and solely to the extent consistent with the applicable terms and conditions of Intercell's agreements with Sublicensees and Marketing Partners."

(c) In Section 4.5 the clause "Subject to the parties' agreement with respect to VaccGen's co-promotional and co-marketing efforts pursuant to Section 2.3," is hereby deleted.

This letter, the Sublicense Agreement (as previously amended), and such other agreements as are referenced in Section 12.1 of the Sublicense Agreement constitute the entire agreement between the parties relating to the subject matter hereof. Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement (as previously amended) shall remain in full force and effect as set forth therein. Each party represents and warrants to the other party that this Amendment has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

By signing this Letter below the parties agree as set forth herein.

/s/ [***]	*/s/ [***]*
For VaccGen International LLC	For Intercell AG
[***], Member / Manager	[***],CEO
By (name and title)	By (name and title)
April 12, 2006	April 12, 2006
Date	Date

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/s/ [***]
For Intercell AG

[***] CFO
By (name and title)

April 12, 2006
Date

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21st November 2006

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14, 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine as further described in the Sublicense Agreement (the "Vaccine").

Intercell intends to appoint Novartis Vaccines and Diagnostics, Inc,. a Delaware corporation with a place of business at 4560 Horton Street, Emeryville, CA 94608, USA ("NOVAD") as its exclusive marketing partner for the Vaccine in certain territories (the "Marketing Partnership"). Intercell represents and warrants that all agreements executed between Intercell and NOVAD related to the Marketing Partnership. including any future amendments, shall be consistent with the terms and conditions of the Sublicense Agreement. In connection with the Marketing Partnership. Intercell and VaccGen wish to agree, and hereby agree. as follows:

1. For the avoidance of doubt with respect to NOVAD's activities under the Marketing Partnership, NOVAD shall be deemed to be "a Person acting on behalf of InterCell" purposes of Section 10.1 of the Sublicense for purposes of Sections 10.2 and 10.3 of the Sublicense Agreement:

2. Section 7.4(iii)(d) of the Sublicense Agreement is hereby amended as follows by adding the following sentence at the end of such Section:

> "In the event of termination of this Agreement, NOVAD shall have a right to enter into an agreement with VaccGen under which VaccGen would grant to NOVAD rights substantially similar to those granted to Intercell in this Agreement, and under terms and conditions substantially similar to those set forth in this Agreement, provided that in no event shall such rights be (A) broader or otherwise more extensive than the rights granted to NOVAD under its applicable agreement with Intercell, or (B) otherwise inconsistent with NOVAD's applicable agreement with Intercell."

3. This letter, the Sublicense Agreement (as amended), and such other agreements as are referenced in Section 12.1 of the Sublicense Agreement constitute the entire agreement between the parties relating to the subject matter hereof, Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement (as amended) shall remain in full force and effect as set forth therein. Each party represents and warrants to the other party that this letter has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

By signing this Letter below the parties agree as set forth herein.

/s/ [***]	*/s/ [***]*
For VaccGen International LLC	For Intercell AG
[***], Member / Manager	[***]
By (name and title)	By (name and title)
November 28, 2006	23/11/2006 / 23/11/2006
Date	Date

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December 21, 2006

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14. 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine as further described in the Sublicense Agreement (the "Vaccine").

Intercell intends to appoint Novartis Vaccines and Diagnostics, Inc., a Delaware corporation with a place of business at 4560 Horton Street, Emeryville, CA 94608, USA ("NOVAD"), as its exclusive marketing partner for the Vaccine in certain territories (the "Marketing Partnership"). Intercell represents and warrants that all agreements executed between Intercell and NOVAD related to the Marketing Partnership, including any future amendments, shall be consistent with the terms and conditions of the Sublicense Agreement.

By signing this letter below, the parties confirm their agreement and understanding of the following provisions of the Sublicense Agreement:

1. Section 2 of the letter agreement between Intercell and VaccGen, dated November 21. 2006 amending the Sublicense Agreement. is hereby amended and restated to read in its entirety as follows:

> "As long as NOVAD is a Marketing Partner. in the event of termination of this Agreement, NOVAD shall have a right to enter into an agreement with VaccGen under which VaccGen would grant to NOVAD rights substantially similar to those granted to Intercell in this Agreement, and under terms and conditions substantially similar to those set forth in this Agreement; provided, that such agreement shall be limited to the geographic territory covered by Intercell's agreement

2. With respect to Section 4.4(i): Intercell may conduct the regulatory activities related to the Vaccine itself or through its designees (including Marketing Partners), and any approvals, registrations and authorizations for the Vaccine may be in the name of Intercell or its designees (including Marketing Partners). '

3. With respect Section 4.6: Intercell may have the Vaccine manufactured at a third party, including NOVAD.

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4. As long as NOVAD is a Marketing Partner, Sections 6.2(v), 6.3(v). and 6.4(i) of the Sublicense Agreement shall apply to NOVAD to the same extent such Sections apply to Intercell and its Sublicensees.

/s/ [***]
For VaccGen International LLC

[***], Member / Manager
By (name and title)

December 21, 2006
Date

/s/ [***]
For Intercell AG

[***],CEO
By (name and title)

January 4, 2007
Date

/s/ [***]
For Intercell AG

[***] CFO
By (name and title)

January 4, 2007
Date

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August 29, 2007

VaccGen International LLC
8 Cambridge Court
Larchmont, New York 10538
USA
Att: Mr. [***]

Dear [***]:

Intercell AG ("Intercell") and VaccGen International LLC ("VaccGen") have entered into that certain Sublicense Agreement, effective April 14, 2003 (as amended from time to time, the "Sublicense Agreement"), relating to a prophylactic second-generation, purified, inactivated Japanese encephalitis vaccine (the "Vaccine").

Capitalized terms used but not otherwise defined in this letter shall have the respective meanings assigned to such terms in the Sublicense Agreement.

WHEREAS, VaccGen has recently amended the Cheil License Agreement to transfer all rights to the Vaccine in Korea from CJ Corporation to VaccGen.

WHEREAS, Intercell and VaccGen now wish to amend the Territory, as defined in the Sublicense Agreement, to transfer all rights to the Vaccine in Korea from VaccGen to Intercell.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements hereinafter set forth, the parties hereto, intending to be legally bound hereby, agree as follows:

1. The following provisions of the Sublicense Agreement are hereby amended as follows:

   (a) Section 1.24 is hereby amended and restated in its entirety to read as follows:

   "Territory shall mean the entire world, except for the Caribbean (Aruba, Antigua, Bahamas, Barbados, Bermuda, Cayman Islands, Curacao, Dominican Republic, Jamaica, Puerto Rico, St. Croix, St. Lucia, St. Martin, St. Thomas, and Turks and Calicos)."

   (b) Section 1.5 is hereby amended and restated in its entirety to read as follows:

   "Cheil License Agreement" shall mean that certain license agreement dated September 24, 1998, as amended, between Cheil and VaccGen pursuant to which VaccGen acquired an exclusive, worldwide license to the Vaccine from Cheil in order for VaccGen (either directly and/or via sublicense arrangements) to develop, gain regulatory approval, market, manufacture, distribute, use, sell, and otherwise commercially exploit the Vaccine."

   (c) Section 2.4 is hereby amended and restated in its entirety to read as follows:

   "Nothing in this Agreement shall be construed to constitute a grant to InterCell and/or the Sublicensees of any rights other than those expressly granted herein.

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InterCell shall sell the Vaccine in the Territory only.

Nothing in this Agreement shall be construed to constitute a grant to VaccGen, Cheil or WRAIR of any rights other than those expressly granted herein."

(d) Section 4.2(iii) is hereby amended by deleting the words "Korea and" in the parenthetical in the third line of the first sentence.

(e) Section 4.2(iv) is hereby amended by deleting the words "and in Korea" in the third line from the end of the sentence.

2. VaccGen represents and warrants to InterCell that:

(a) VaccGen possesses, pursuant to the Cheil License Agreement, as amended, all rights and interest, as the exclusive worldwide licensee of the Vaccine, in and to the Vaccine and Vaccine Patents necessary to give effect to the amendments granted pursuant to Section 1 hereof without restriction or limitation except as expressly provided in the Sublicense Agreement.

(b) As of the date hereof, VaccGen has not received any notice nor is VaccGen aware of any claim that the manufacture, use or sale of the Vaccine in Korea or the exercise of rights under the Vaccine Patents in Korea infringes upon any third party's know-how, patent, or intellectual property rights, except those patents and patent applications that were discussed between InterCell and VaccGen prior to the Effective Date (Exhibit C to the Sublicense Agreement).

3. In consideration of the amendments granted pursuant to Section 1 hereof, Intercell shall make non-creditable, non-refundable payments to VaccGen in accordance with the following schedule:

(a) Intercell shall pay VaccGen fifty thousand United States dollars (US$50,000) upon execution of this letter.

(b) Intercell shall pay VaccGen fifty thousand United States dollars (US$50,000) upon regulatory approval of the Vaccine in Korea.

The payments under this Section 2 are in addition to the Milestone Payments owed to VaccGen by Intercell under Article 3.2 of the Sublicense Agreement.

4. This letter, the Sublicense Agreement (as amended), and such other agreements as are referenced in Section 12A of the Sublicense Agreement constitute the entire agreement between the parties relating to the subject matter hereof. Except as expressly modified in this letter, all terms and conditions of the Sublicense Agreement (as amended) shall remain in full force and effect as set forth therein. Each party represents and warrants to the other party that this letter has been duly authorized, executed and delivered by it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

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By signing this letter below the parties agree as set forth herein.

/s/ [***]
For VaccGen International LLC

[***], Member / Manager
By (name and title)

August 29, 2007
Date

/s/ [***]
For Intercell AG

[***],CEO
By (name and title)

August 08, 2007
Date

/s/ [***]
For Intercell AG

[***] CSO
By (name and title)

August 08, 2007
Date

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AMENDMENT NO. 9 TO THE SUBLICENSE AGREEMENT

THIS **AMENDMENT NO. 9 TO THE SUBLICENSE AGREEMENT** ("Amendment No. 9") is made and executed as of February 22, 2010 (the "Effective Date") by and between **Intercell AG**, having its principal place of business at Campus Vienna Biocenter 6, A-1030, Vienna, Austria (hereinafter "Intercell") and **VaccGen International, LLC**, having its principal place of business at 8 Cambridge Court, Larchmont, New York 10538, U.S.A. (hereinafter "VaccGen") (collectively, the "Parties").

Capitalized terms which are used, but not defined in this Amendment No. 9, shall have the meaning set forth in the Sublicense Agreement entered into by and between Intercell and VaccGen on April 14, 2003 (as amended from time to time, the "Sublicense Agreement").

Background

WHEREAS, Intercell and VaccGen have entered into that certain Sublicense Agreement;

WHEREAS, the Parties have previously entered into a Disclosure Agreement dated as of February 22, 2010, a copy of which is attached hereto as **Annex A** (the "Disclosure Agreement"); and

WHEREAS, the Parties wish to amend the Sublicense Agreement.

Agreement

NOW, THEREFORE, for good and valid consideration and intending to be legally bound, the Parties hereby agree as follows;

1. Intercell hereby discloses to VaccGen the sequence information set forth on **Annex A** attached hereto (the "Sequence Information") and the sequence information report set forth on **Annex B** attached hereto (together with any and all information contained in such report, the "Sequence Information Report"). Intercell represents that the Sequence Information and Sequence Information Report refer to the data and information, which to our knowledge reflect the nucleotide and amino acid sequencing performed by or for Intercell on the product known as IXIARO® and on the JEV master and working virus seeds used for production of IXIARO®, and to our knowledge should be suitable for the purposes set forth in Section 2(b) of this Amendment No. 9.

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2. The Parties covenant and agree that: (a) the Sequence Information and the Sequence Information Report are confidential to Intercell, and shall be maintained under secure conditions, using reasonable security measures and in any event not less than the same security measures used by the receiving party for the protection of its confidential information of a similar kind; (b) the Sequence Information and the Sequence Information Report shall be used solely for purposes of prosecuting and maintaining the Vaccine Patents in accordance with Section 6.1 of the Sublicense Agreement, and (c) VaccGen shall be entitled to share the Sequence Information and the Sequence Information Report with third parties (including Cheil and WRAIR) on the condition that any such third party (including Cheil and WRAIR) agrees in advance, in writing, to be bound by the terms, conditions and restrictions set forth in Sections 2(a) and 2(b) above. For the avoidance of doubt, effective as of the Effective Date, Bryan Cave LLP is hereby permitted to share the Sequence Information (as defined in the Disclosure Agreement) with VaccGen.

3. The Parties agree to meet and to discuss, in good faith, the Sequence Information and the Sequence Information Report. The Parties agree that Cheil and WRAIR may be informed by VaccGen regarding any and all discussions which VaccGen may have with Intercell regarding the Sequence Information and the Sequence Information Report. Notwithstanding anything to the contrary hereinabove, should it be determined to disclose the Sequence Information and/or the Sequence Information Report, or any portion thereof, to a governmental authority for the purpose of prosecuting and maintaining the Vaccine Patents in accordance with Section 6.1 of the Sublicense Agreement, the disclosing party shall notify the other party to this Amendment No. 9 in writing [***] in advance of any such disclosure.

4. Intercell and VaccGen hereby agree to amend the Sublicense Agreement by adding the following Section 3.3(vi) to the Sublicense Agreement:

"Notwithstanding anything to the contrary contained in this Section 3.3 or elsewhere in this Sublicense Agreement:

(A) For Vaccine marketed, sold, and distributed by Intercell and/or its Affiliates or by Intercell's Marketing Partners in any of the countries specified on **Annex 3.3(A)** (the "Identified Countries"), Intercell only shall pay VaccGen a Royalty as follows: (w) a Royalty equal to [***] percent ([***]%) of applicable Net Sales (all as calculated on a country-by-country basis) from January 1, 2010 until the fourteenth (14th) anniversary of such date for Vaccine marketed, sold, and distributed by a Marketing Partner in any country in Group A of the Identified Countries; (x) a Royalty equal to [***] percent ([***]%) of applicable Net Sales (all as calculated on a country-by-country basis) from January 1, 2010 until the fourteenth (14th) anniversary of such date for Vaccine marketed, sold, and distributed by Intercell in any country in Group A of the Identified Countries; (y) a Royalty equal to [***] percent ([***]%) of applicable Net Sales (all as calculated on a country-by-country basis) for fourteen (14) years from the date of regulatory approval in a country in Group B of the Identified Countries (on a country-by-country basis) for Vaccine marketed, sold, and distributed by

a Marketing Partner in such country; and (z) a Royalty equal to [***] percent ([***]%) of applicable Net Sales (all as calculated on a country-by-country basis) for fourteen (14) years from the date of regulatory approval in a country in Group B of the Identified Countries (on a country-by country basis) for Vaccine marketed, sold, and distributed by Intercell in such country.

(B) For the elimination of doubt, solely for the purposes of Section 3.3(A), all references to "Vaccine" in Section 3.3(A) shall constructively be deemed to assume that the manufacture, use and/or sale of such Vaccine is covered by a Valid Claim.

(C) Royalties shall only be payable once with respect to any specific Net Sales of the Vaccine (and, for the avoidance of doubt, any particular Net Sales amount shall only be subject to Royalty payment obligations under one, but only one, subclause of this Section 3.3)."

5. **Annex C** sets forth a geographical summary of the Royalty rates and payment periods for amounts payable by Intercell to VaccGen pursuant to Net Sales of IXIARO® and JESPECT® (or any other future trade names) by Intercell and/or its Affiliates or by Intercell's Marketing Partners in the countries set forth in **Annex C**, in each case in accordance with and subject to the terms and conditions of the Sublicense Agreement (as amended).

6. This Amendment No. 9, including the Annexes hereto, the Sublicense Agreement (as amended) and such other agreements and documents as are referenced in the Sublicense Agreement constitute the entire agreement between the Parties relating to the subject matter hereof. Except as expressly modified in this Amendment No. 9, including the Annexes hereto, all of the terms and conditions of the Sublicense Agreement (as amended) shall remain in full force and effect as set forth therein. Each Party represents and warrants to the other Party that this Amendment No. 9, including the Annexes hereto, has been duly authorized, executed and delivered by and it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

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VACCGEN INTERNATIONAL, LLC

By: */s/ [***]*
Name: [***]
Title: Member / Manager
Date: February 25, 2010

INTERCELL AG

By: */s/ [***]*
Name: [***]
Title: Chief Financial Officer
Date: February 22, 2010

By: /s/ [***]
Name: [***]
Title: Chief Executive Officer

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Annex A
Disclosure Agreement

DISCLOSURE AGREEMENT

THIS **DISCLOSURE AGREEMENT** (the "Disclosure Agreement") is made and executed as of February 22, 2010 (the "Effective Date") by and between **Intercell AG**, having its principal place of business at Campus Vienna Biocenter 6, A-1030, Vienna, Austria (hereinafter "Intercell") and **VaccGen International, LLC**, having its principal place of business at 8 Cambridge Court, Larchmont, New York 10538, U.S.A. (hereinafter "VaccGen") (collectively, the "Parties").

Capitalized terms which are used, but not defined in this Disclosure Agreement, shall have the meaning set forth in the Sublicense Agreement entered into by and between Intercell and VaccGen on April 14, 2003 (as amended from time to time, the "Sublicense Agreement").

Background

WHEREAS, Intercell and VaccGen have entered into that certain Sublicense Agreement;

WHEREAS, the Parties wish to consider after the Effective Date, entering into an amendment to the Sublicense Agreement in a form mutually agreed to by the Parties (such amendment as executed, the "Amendment No. 9"), and

WHEREAS, the Parties have agreed to the terms and conditions of this Disclosure Agreement in advance of entering into any amendment to the Sublicense Agreement.

Agreement

NOW, THEREFORE, for good and valid consideration and intending to be legally bound, the Parties hereby agree as follows:

1. Intercell hereby discloses solely to VaccGen's outside legal counsel, Bryan Cave LLP, the vaccine sequence information set forth on **Exhibit A** attached hereto (the "Sequence Information") on a "HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL ONLY" basis. VaccGen covenants and agrees with Intercell that: (a) the Sequence Information is confidential to Intercell and shall be maintained under secure conditions, using reasonable security measures and in any event not less than the same security measures used by VaccGen for the protection of its confidential information of a similar kind, (b)VaccGen shall direct Bryan Cave LLP not to disclose any of the Sequence Information to VaccGen or any individual or entity affiliated with VaccGen, Cheil or WRAIR (including, but not limited to, experts, consultants, in-house or outside counsel of any of the foregoing) prior to the effective date of Amendment No. 9, and as from the effective date of Amendment No. 9, to disclose Sequence Information only as expressly permitted by Amendment No. 9, and (c) prior to the effective date of Amendment No. 9, no individuals affiliated with Bryan Cave LLP, VaccGen, Cheil or WRAIR (including, but not limited to, experts,

consultants, in-house or outside counsel of any of the foregoing) who have had access to the Sequence Information will prosecute, supervise, or assist in the prosecution or amendment of any of the Vaccine Patents, and as from the effective date of Amendment No. 9, will be permitted to prosecute, supervise, or assist in the prosecution or amendment of any of the Vaccine Patents only as expressly permitted by Amendment No. 9. For purposes of this Section I, prohibited prosecution shall include, without limitation: invention identification, invention evaluation, the decision whether to file a patent application for an invention, preparation of and/or amendments to original, continuation, divisional, continuation-in-part, request for continued examination, reexamination, reissue, substitute, renewal or convention patent applications, claim drafting, drafting of any document to be filed with the United States Patents and Trademark Office or any foreign patent office, or consultation on any of the above matters with others performing these activities.

2. Notwithstanding anything to the contrary hereinabove, should Bryan Cave LLP (including, but not limited to, experts, consultants or counsel thereto) be obligated by law or legal process to disclose the Sequence Information, or any portion thereof, to a governmental authority, VaccGen shall notify Intercell in writing [***] days in advance of any such disclosure. For the avoidance of doubt, VaccGen and Intercell agree that any portion of the Sequence Information so disclosed shall nonetheless continue to be treated as confidential information.

3. This Disclosure Agreement, including the Exhibit hereto, constitutes the entire agreement between the Parties relating to the subject matter hereof. For the avoidance of doubt, all of the terms and conditions of the Sublicense Agreement shall remain in full force and effect as set forth therein. Each Party represents and warrants to the other Party that this Disclosure Agreement, including the Exhibit hereto, has been duly authorized, executed and delivered by and it and constitutes a valid and legally binding agreement with respect to the subject matter contained herein.

VACCGEN INTERNATIONAL, LLC

By: */s/ [***]*
Name: [***]
Title: Member / Manager
Date: February 25, 2010

INTERCELL AG

By: */s/ [***]*
Name: [***]
Title: Chief Financial Officer
Date: February 22, 2010

By: */s/ [***]*
Name: [***]
Title: Chief Executive Officer

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Exhibit A to the Disclosure Agreement

Sequence Information

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Annex B

Sequence Information Report

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Annex 3.3(A)

Identified Countries

Group A

[***]

Group B

[***]

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Annex C

Royalty Rates payable by Intercell to VaccGen

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ANNEX C to Amendment 9

Geographical Summary of Royalty Rates and Payment Periods[1]
Based on the Status on the Effective Date of Amendment 9

[***]

1 [***]

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Exhibit 10.7

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SUPPLY AGREEMENT

- Vaccine against Japanese encephalitis virus

by and among

INTERCELL AG

and

VETTER PHARMA-FERTIGUNG GMBH & CO. KG

And

INTERCELL BIOMEDICAL LTD.

dated as of March 1, 2008

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ANNEXES

ANNEX 1: PRICES

ANNEX 2: AGREED VALUE OF FINAL BULK VACCINE AND INTERCELL MATERIALS

ANNEX 3: FORECAST, UPDATE, AND PURCHASE ORDER

ANNEX 4: QUALITY AGREEMENT

ANNEX 5: CONFIDENTIALITY AGREEMENT

ANNEX 6: CYCLE TIMES

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THIS COMMERCIAL SUPPLY AGREEMENT, made and entered into as of this 1st day of March, 2008 (hereinafter referred to as the "Agreement"), by and among Intercell Biomedical Ltd., a company registered in Scotland under the Companies Act of 1985 with registered number SC 260350, having its registered office at 30-31 Queen Street, Edinburgh, Scotland ("Intercell"), Intercell AG, a company duly organized and existing under the laws of Austria, having its principal place of business located at Campus Vienna Biocenter 2, 1030 Vienna, Austria, FB-NR. 166438 M/HG Wien, in its capacity as parent company guarantor ("Intercell AG"), and Vetter Pharma-Fertigung GmbH & Co. KG, a company duly organized and existing under the laws of Germany, having its principal place of business at Schützenstraße 87, 88212 Ravensburg, Germany ("Vetter") Intercell and Vetter hereinafter individually also referred to as "Party" and collectively as the "Parties",

W I T N E S S E T H:

WHEREAS, Intercell AG and Vetter have entered into a Confidentiality Agreement and a Development Agreement, both as defined below; and

WHEREAS, Intercell manufactures certain liquid vaccine solution containing purified, inactivated Japanese encephalitis virus strain SA 14-14-2 adjuvanted with aluminum hydroxide which vaccine is intended for the prophylactic treatment in humans of Japanese encephalitis; and

WHEREAS, Intercells desires Vetter to perform (as set forth herein and in the Quality Agreement attached hereto) certain production of a 1.25 ml SCF syringe pre-filled with said vaccine;

WHEREAS, Intercell wishes Vetter to produce such syringe as so produced for commercial sale within the Territory as below defined; and

WHEREAS, Vetter owns and possesses the requisite expertise, personnel, know-how, and facilities to perform such production in accordance with this Agreement and specifically the Quality Agreement attached hereto;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this Agreement, the Parties hereto agree as follows:

1. ARTICLE 1: DEFINITIONS

For all purposes of this Agreement and specifically the attached Quality Agreement including its Appendices, and all amendments hereto and thereto, the following capitalized terms so hereafter and therein used shall have the same and uniform meanings as herein underneath defined and specified, unless the context otherwise requires:

1.1 "Accumulated Surplus" shall have such meaning as set forth in Section 4.4 hereof.

1.2 “Affiliate” shall mean, with respect to Intercell, any person, firm, company, or organization which is controlled by Intercell AG only, and with respect to Vetter, any person, firm, company, or organization, which is under common control of the executors of the estate of Helmut Vetter, and furthermore, for the purposes contained herein, “control” shall mean direct or indirect ownership of more than fifty percent (50%) of the voting stock or ownership interests.

1.3 “Agreed Specifications” or “Specifications” shall have such meaning as set forth in the Quality Agreement, Appendix 5 thereof.

1.4 “Agreement” shall mean this agreement and its Annexes.

1.5 “Annex” shall mean an annex attached hereto.

1.6 “Appendix” shall mean an appendix attached to the Quality Agreement.

1.7 “Bulk Vaccine” or “Final Bulk Vaccine” shall mean the bulk form of a certain liquid vaccine solution for the prophylactic treatment of Japanese encephalitis (also known as IC 51) manufactured by Intercell.

1.8 “Business Day” shall have such meaning as set forth in Section 23(1) hereof.

1.9 “cGMP” shall have such meaning as in the Quality Agreement set forth.

1.10 “Confidential Information” shall mean COMPANY Confidential Information in respect of Intercell and VETTER Confidential Information in respect of Vetter, all as defined and set forth in the Confidentiality Agreement.

1.11 “Confidentiality Agreement” shall mean the confidentiality agreement between Intercell AG and Vetter, dated as of September 30, 2002, attached hereto as Annex 5.

1.12 “Costs” shall have the meaning as in Section 13(1) hereof set forth.

1.13 “Cycle Time” shall mean the processing time of a manufacturing process or sub-process.

1.14 “Development Agreement” shall mean the development agreement between the Parties dated as of December 23, 2005.

1.15 “Effective Date” shall mean the day and year set forth in the first paragraph of this Agreement.

1.16 “EMEA” shall mean the European Medicines Agency.

1.17 “Equipment” shall mean the equipment used by Vetter to Produce the Product.

1.18 “Facility” or “Facilities” shall mean the production and testing facilities of Vetter located in Schützenstraße 87 or Holbeinstraße 40, both 88212 Ravensburg, Mooswiesen 2, 88214 Ravensburg and Eisenbahnstraße 2-4, 88085 Langenargen, all Germany.

1.19 “FDA” shall mean the United States Food and Drug Administration.

1.20 “Information” shall, by virtue of this Agreement in amendment of Article 9 of the Confidentiality Agreement for the exclusive purposes contemplated hereunder, mean any information of each Party, especially such relating to business, affairs, operations, scientific and medical research, finances, plans, data, trade secrets, as well as intellectual property (including, but not limited to, all discoveries, inventions, copyrights, trademarks, industrial design, know-how, improvements, formulas, ideas, devices, products, writings, or other intellectual property relating to the Products, notes, records, reports, sketches, plans, memoranda and other tangible or intangible information), which is disclosed to the other Party during the Term in tangible form (including, among other, writings, drawings, photographs, magnetic tapes or models) and in other forms, such as orally, observed or heard also during the presence at premises, including the Facilities.

1.21 “Instructions of Intercell” or “Intercell’s Instructions” shall have such meaning as set forth in the Quality Agreement, Appendix 4 thereof.

1.22 “Intercell” shall have the meaning set forth in the first paragraph of this Agreement.

1.23 “Intercell Materials” shall mean the Bulk Vaccine and the other materials and components supplied or approved by Intercell, all as listed and set forth in Appendix 2 of the Quality Agreement.

1.24 “Product” shall have the meaning set forth in Appendix 1 of the Quality Agreement.

1.25 “Production” or “Produce” shall mean the production of the Product from Vetter Materials and Intercell Materials, all in accordance with the Agreed Specifications.

1.26 “Purchase Order” shall mean a purchase order signed on behalf of Intercell which shall be binding and irrevocable and shall be used only for the purpose of confirming quantities, and prospective delivery dates, of the Final Product and/or Semi-Finished Product; provided, however, no pre-printed or other term on any such purchase order shall have any force or effect, all of which pre-printed or other terms shall be null and void unless otherwise specifically agreed to in writing by and between the Parties hereto and, furthermore, the provisions contained in this Agreement shall be deemed incorporated into any such purchase order.

1.27 “Quality Agreement” shall mean that certain quality agreement effective as of the Effective Date, as may be amended from time to time as provided therein, attached hereto as Annex 4.

1.28 “Regulatory Authority” or “Regulatory Authorities” shall respectively mean the FDA, and/or the EMEA, and German national health authorities, individually or collectively, and the supplemental regulatory authorities, if any, with respect to which Vetter has given its express written consented and as to which the Parties have agreed in writing upon, among other things, the allocation of any additional costs in connection therewith.

1.29 “Semi-Finished Product” shall mean a syringe filled with Final Bulk Vaccine and inspected but not labelled and packaged for a specific country.

1.30 “SOPs” shall have such meaning as set forth in the Quality Agreement.

1.31 “Term” shall have the meaning set forth in Article 13 hereof.

1.32 “Territory” all nations of the world except Japan, it being understood that Japan may be included therein if the Parties have agreed upon particular provisions applicable to such Products (including any technical, commercial, legal, quality assurance, and price aspects thereof) considered for the Japanese market.

1.33 “Vetter” shall have the meaning set forth in the first paragraph of this Agreement.

1.34 “Vetter Inventions” shall have the meaning set forth in Section 10(3) hereof.

1.35 “Vetter Materials” shall mean such materials and components supplied by Vetter, all as listed and set forth in Appendix 3 of the Quality Agreement.

2. ARTICLE 2: PRODUCTION

2.1 Vetter agrees to Produce the Products from Intercell Materials and Vetter Materials, all in accordance with the Agreed Specifications. Vetter shall sell and deliver the Products, for the prices herein set forth, or determined in accordance with the provisions hereof, to Intercell.

2.2 Intercell shall keep Vetter informed of the legislation and the relevant rules and the regulations, especially including any affecting the specific Product related SOPs of the Regulatory Authorities which may affect the Product and its Production and shall specifically inform Vetter of the effect of any thereof, along with all of the relevant rules and regulations promulgated by any Regulatory Authorities other than FDA and EMEA which have been agreed upon in writing by the Parties as set forth herein (except, with respect to such obligation of Intercell to specifically inform Vetter thereof, to the extent that the Parties may otherwise expressly thereupon agree). Subject to the terms of Section 12.4, to the extent Intercell fails to so inform Vetter, Vetter shall have no liability with respect to the Products for the consequences of any such failure.

2.3 (a) Changes to the Agreed Specifications are subject to the change control procedures set forth in the Quality Agreement. Intercell may request that any changes be made to the Agreed Specifications and incorporated in the Product, subject to Vetter and Intercell prior agreeing in writing to any necessary amendments to this Agreement, including, without limitation, price adjustment or other allocation of costs and expenses reasonably required for implementation of such changes. In accordance with the change control procedures, Vetter shall keep Intercell informed of significant contemplated changes, including improvements, in the materials to be supplied by Vetter and to be incorporated in the Product.

(b) If either Party believes any change is required by applicable law, regulation and/or practices of regulatory authorities (including Regulatory Authorities) (together, a "Legal Requirement"), such Party shall immediately send the other Party a written request for such change (the "Change Request"). Within [***] following such other Party's receipt of the Change Request, the Parties' relevant subject matter experts shall meet in person or by phone to seek a solution. If such subject matter experts have not agreed a solution within [***] of such meeting, the matter shall be referred to executives of Intercell (COO) and Vetter (General Manager) for resolution. If such executives have not agreed a solution within [***] of the matter having been referred to them, than an independent expert (the "Independent Expert") shall be agreed upon and engaged to advise the Parties on such matter. The Parties shall share the cost of the Independent Expert equally. The recommendations of the Independent Expert for resolution of the matter shall be binding upon both Parties. Intercell acknowledges and agrees that Vetter shall cease further Production for Intercell hereunder pending and subject to the resolution of any disputes arising in connection with, and in accordance with the terms of, this Section 2.3(b).

2.4 Without prejudice to any of Intercell's other rights under this Agreement, Vetter shall inform Intercell promptly in the event Vetter has knowledge that any authorization or permit with respect to the Facilities relevant to the Production is not obtained timely or is withdrawn or otherwise under investigation.

2.5 Other than the subcontracting of warehousing and internal logistic operations to a third party (currently a company named [***]) and re-qualification of certain materials and substances provided to Vetter by suppliers thereof, by an external laboratory or other party, the Production and any other services under this Agreement shall be performed only by qualified employees of Vetter (in accordance with Vetter's SOPs and including any temporary employees engaged by Vetter, who shall not be deemed to be subcontractors) and Vetter shall not subcontract or otherwise delegate any Production or other activities under this Agreement without the advance written approval of Intercell, which shall not be unreasonably withheld, it being acknowledged and understood by Intercell that as Production is performed, third party services and expertise may be necessary, advisable and expedient. In the event that Vetter proposes use of subcontractors for particular services, it shall undertake commercially reasonable efforts to cause same to permit Intercell reasonable access to such subcontractors as well as their respective facilities and records for audit purposes; provided that Vetter shall have no liability hereunder in the event of failure of such subcontractors to provide such access or if such access is not provided in a manner satisfactory to Intercell; and provided further that failure of a

proposed subcontractor to agree that Intercell shall be permitted reasonable access to their facilities for audit purposes shall be deemed to be reasonable grounds for Intercell to withhold its approval of such subcontractor. A Vetter representative may accompany Intercell on such audits. If Intercell approves use of any subcontractors, any such subcontractors shall be bound to written terms regarding confidentiality which are no less strict as those set forth herein or to Vetter's standard confidentiality agreement. None of either Party's rights and/or obligations under this Agreement shall be affected by Vetter's engagement of subcontractors pursuant to this Section 2.5, except to the extent, if at all, the Parties have expressly agreed in writing to the contrary. In connection with any subcontractor approved by Intercell pursuant to this Section 2.5, Vetter shall pass along to Intercell the benefit of any warranties to Vetter made by such subcontractor except to the extent, if at all, that any subject liability in connection with such respective warranty is assumed in a separate writing by Vetter. Notwithstanding anything to the contrary herein, Vetter will not be responsible or liable for the provision or performance of third party services or subcontractors.

3. ARTICLE 3: MATERIALS

3.1 (a) Intercell shall in accordance with the Quality Agreement timely supply and deliver to Vetter, [***], such quantities of Final Bulk Vaccine and Intercell Materials as Vetter shall require to properly undertake necessary preparations for Production and to timely fulfill Intercell's Purchase Orders. The Parties shall agree the specific delivery dates of Final Bulk Vaccine and Intercell Materials on a [***] basis. Any delay period of Production arising from insufficient delivery of Final Bulk Vaccine or Intercell Materials (whether timely or in quantity) shall postpone any delivery date requested by Intercell in any Purchase Order and confirmed by Vetter, including any time period Vetter may reasonably determine, in good faith consultation with Intercell, based on Vetter's general production schedule as consequence of said Final Bulk Vaccine or Intercell Material delivery delay.

(b) Vetter shall in accordance with the Quality Agreement timely supply such quantities of Vetter Materials as Vetter shall require to properly undertake Production and to timely fulfill Intercell's Purchase Orders.

(c) Vetter acknowledges that Intercell is committed to providing a steady supply of Product to the market, and that to meet this commitment it is necessary to build up and maintain a certain level of stock of the Product. The Parties shall use mutual reasonable commercial efforts to coordinate between themselves to reasonably meet (and reasonably/adjust, if necessary, Intercell's order pursuant to) this commitment, including, without limitation, putting into place reasonably necessary joint plans to meet the initial Purchase Orders.

3.2 (a) Final Bulk Vaccine and Intercell Materials shall be used by Vetter only for the Production. Intercell shall be notified by Vetter of any surplus thereof and any such surplus shall be disposed of, returned to Intercell or otherwise handled, all as reasonably directed by Intercell, and at Intercell's cost and expense. Upon request of Intercell, Vetter shall provide Intercell with copies of a computerized inventory list with respect to Intercell Materials stored at the Facility, all as prior specifically agreed between the Parties in writing.

(b) Intercell may choose, upon prior written notice, to perform a physical inventory inspection. In the first year Intercell has the right to inspect the inventory up to [***] times. In case no major concerns are identified such an inventory inspection will take place [***] a calendar year upon such dates as may be mutually agreed upon. [***]. Based on said inventory list provided by Vetter, Intercell shall indicate such pallets of Product, Intercell Materials and Final Bulk Vaccine including cooled or frozen bulk vaccine, which shall be physically checked, on a random basis and during normal business hours. Any such inventory inspection shall not exceed a total number of [***], it being agreed that any inspection in excess of [***] and/or [***] inspection shall be reasonably accepted by Vetter in writing upon prior mutual agreement between the Parties clarifying the conditions and costs thereof Any such inventory inspection shall be limited to Product and Intercell Materials. The Parties shall also mutually agree on inspection schedules and members of the inspection team, which members of Intercell's inspection team shall explicitly be bound by and be subject to the Confidentiality Agreement entered into by and between the Parties hereto. The inspection team shall at all times be accompanied by members of Vetter's personnel, and not be divided into sub-teams. Any inventory inspection shall be conducted in accordance with cGMP. For the avoidance of doubt, this paragraph refers only to inventory inspections, not to quality inspections which are provided for in the Quality Agreement.

3.3 (a) All Vetter Materials and Intercell Materials used in the Production of Product shall be tested in accordance with SOPs and other Vetter procedures, unless otherwise agreed upon in writing, including (i) the conducting of incoming inspection upon delivery of any thereof to verify correct quantity and labelling; (ii) visual inspection to identify obvious defects or violations due to transport; (iii) for identity in accordance with, and as such term is defined by, United States Pharmacopoeia and European Pharmacopoeia; (iv) the maintenance and operation of Equipment and other equipment in accordance with SOPs; and (v) otherwise as set forth in the Quality Agreement.

(b) EXCEPT AS HEREIN AND IN THE QUALITY AGREEMENT SET FORTH TO TEST AND EXAMINE, VETTER SHALL HAVE NO OBLIGATION AND MAKES NO WARRANTIES, REPRESENTATIONS, COVENANTS OR AGREEMENT (EXPRESS OR IMPLIED) WITH RESPECT TO THE VETTER MATERIALS AS SUCH TERM IS DEFINED HEREIN, OR OTHERWISE, OTHER THAN TO THE EXTENT (IF AT ALL) EXPRESSLY SET FORTH HEREIN AND THEREIN. VETTER DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES WITH RESPECT TO ANY INTERCELL MATERIALS, OR MATERIALS PROVIDED BY THIRD

PARTIES. ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT SET FORTH IN THIS AGREEMENT IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES, WRITTEN OR ORAL, DIRECT, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, EXPRESS OR IMPLIED WARRANTIES FOR MERCHANTABILITY, QUALITY OR FITNESS FOR A PARTICULAR PURPOSE.

3.4 Intercell shall utilize commercially reasonable efforts, [***], at all times during the Term and any subsequent term hereof, including without limitation following completion of Production until pickup from Vetter pursuant to Section 6(6) herein below, to provide for and cover the costs of adequate theft, casualty and extended loss insurance in an amount and on terms satisfactory to Intercell for Final Bulk Vaccine and Intercell Materials (whether or not included as part of the Product or otherwise and which shall remain the property of Intercell), as well as for all shipment and storage. In amplification of the foregoing, and not in limitation thereof, and notwithstanding anything to the contrary contained in this Agreement, Vetter shall have no obligation or liability to Intercell (or any party acting in the name of or on behalf of Intercell) in respect of the foregoing items in the occurrence of any theft, casualty or extended loss except to the extent that Vetter shall have been deemed negligent and such occurrence shall not have been covered by such insurance in which event Vetter's only liability shall be, per calendar year, to reimburse Intercell in [***].

4. ARTICLE 4: YIELD

4.1 The Parties shall evaluate and mutually determine after the Production of [***] commercial batches of Product of not less than [***] and not more than [***] of Final Bulk Vaccine which during the normal course of Production would be required and acceptable to the Parties to achieve a certain specified result defined in percent, hereby taking into account, among other things, fixed ([***]) and flexible Production losses, and thereby describing a targeted yield in respect of, and in comparison to, the quantities of such supplied Final Bulk Vaccine ("Target Yield"). The mutual determination of Target Yield pursuant to this Section 4.1 shall factor out an agreed upon constant (i.e., irrespective of batch size) for intentional and/or otherwise fixed losses ("Fixed Losses"); provided, however, that in the event the amount of Fixed Losses positively or negatively varies ([***]), the Parties shall from time to time accordingly adjust up or down the applicable allowance in respect of such variance.

4.2 Until the Target Yield has been established and is applicable as set forth herein below, all losses of Final Bulk Vaccine, and any costs and expenses incurred in respect thereof, shall be borne by Intercell and, in amplification thereof, such evaluation of the Target Yield as described hereinabove shall not be applicable to any batches consisting of less than [***] or more than [***] of Final Bulk Vaccine, and shall furthermore not apply if Production has been halted or interrupted for extended time period(s) unless the halt occurred due to Vetter's fault and/or if, in any calendar year, less than [***] commercial batches of Products shall be or have been Produced by Vetter subject to Purchase Orders.

4.3 The first Target Yield so established as set forth herein shall apply for the remainder of the calendar year of its determination only. Thereafter, the Target Yield and Fixed Losses shall be reviewed annually and agreed on by the Parties for each calendar year during the Term and any subsequent term of this Agreement through good faith negotiations, taking into account the previous calendar year's performance, process enhancements and Production improvements, any current or updated requirements of any Regulatory Authority and cGMP requirements, as well as all other relevant circumstances, it being understood and agreed by the Parties that the previous calendar year's performance shall not be determinative and shall not set any precedence for such review, good faith negotiations, and agreement in respect hereof, and furthermore, the Parties shall, at the end of each calendar year, mutually determine and agree on the cumulative actual losses of Final Bulk Vaccine throughout the elapsed calendar year, excluding the aggregate amount of all Fixed Losses, and thereby determine the actual yield in respect of the use of Final Bulk Vaccine so required by Vetter for Production in said year[. ("Actual Yield").

4.4 To the extent that the Actual Yield is equal to, or greater than, the Target Yield, all losses of Final Bulk Vaccine, and all costs and expenses incurred in respect thereof, shall remain to be solely borne by Intercell; and, furthermore, the positive difference between Actual Yield and Target Yield shall accrue, offset by losses, if any, resulting from the Target Yield exceeding the Actual Yield (the "Accumulated Surplus"). However to the contrary of the immediately preceding sentence, Vetter shall reimburse Intercell at the mutually agreed contractual value of Final Bulk Vaccine as set forth in Annex 2 attached hereto and multiplied by [***], for any such costs and expenses involved in respect thereof (after being offset by the Accumulated Surplus) in the event any Actual Yield should be mutually determined, in accordance with said agreement referred to hereinabove, to be less than the Target Yield (and accounting for such offset).

5. ARTICLE 5: INSPECTION AND TESTING OF PRODUCT

5.1 Intercell shall inspect or have inspected all Products upon receipt promptly and without delay. Every inspection and testing data evaluation procedure used by Intercell shall substantially correspond with the procedures used by Vetter before delivery of Product to Intercell, and a copy of the results of such inspection performed by or on behalf of Intercell shall be submitted to Vetter. If such Products do not pass such inspection, then within [***] after their receipt, Intercell shall promptly notify Vetter in writing, and, in accordance with the instructions of Vetter, Intercell shall either return the rejected batch to Vetter, said return at Vetter's cost and expense only in such event of justified rejection as provided hereunder, or shall otherwise dispose of the Products.

5.2 Any Product, which is not rejected as in Section 5(1) provided, shall be deemed accepted by and approved of by Intercell to the extent that it contains any non-latent defect. Any Product which contains any latent defect shall be deemed accepted and approved unless of its rejection thereof Intercell shall in writing notify Vetter within [***] after delivery. Intercell agrees to notify Vetter in writing promptly after the discovery of any latent Product defect. In amplification of the foregoing, and not in limitation thereof, it is agreed and understood that in the event of a single defect (i.e., a defect clearly affecting only particular units of Product, to the extent such defect is readily capable of cure by Vetter's replacement of such units) Intercell shall have no right to reject, at Vetter's cost, the Product or the batch in which such single defect is detected.

5.3 Vetter shall have no obligation to correct or dispose of any defective Product, or supply a replacement Product, at its own cost, unless the defect, whether detected prior to delivery of Product to Intercell or thereafter, is based solely on Vetter's negligent failure to provide the Product in accordance with the Agreed Specifications; provided, however, that Vetter shall be deemed not negligent if Vetter can show by way of the batch documentation required under this Agreement (including samples of Product if so available) that the Product has been Produced in accordance with the Agreed Specifications.

5.4 Subject to Section 5(3), Vetter shall correct any defective Product that has been rejected in accordance with Section 5(1) or, if this is not possible, Vetter shall, upon Intercell's reasonable request use reasonable efforts to supply replacement Product [***]. If Vetter determines that it will not be possible to supply replacement Product [***], then Vetter shall notify Intercell of that immediately, and within [***] of receipt by Intercell of such notification, the Parties shall meet in person or by phone to agree to the earliest practicable timing of the supply by Vetter of the replacement Product, taking into account (i) Intercell's obligations to supply the Product to the markets, where in certain cases Intercell may be the only supplier to the market and (ii) [***]; provided, however, it is agreed that for the purposes hereof, Intercell shall supply Vetter with the necessary Final Bulk Vaccine and Intercell Materials and, furthermore, it is understood that in addition to such correction or replacement, Vetter's only liability shall be to reimburse Intercell for the value of Final Bulk Vaccine, and Intercell Materials, both as mutually agreed and set forth in Annex 2 attached hereto, respectively multiplied by [***], which reimbursement shall, per calendar year, in no event exceed the [***].

6. ARTICLE 6: FORECAST, UPDATE, AND PURCHASE ORDERS

6.1 Forecast, Update and Purchase Order, Cycle Time (as in Annex 3)

(a) Forecasts.

(i) By May 1st, 2008, Intercell shall provide Vetter a forecast, as described in more detail in subclause (iii) below, of Intercell's projected quantity requirements for the Semi-Finished Product during the [***] following the anticipated first commercial sale and the quantity requirements for the launch prior to obtaining the relevant regulatory approval. Thereafter, Intercell shall provide an updated forecast on a rolling basis by the [***] Business Day of each calendar month, covering continuously Intercell's projected quantity requirements for the Product for the following [***] period (each, a "Rolling Forecast").

(ii) Each Rolling Forecast shall list the projected quantity requirements as set out in Annex 3 for Product on a monthly basis for the [***] country-by-country (i.e., packaging).

(iii) The first [***] of each Rolling Forecast shall constitute a binding and irrevocable commitment and Intercell will order such quantities and Vetter will Produce and supply such quantities Intercell shall issue corresponding Firm Orders on a monthly basis by the first business day of the applicable calendar month so that the first [***] of a given Rolling Forecast are subject to Firm Orders.

(iv) The subsequent [***] of each Rolling Forecast (*i.e.*, [***]) shall constitute a binding commitment to order no less than [***] of the quantity of Product projected for such time period. The maximum expected quantity for such [***] period shall be [***] of the projected Product quantity.

The subsequent [***] of each Rolling Forecast (*i.e.*, [***]) shall constitute a binding commitment to order no less than [***] of the quantity of Product projected for such time period. The maximum expected quantity for such [***] period shall be [***] of the projected Product quantity.

(v) It is agreed and understood that based on such Forecast (and, to the extent commercially practicable, on any Updates) Vetter may place, in accordance with its customary business practices, binding orders for Vetter Materials, including supplies and other components for the Products which in accordance hereto shall not be supplied by Intercell.

Each Rolling Forecast shall reflect at least the firm commitment described in the foregoing. No Rolling Forecast shall, with respect to the same time period, reflect more than the maximum expected quantities as determined pursuant to the previous Rolling Forecast.

(b) Purchase Orders. Intercell shall place written Purchase Orders consistent with the terms and conditions hereof setting forth Intercell's order number, quantity of Product ordered, requested delivery date, the country in which such Products will be sold and any country-specific packaging and labelling requirements under applicable Laws and Regulations or otherwise requested by Intercell and any other relevant information ("Purchase Order"). No Purchase Order shall contain any terms or conditions that conflict with or are in addition to the terms and conditions of this Agreement and in any such event the terms of this Agreement will control. All Purchase Orders that are consistent with the terms and conditions of this Agreement and do not exceed the maximum expected quantity shall be deemed accepted by Vetter upon receipt.

(c) If any Purchase Order on its face appears duly signed on behalf of Intercell, Vetter may fully rely thereon without independent investigation and such Purchase Order shall be valid for all purposes hereof.

Vetter shall establish and maintain a safety stock level for primary packaging material equivalent to the then-current order volume for the subsequent [***], and with respect to secondary packaging materials in accordance with Vetter's customary practices for such materials. The Parties may discuss together from time to time the relevant factors affecting Intercell's anticipated requirements, such as market circumstances; provided, Vetter agrees to adjust such levels upward as commercially reasonable and practicable to meet increased anticipated potential requirements on the condition that Intercell reimburses Vetter for all primary and secondary packaging materials that are not used in Product but not (without written agreement by the Parties to the contrary) longer than [***] (or as needed to fulfil any outstanding firm orders).

(d) Cycle Time: see Annex 6

If and when commercially reasonable and practicable, based on capacity, availability, and other supply commitments, Vetter shall endeavor to accommodate shorter Cycle Times.

(e) Shipment. Vetter will fulfill all accepted Purchase Orders on or before the requested delivery date, unless an earlier delivery date has been expressly accepted by Vetter in writing. Intercell may notify Vetter in writing of any requested change of the country in which ordered Products will be sold, together with notification of any country-specific packaging and labelling requirements under applicable Laws and Regulations or otherwise requested by Intercell, provided that if any such request is made less than [***] prior to the agreed delivery date, the delivery date shall be modified to be up to [***] after Vetter's receipt of such notification.

Upon each Intercell's written notification by Vetter of Product release, Intercell shall meet its responsibility for arranging delivery Ex Works Facility (EXW Incoterms 2000) of Product from Vetter to Intercell or to such other locations as may be designated by Intercell. Vetter shall cooperate with Intercell in addressing customs or special shipping requirements in Germany and in obtaining any permits required to deliver Product to the designated locations. The costs of any delivery, customs, and any applicable transport insurance, shall be borne by Intercell.

7. ARTICLE 7 : PRICE; PAYMENT

7.1 The prices to be paid for the Product are as set forth in Annex 1 hereof, which may be changed from time to time pursuant to prior written agreement of the Parties.

7.2 All payments shall be [***] and shall be made in Euro (EUR) [***]. In the event Intercell pays (receipt of readily available funds by Vetter) later than [***] of receipt of the invoice (except when payment is subject to a good-faith resolution of any dispute), Vetter shall be entitled to interest payments in the amount of [***] of the invoiced amount per month and Intercell shall add such interest accumulated in accordance with this Article as of the time of payment, to the invoiced amount with Intercell's payment.

8. ARTICLE 8 : CERTAIN REPRESENTATIONS AND AGREEMENTS

8.1 Intercell represents and warrants that it has inspected the Facility or Facilities which shall be used for the Production and confirms its or their, as the case may be, suitability for the Production of the Product.

8.2 Intercell represents and warrants that Intercell's Instructions are and shall be its property and that Intercell has the right to provide Vetter with Intercell's Instructions and for the purposes herein contemplated.

8.3 Intercell represents and warrants that Intercell's Instructions are and shall be sufficient to function as a basis for Vetter to develop, in cooperation with Intercell, the Agreed Specifications necessary to engage in the packaging of the Semi-Finished Product as herein contemplated.

8.4 Intercell represents and warrants that Intercell or any third party will not undertake to register the Product, file a drug application or otherwise will entertain efforts to obtain further governmental licenses or similar approvals with regard to the Product outside the Territory without Vetter's prior written consent.

8.5 Vetter represents and warrants that it holds all necessary authorizations and permits with respect to the Facilities relevant to the Production from the authorities of the country where such Production takes place; provided that, for the avoidance of doubt, the Parties agree that this Section 8.5 does not refer to any Product-specific authorization or permit.

8.6 Each Party represents that it has sufficient authority to enter into this Agreement and that, by entering into this Agreement and fulfilling its obligations under this Agreement, it will not violate any other agreement to which it is a party, or, subject to the limitation on Vetter's obligations set forth in Section 2.2 hereof (and Intercell's obligation to inform Vetter pursuant to Section 2.2), any requirement of Regulatory Authorities. To the extent of each Party's respective knowledge and information, each Party represents and warrants that it (a) has sufficient right, title and interest in the United States and the EU (as constituted prior to May 1, 2004) to its intellectual property as utilized in the Production of (and as incorporated within) the Product to perform its respective obligations pursuant to this Agreement and (b) has not received any written notice that its use of such Production intellectual property in the Production of the Product infringes any valid and enforceable rights of any third party which have not been resolved so as to permit it to perform its obligations hereunder.

9. ARTICLE 9 : GOVERNMENT APPROVAL

9.1 Intercell shall be responsible for obtaining and maintaining, at Intercell's cost, all appropriate governmental approvals, consents and clearances for the matters herein contemplated, including the sale and distribution of the Product in the Territory, and Intercell shall not sell the Products or allow the Products to be sold without first securing such approvals, consents and clearances. For the sake of clarification, these costs shall include, but not be limited to, such reasonable costs associated with governmental audits of Vetter pertaining to the Product. Vetter shall cooperate and make every reasonable effort, at Intercell's reasonable expense, in providing such information and other assistance as Intercell may reasonably request to expedite all such governmental approvals, including, without limitation cooperating with all relevant Regulatory Authorities during any inspection of the Facility.

9.2 Intercell understands and acknowledges that the Regulatory Authorities may still have to approve the Production of the Product at the Facility and that Vetter does not represent or warrant to Intercell such approval.

10. ARTICLE 10 : TRADEMARK AND INTELLECTUAL PROPERTY

10.1 Each Party shall continue to own all of its intellectual property including patents, trademarks, copyrights, trade secrets and other intellectual property (patentable or not) existing prior to the Effective Date, and, except as granted herein to the other Party by virtue of this Agreement, neither Vetter nor any third party shall acquire any right, title or interest in any such existing intellectual property of Intercell and similarly, neither Intercell nor any third party shall acquire any right, title or interest in any such existing intellectual property of Vetter.

10.2 Final Bulk Vaccine Inventions. In respect of any inventions, improvements, enhancements or alike made during the Term or any subsequent term of this Agreement and conceived or reduced to practice or generated by Intercell and/or Vetter only in respect of Final Bulk Vaccine, Intercell shall own all intellectual property including patents, trademarks, copyrights, trade secrets and other intellectual property (patentable or not) relating thereto and Vetter shall have the right to use such intellectual property only in connection with the performance of its obligations hereunder.

10.3 Production Inventions. In respect of any inventions, improvements, enhancements or alike made during the Term or any subsequent term of this Agreement and conceived or reduced to practice or generated by Intercell and/or Vetter in respect of Production (including manufacturing procedure other than if only related to Final Bulk Vaccine), Vetter shall own all intellectual property including patents, trademarks, copyrights, trade secrets and other intellectual property (patentable or not) relating thereto excluding any such inventions, improvements, enhancements or alike to the extent solely applicable to Final Bulk Vaccine (as to which Vetter shall have the right to use such intellectual property only in connection with the performance of its obligations hereunder) ("Vetter Inventions") and

shall promptly upon becoming aware thereof disclose such Vetter Inventions in writing to Intercell; provided, however, for the sake of clarification, such Vetter ownership shall exclude any thereof which constitutes Confidential Information of Intercell, disclosed in writing by Intercell, in respect of which Intercell shall grant to Vetter irrevocable, perpetual, worldwide, non-exclusive and royalty-free license(s) thereunder to the extent such can be generally applied other than solely in respect of Final Bulk Vaccine. Vetter grants to Intercell a non-exclusive, non-sublicensable, royalty-free (except for the payments herein required to be made to Vetter) license to the Vetter Inventions (as embodied in the Product) in the Territory, to use, have used, sell, have sold, offer for sale, import, export, have imported and have exported the Product Produced by Vetter under this Agreement, whether during (i) the initial or any subsequent term of this Agreement; or (ii) thereafter simultaneous with the shelf-life of the Produce, as so and only Produced for Intercell by Vetter in the course of this Agreement.

10.4 [***].

11. ARTICLE 11 : INFRINGEMENT

11.1 Intercell shall be responsible for all suits and actions based upon any claim that Intercell Materials, any Information of Intercell, Intercell's Instructions or other matter provided by Intercell hereunder or the use by Vetter of any thereof infringes on any third party's patent, trademark or other registered proprietary rights in the Territory.

11.2 [***].

11.3 The Parties shall keep each other informed in writing about any such action, and shall provide reasonable cooperation to each other in the defense of any such suit.

12. ARTICLE 12: INDEMNIFICATION AND RECALL OF PRODUCT

12.1 Vetter and Intercell shall at all times during the Term or any subsequent term hereof each indemnify, defend, and hold the other, its Affiliates, and their respective trustees/executors, officers, directors, agents and employees, harmless from and against any and all claims, suits, damages, liabilities, judgments, costs, awards, and expenses (including reasonable attorneys' fees) of any third party whether based on product or producer liability or otherwise (collectively, the "Costs"), resulting from or arising out of any negligence (as defined under the laws of Germany) or willful misconduct by Vetter or Intercell, as the case may be, or any breach by Vetter or Intercell, as the case may be, of its representations, warranties, agreements or other obligations contained in this Agreement.

12.2 In amplification of the foregoing, and not in limitation thereof, Intercell shall indemnify and hold Vetter, its Affiliates, and each of their respective trustees/executors, officers, directors, agents end employees, harmless from all Costs (i) in excess of [***]; or which arise out of (ii) Vetter's compliance with the Agreed Specifications, Intercell's Instructions, or any other Information or written direction given by Intercell; or (iii) the use by Intercell, Vetter, or any other person or party, of Intercell Materials, Vetter Materials [, or any other components supplied or approved by Intercell; or (iv) the distribution, sale or use of the Products by Intercell, Vetter, or any other person or third party.

[***] = 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.

12.3 Other than the obligation in Subsection 12.2(i) herein above, in all cases but the willful misconduct of Vetter (to which extent Intercell shall have no obligation pursuant to Subsection 12.1), such indemnification obligation of either Party for the benefit of the other Party shall not apply if and to the extent all of the following circumstances apply: (x) the other Party had actual prior knowledge of a fact or circumstance attributable to such Party or within the sole control of such Party that has caused, in whole or in part, the damage for which indemnification is sought; (y) such Party's failure to act upon such actual knowledge constituted willful misconduct with respect to the proximate cause of such damage; and (z) but for such Party's failure to act upon such actual knowledge the damage would not have taken place.

12.4 Vetter shall not be deemed negligent as long as Vetter follows the Agreed Specifications, Intercell's Instructions, and any other Information or written direction given by Intercell. Vetter may rely on the correctness and completeness of the Agreed Specifications, Intercell's Instructions, and any other Information or written direction given by Intercell. Compliance of Vetter with the obligations under the foregoing sentence shall be evidenced by the batch documentation (including samples of Product if so available) provided for in accordance with both this Agreement and the Quality Agreement.

12.5 The Parties shall promptly notify each other in writing of any claims and suits brought or threatened and shall permit, subject to the rights of any insurer, the other Party to join in the defense thereof.

12.6 It is understood that Vetter shall not be liable for and that Vetter does not warrant or represent to Intercell any Intercell Materials, or other materials or services manufactured or supplied by Intercell or any third party; provided, however, Vetter agrees to transfer promptly to Intercell any warranties of such third parties at the time of Vetter's receipt thereof, if, and as so received by Vetter in respect thereof, including, without limitation, warranties received by Vetter from [***].

12.7 Vetter shall maintain product liability insurance, as long as commercially reasonable and practicable, for a sum of not less than [***] per calendar year (with [***] in the event of personal injury and [***] in the event of property damage), with a reputable insurance company, which sum shall include (namely be reduced by) attorneys' fees for any action brought in the United States or Canada or any of either of their territories or possessions. Vetter shall have no liability vis-à-vis Intercell, its Affiliates, and both its respective trustees/executors, officers, directors, agents and employees, for any product or producer liability claim in excess of [***]; provided, however, and not withstanding anything in this Agreement to the contrary contained, it is agreed and understood by Intercell that, if Vetter should be compelled by Intercell, any of its Affiliates, or parent companies (if any) to undertake any action which could or would lead, or has led, to the loss of its liability insurance coverage then Vetter shall hereby be entitled to seek indemnification hereunder from Intercell above [***] per calendar year.

12.8 In the event that any Product is recalled by Intercell or by order of any government authority (including Regulatory Authorities), Vetter shall comply with the relevant provisions of the Quality Agreement and shall have liability with respect to such recall to the extent such recall is based on Vetter's gross negligence to supply Product in accordance with the Agreed Specifications, in which event Vetter, as it may determine, shall either supply replacement Product as in Section 5.3 provided or reimburse Intercell by either amount as set forth in Section 5.4 hereof.

12.9 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT CONTAINED, NEITHER PARTY SHALL BE RESPONSIBLE TO THE OTHER OR ANY AFFILIATE OF THE OTHER FOR ANY REASON WHATSOEVER FOR LOSS OF PROFITS (EXCEPT ANY PROFITS CONTAINED IN THE PRICES TO WHICH VETTER MAY BE ENTITLED FOR COMPLETION OF ITS CONTRACTUAL OBLIGATIONS HEREUNDER), LOSS OF GOODWILL, LOSS OF BUSINESS, OR INDIRECT, INCIDENTAL, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES.

13. ARTICLE 13: TERM AND TERMINATION

13.1 This Agreement shall be effective as of the Effective Date for a term of three (3) years (the "Term") subject to the termination provisions of this Article 14. Upon the expiration of the Term or any subsequent term, this Agreement shall automatically renew for a period of one (1) year unless either Party notifies the other Party in writing [***] prior to any expiration date of its intention to not renew this Agreement.

13.2 Each Party shall have the right to terminate (with immediate effect or, if applicable, after the expiration of the [***] period hereinafter referred to) this Agreement upon prior written notice in the event the other Party is in major default in the fulfillment of any obligation hereunder. The term "major default" shall include, but not be limited to (i) in respect of Intercell, the failure to maintain insurance as herein provided, or pay any amount when due; (ii) in respect of Vetter, Production of [***] consecutive lots of Product that fail to meet the Agreed Specifications; (iii) the insolvency, bankruptcy or liquidation of a Party or the appointment of a receiver of any significant part of the property of a Party or the occurrence of any similar event; (iv) in the case of any other default which can be cured, the failure to remedy or make good the default during a period of [***] after the giving of any written notice specifying such curable default, and, furthermore provided, if such notice as herein referred to has been given no additional notice shall be necessary to effect the termination of this Agreement after the expiration of such [***] period if the Party in default did not undertake any action reasonably capable of initiating said remedy; and (v) the request by any Regulatory Authority that Vetter should implement any changes which are related to the Product which change Intercell does not approve of, or for which Intercell declines to pay.

13.3 Upon any termination of this Agreement, for any reason whatsoever, Vetter shall sell to Intercell, and Intercell shall purchase, at the prices herein provided, all Products for which Purchase Orders have been placed, or are required to be placed, on or prior to the date of termination, and, at the prices thereof, all Vetter Materials, and other materials, as have been ordered by Vetter as contemplated in or permitted under this Agreement.

13.4 Intercell shall have the right to terminate this Agreement upon [***] prior written notice to Vetter in the event that any of EMEA, the FDA, or WHO shall have failed to grant regulatory approval of the Product within [***] of the Effective Date.

13.5 Vetter shall deliver to Intercell, unless otherwise directed by Intercell, at Intercell's cost and expense, any quantities of Intercell Materials in its possession. Vetter shall return to Intercell all documentation constituting Information of Intercell (including copies thereof) which has been provided by Intercell to Vetter hereunder; provided, however, and notwithstanding the foregoing, Vetter may retain such limited amount of Products and Intercell Materials (all thereof sufficient for [***] analyses) as well as such documentation, as may be necessary for proper record keeping or the satisfaction of legal requirements.

13.6 Upon any termination of this Agreement, for any reason whatsoever, Intercell shall return to Vetter all documentation constituting Information of Vetter (including copies thereof) which has been provided by Vetter to Intercell hereunder; provided, however, Intercell may retain such limited number thereof as may be necessary for proper record keeping or the satisfaction of legal requirements, subject to the provisions as in the Confidentiality Agreement contained and applicable hereto, including its alterations made hereunder.

Additionally upon any termination of this Agreement, Vetter agrees to promptly return to Intercell, at Intercell's cost, all unused Final Bulk Vaccine and/or Intercell Materials, all Product (subject to Intercell's obligation fulfilled to pay as herein provided), all Confidential Information of Intercell, Equipment (if procured for, paid and owned by, Intercell), Product-specific Specifications, batch records and other documents relating solely to the Product; provided, however, that Vetter may retain one (1) copy of the foregoing as may be necessary to comply with law and the regulations of Regulatory Authorities, subject to the provisions as in the Confidentiality Agreement contained and applicable hereto, including its alterations made hereunder.

14. ARTICLE 14: FORCE MAJEURE

14.1 Neither Party shall be responsible to the other, and no default shall be deemed to have occurred hereunder, for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof if such failure, delay or non-performance is caused by or arises from strike, stoppage of labor, lockout or any other labor trouble, shortage of energy or raw material or any other inability to obtain any materials or shipping space, breakdown or delays of carriers or shippers, default or delay by any supplier or sub-contractor, fire, flood, lightning, fog, storm, or other unusual weather conditions, explosion, accident, earthquake, epidemics, act of God, any public enemy, sabotage, invasion, war (declared or undeclared), riot, embargo, governmental or administrative act

or restraint, prohibition on import or export of the Product or materials incorporated therein or parts thereof, or any other cause that is beyond the reasonable control of the affected Party, including such events which stem from the internalization of such operations and services which typically and customarily are provided by a third party (any such matter or cause, "force majeure"). A Party shall be under no obligation to settle a strike, labor stoppage, lockout, or any other labor trouble by entering into any agreement to settle such matter and until such matter is settled to the satisfaction of the affected Party, such matter shall continue to be a matter beyond the reasonable control of the affected Party.

14.2 The Party claiming force majeure hereunder shall promptly notify the other specifying the cause and probable duration of the delay or non-performance. Vetter shall be under no obligation to Produce the Product scheduled to have been Produced during a time period of force majeure; however, each affected Party shall undertake every reasonable effort to fulfill its contractual obligations to the extent reasonably possible under the circumstances.

15. ARTICLE 15: CONFIDENTIALITY

The provisions of the Confidentiality Agreement shall govern this Agreement in every respect, except that, the confidentiality obligations in the Confidentiality Agreement shall survive the expiration of the Term and thereafter remain in full force and effect for a period of [***].

16. ARTICLE 16: UN CONVENTION

UN Convention. Notwithstanding anything herein to the contrary contained in this Agreement and its Annexes, the United Nations Convention on Contracts for the International Sale of Goods shall have no application to, and shall be of no force and effect with respect to, this Agreement or the matters herein set forth or contemplated.

17. ARTICLE 17: TIMELY PERFORMANCE

Failure by a Party, at any time, to request performance by the other Party or to claim a breach of this Agreement, unless such request or claim is reduced to writing, shall not be construed as a waiver of any right under this Agreement, nor affect any subsequent breach nor affect the effectiveness of the Agreement or any part thereof, nor prejudice such Party with respect to any subsequent action.

18. ARTICLE 18: ENTIRE AGREEMENT

18.1 This Agreement, the Confidentiality Agreement and the Quality Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof and (together with the Confidentiality Agreement, as amended by effect of Section 1[**(18)**] and Article 16 hereof, and the Quality Agreement) in such respect (but solely in such respect) shall supersede all prior proposals (including the Offer), negotiations, conversations, discussions and agreements by and between the Parties concerning the subject matter hereof as in the recitals hereof referred to.

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18.2 Any provision of this Agreement which might be, or become, void, invalid, or unenforceable, shall be replaced by mutually agreed provisions valid and enforceable in compliance with the commercial and lawful purposes and intentions of the Parties hereto as contained in and shown by this Agreement. The validity of this Agreement shall remain independently of any provision therein contained which provision might be or has become void, invalid, or unenforceable, except in the event that the Parties would not have entered into the Agreement given any impossible replacement as herein mentioned. In case of any gap contained in this Agreement and initially unconsidered by and between the Parties, such reasonable provision shall be effective in order to complete the Agreement, which approaches the respective consideration of the Parties to a maximum extent.

19. ARTICLE 19: CONFLICT

In the event of any conflict between any provision of this Agreement and any of those contained in the Quality Agreement the provisions of the Quality Agreement shall govern and control in respect of quality issues only, whereas this Agreement (excluding its Annexes) shall govern and control in all other respects.

20. ARTICLE 20: AMENDMENTS

Any amendment to or alteration of the provisions in this Agreement contained, specifically including this Article 21, shall take effect only by a written document signed by the duly authorized representatives of each of both Parties.

21. ARTICLE 21: ASSIGNMENT

Neither this Agreement nor any rights or obligations hereunder shall be assignable or transferable by either of the Parties hereto without the prior written consent of Vetter, Intercell and Intercell AG, except that either Party may assign this Agreement to an Affiliate, provided that such assigning Party shall remain jointly and severally responsible liable to the non-assigning Party along with such Affiliate and such Affiliate may not further assign this Agreement without the consent in writing of the non-assigning Party, and except that Vetter may assign warehousing and internal logistic operations to an independent contractor (currently [***]); provided, however, Vetter shall be liable for said contractor as if it had performed itself.

22. ARTICLE 22: NOTICES

22.1 All notices, requests, demands and other communication hereunder, shall be addressed as follows (or to such other address, telex number with confirmed answer back, or fax number, as each Party may specify in a notice pursuant hereto) and be deemed to have been duly given upon receipt (provided receipt is on Monday, Tuesday, Wednesday, Thursday, or Friday, which is not a national holiday at the place of receipt and during normal business hours of the recipient (the “Business Day”), otherwise on the next succeeding Business Day), when delivered personally, mailed by registered or certified mail, return receipt requested, or telexed with confirmed answer back, or faxed, to

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Intercell: Intercell AG
Headquarters
Campus Vienna Biocenter 2
1030 Vienna, Austria
Attn.: Chief Operating Officer
Telephone: [***]
Fax: [***]

With a copy to:

Intercell AG
Headquarters
Campus Vienna Biocenter 2
1030 Vienna, Austria
Attn.: General Counsel
Telephone: [***]
Fax: [***]

Vetter: Vetter Pharma-Fertigung GmbH & Co. KG
Schützenstraße 87
88212 Ravensburg, Germany
Attn.: Director, Key Account Management
Phone: [***]
Fax: [***]

22.2 Each Party hereto may change its address set forth above by giving notice to the other Party as herein provided.

23. ARTICLE 23: HEADINGS

The headlines of the Articles hereof are for convenience of reference only and shall not affect the interpretation of the respective Articles of this Agreement.

24. ARTICLE 24: INDEPENDENT PARTIES

Intercell and Vetter are independent parties and nothing in this Agreement is intended or shall be deemed to create a partnership, agency, employer/employee or joint venture relationship between the Parties or between each Party and any employee, agent, officer, director, or trustee/executor, of the other Party. No Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for herein or as authorized by the Party intended to be bound in writing.

25. ARTICLE 25: LANGUAGE

All notices and other communications hereunder shall be in English.

26. ARTICLE 26: RISK MANAGEMENT/BUSINESS CONTINUITY

In order to ensure continuity of Production and in connection with diligent risk management practices, Vetter will implement a risk management program consistent with Vetter's SOPs, existing policies and according procedures. Such program shall include development of a "business continuity plan" for the Product planning for events involving third party supplier disruptions and delays. Vetter agrees that such risk management and business continuity planning shall be conducted with reasonable diligence, and reflect the application of commercially reasonable principles, which for avoidance of doubt Intercell acknowledges and agrees shall be, with respect to such diligence and principles, consistent with Vetter's relevant standard procedures and policies.

27. ARTICLE 27: PARENT COMPANY GUARANTOR

In witness whereof, Intercell AG acknowledges all of the terms set forth in this Agreement, including the right to make changes and amendments thereof as herein set forth, and hereby agrees and declares that it is directly fully responsible to Vetter for the services to be performed by Intercell and guarantees to Vetter the due performance and/or payment of all of the obligations and liabilities of Intercell pursuant to this Agreement, provided, however, that Vetter has first requested performance or payment from Intercell as in this Agreement provided prior to any claim made to Intercell AG and that Vetter has first reasonably concluded that it will not be paid by Intercell and/or said performance will not be made by Intercell, as the case may be, in a timely manner as herein specified or, in the event no time period is so specified for such payment or performance herein, in a reasonable time period. Intercell AG further acknowledges and agrees that, in the event of any full or partial permitted assignment by Intercell to any Affiliate(s) pursuant to Article 21 of this Agreement, Intercell AG shall act, in respect of such assignee Affiliate(s) in the same capacity as is set forth in this Article 27 with respect to Intercell.

28. ARTICLE 28: GOVERNING LAW

The Parties shall attempt to amicably settle and in good faith resolve any dispute arising between the Parties in connection with this Agreement. Should such attempt fail, this Agreement shall be construed and interpreted in accordance with and governed by the laws of Germany without giving effect to any conflict-of-laws provisions and the competent court of Frankfurt am Main shall have exclusive jurisdiction.

(Remainder of this page left blank intentionally.)

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IN WITNESS WHEREOF, the duly authorized representatives of each Party hereto have as of the days and year and in the locations below written executed this Agreement.

INTERCELL BIOMEDICAL LTD.:

Livingston, Scotland

(signed) *[***]*
(month) April (day) 30, 2008
Name: [***]
Title: VP Finance

VETTER PHARMA-FERTIGUNG GMBH & CO. KG:

Ravensburg, Germany

(signed) *[***]*
(month) May (day) 20, 2008
Name: [***]
Title: VP Key Account Management

INTERCELL AG (IN ITS CAPACITY AS PARENT COMPANY GUARANTOR):

Vienna, Austria :

(signed) *[***]*
(month) April (day) 30, 2008
Name: [***]
Title: Chief Operating Officer

Ravensburg, Germany

(signed) *[***]*
(month) April (day) 30, 2008
Name: [***]
Title: Key Account Manager

INTERCELL AG (IN ITS CAPACITY AS PARENT COMPANY GUARANTOR):

Vienna, Austria :

(signed) *[***]*
(month) April (day) 30, 2008
Name: [***]
Title: Chief Executive Officer

ANNEX 1: PRICES

[***]

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[***]

Vetter Pharma-Fertigung GmbH & Co. KG · Schützenstraße 87 · 88212 Ravensburg · Germany
Telefon: +49-(0)751-3700-0 · Telefax: +49-(0)751-3700-4000 · Internet: www.vetter-pharma.com

Sitz in Ravensburg und eingetragen im Reg.-Gericht Ulm HRA 550954 · persönlich haftende Gesellschafterin: Vetter Pharma-Fertigung Verwaltungs GmbH · Sitz in Ravensburg und eingetragen im Reg.-Gericht Ulm HRB 551139
Hauptgeschäftsführer: Klaus Schönwetter, Geschäftsführer: Max Hoen, Dr. Jürgen Koch, Thomas Otto

Deutsche Bank AG, Ravensburg · Konto-Nr: 0414 300, BLZ 650 700 64, BIC: DEUTDESS650, IBAN: DE78650700640414300000
Baden-Württembergische Bank, Ravensburg · Konto-Nr: 4 607 767, BLZ 600 501 01, BIC: SOLADEST, IBAN: DE31600501010004607767
Bayerische Hypo- und Vereinsbank AG, Ravensburg · Konto-Nr: 5 497 123, BLZ 650 201 66, BIC: HYVEDEMM483, IBAN: DE19650201660005497123
Dresdner Bank AG, Ravensburg · Konto-Nr: 202 311 100, BLZ 650 800 09, BIC: DRESDEFF650, IBAN: DE62650800090202311100
Ust-Ident-Nr. DE 145 326 543

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ANNEX 2: AGREED VALUE OF Final Bulk Vaccine AND INTERCELL MATERIALS

1. [***].

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ANNEX 3: [***]

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ANNEX 4: QUALITY AGREEMENT

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ANNEX 5: CONFIDENTIALITY AGREEMENT

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ANNEX 6: CYCLE TIMES

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SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE 1 OF 11
1000079320	

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
SPE2DP-20-D-0005	2020 SEP 09		SPE2DP-19-R-0112	2020 MAR 06

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER (No collect calls)	8. OFFER DUE DATE/ LOCAL TIME
▶			

9. ISSUED BY CODE

DLA TROOP SUPPORT
MEDICAL SUPPLY CHAIN PHARM FSA
700 ROBBINS AVENUE
PHILADELPHIA PA 19111
USA
Local Admin: [***]
Email: [***]

10. THIS ACQUISITION IS

- ☒ UNRESTRICTED OR ☐ SET ASIDE: ___ % FOR:
- ☐ SMALL BUSINESS
- ☐ WOMEN-OWNED SMALL BUSINESS
- ☐ HUBZONE SMALL BUSINESS
- ☐ (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS:
- ☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- ☐ EDWOSB
- ☐ 8 (A) SIZE STANDARD:

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING / 14. METHOD OF SOLICITATION
☐ SEE SCHEDULE	Net 30 days	☐	☐ RFQ ☐ IFB ☒ RFP

15. DELIVER TO CODE

SEE SCHEDULE

16. ADMINISTERED BY CODE SPE2DP

SEE BLOCK 9
Criticality: PAS : None

17a. CONTRACTOR/ OFFERER CODE 43FM1 FACILITY CODE

Valneva USA, Inc.
910 Clopper Rd Ste 160S
GAITHERSBURG MD 20878-1361
USA

TELEPHONE NO. 2404547265

18a. PAYMENT WILL BE MADE BY CODE SL4701

DEF FIN AND ACCOUNTING SVC
BSM
P O BOX 182317
COLUMBUS OH 43218-2317
USA

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	See Schedule *(Use Reverse and/or Attach Additional Sheets as Necessary)*				

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.

☒ 29. AWARD OF CONTRACT: REF. Valneva's OFFER DATED 2020-Apr-01 YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR	31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*
/s/ [***]	/s/ [***]

30b. NAME AND TITLE OF SIGNER *(Type or print)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(Type or print)*	31c. DATE SIGNED
[***]	9/3/2020	[***]	2020 SEP 09

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PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 02/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE 32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER

38. S/R ACCOUNT NO.	39. S/R VOUCHER NO.	40. PAID BY

41.a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41C. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/DD)*	42d. TOTAL CONTAINERS

STANDARD FORM 1449 (REV. 2/2012)

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Form

1. Contract SPE2DP-20-D-0005 is the result of Valneva's proposal submission dated April 1, 2020 in response to solicitation SPE2DP-19-D-0112. Valneva's offer was revised via correspondences dated June 5, 2020 and June 16, 2020, a response to the Final Proposal Revision (FPR) dated July 17, 2020, and a response to the second FPR dated August 11, 2020. Valneva also signed amendment 0002 and returned it with their June 16, 2020 response.

2. This document represents the basic contract against which delivery orders may be placed.

3. Schedule of Supplies

Item Identification: Japanese Encephalitis Virus (JEV), Purified, Inactivated Vaccine, EA (1 pre-filled syringe), NDC 42515-0002-01, "IXIARO"

National Stock Number: (NSN 6505-01-607-7018)

Item: 0001

Description - Base Year

Minimum Quantity: [***] each

Maximum Quantity: [***] each

Unit Price: [***]

Minimum Contract Price (Base Year): [***]

Description -Option Year 1

Minimum Quantity: [***] each

Maximum Quantity: [***] each

Unit Price: [***]

Minimum Contract Price (Option Year 1): [***]

Description -Option Year 2

Minimum Quantity: [***] each

Maximum Quantity: [***] each

Unit Price: [***]

Minimum Contract Price (Option Year 2): [***]

[***]

4. The effective ordering period shall be from the date of award through one year thereafter.

CONTINUED ON NEXT PAGE

Form (CONTINUED)

5. Delivery shall be FOB Destination and delivered within 120 days from date of the delivery order.

6. [***]

7. Delivery destination (to be indicated on each delivery order):

Defense Logistics Agency Distribution, Susquehanna PA (DDSP)
Unit Set Assembly Operation
Bldg 89, Avenue U, Door 6
New Cumberland, PA 17070-5000
Attention: [***]

Defense Logistics Agency Distribution, Yokosuka Japan (DDYJ)
FLT ACT YOKOSUKA PH 01181468168344
HONCHO 1 CHOME YOKOSUKA SHI B 5010
YOKOSUKA JP 238-0041

8. Inspection and acceptance shall be at destination.

9. The guaranteed minimum (GM) quantity to be ordered during the base year is [***] each. The GM quantity for option year 1 is [***] each and [***] each for option year 2.

10. Valneva's offer on solicitation SPE2DP-19-R-0112, including Amendment 0001, Amendment 0002 and correspondence dated June 5, 2020, June 16, 2020, a response to the Final Proposal Revision (FPR) dated July 17, 2020, and a response to the second FPR dated August 11, 2020 are made part of this contract and incorporated by reference.

Part 12 Clauses

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUES OR EXECUTIVE ORDERS – COMMERCIAL ITEMS (JUN 2020) FAR

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses. which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 7 43 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 89(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77, 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate].

(1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUN 2020), with Alternate I (Oct 1995) (41 U.S.C. 4 704 and 10 U.S. C. 2402).

X (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).

(3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

CONTINUED ON NEXT PAGE

Part 12 Clauses (CONTINUED)

X (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

(5) Reserved.

(6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

(7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 7 43 of Div. C).

X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).

X (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).

(10) Reserved.

(11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

(ii) Alternate I (MAR 2020) of 52.219-3.

(12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

(ii) Alternate I (MAR 2020) of 52.219-4.

(13) Reserved

(14)(i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020 (15 U.S.C. 644).

(ii) Alternate I {MAR 2020).

(iii) Alternate II (Nov 2011).

(15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

(ii) Alternate I (MAR 2020) of 52.219-7. (iii) Alternate II (Mar 2004) of 52.219-7.

X (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

(17)(i) 52.219-9, Small Business Subcontracting Plan (JUN 2020) (15 U.S.C. 637(d)(4)).

(ii) Alternate I (MAR 2020) of 52.219-9.

(iii) Alternate II (MAR 2020 of 52.219-9.

(iv) Alternate Ill (JUN 2020) of 52.219-9.

(v) Alternate IV (JUN 2020) of 52.219-9.

(18) 52.219-13, Notice of Set-Aside of Orders (MA 0) (15 U.S.C. 644(r)).

(19) 52.219-14. Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).

X (20) 52.219-16, Liquidated Damages—Subcon-tracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

(21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657 f).

X (22) 52.219-28, Post Award Small Business Program Rerepresentation (MAR 2020) (15 U.S.C. 632(a)(2)).

(ii) Alternate I (MAR 2020) of 52.219-28. 43,500

(23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)). 43501

(24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).

(25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644®). 43526

(26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)). 43527

X (27) 52.222-3, Convict Labor (June 2003) (E.O. 11755).

X (28) 52.222-19, Child Labor •-Cooperation with Authorities and Remedies (Jan 2020) (E.O. 13126).

X (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

X (30) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).

(ii) Alternate I (Feb 1999) of 52.222-26

X (31) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

_(ii) Alternate I (Jul 2014) of 52.222-35

X (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

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Part 12 Clauses (CONTINUED)

_(ii) Alternate I (Jul 2014) of 52.222-36

(33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

X (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

X (35)(i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).

(ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

(37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA -Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

(ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

(38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

(39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

(40)(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).

(ii) Alternate I (Oct 2015) of 52.223-13.

(41)(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).

(ii) Alternate I (Jun 2014) of 52.223-14.

(42) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).

(43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).

(ii) Alternate I (Jun 2014) of 52.223-16.

X (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

(45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

(46) 52.223-21, Foams (Jun 2016) (E.O. 13693).

(47)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(ii) Alternate I (JAN 2017) of 52.224-3.

(48) 52.225-1, Buy American —Supplies (May 2014) (41 U.S.C. chapter 83).

(49)(i) 52.225-3, Buy American —Free Trade Agreements – Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

(ii) Alternate I (May 2014) of 52.225-3.

(iii) Alternate II (May 2014) of 52.225-3.

(iv) Alternate Ill (May 2014) of 52.225-3.

(50) 52.225-5, Trade Agreements (Oct 2016) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

X (51) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

(52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).

(54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).

(55) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

(56) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

X (57) 52.232-33, Payment by Electronic Funds Transfer —System for Award Management (Jul 2013) (31 U.S.C. 3332).

(58) 52.232-34, Payment by Electronic Funds Transfer —Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

(59) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

(60) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

(61) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(12)).

(62)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241 (b) and 10 U.S.C. 2631).

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Part 12 Clauses (CONTINUED)

(ii) Alternate I (Apr 2003) of 52.247-64.

(iii) Alternate II (Feb 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate]

(1) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495).

(2) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).

(3) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

(4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

(5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards —Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U. S.C. chapter 67).

(6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment —Requirements (May 2014) (41 U.S.C. chapter 67).

(7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services –Requirements (May 2014) (41 U.S.C. chapter 67).

(8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

(9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records - Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor’s directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course or business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause —

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (I) of FAR clause 52.222-17.

(vii) 52.222-21, Prohibition of Segregated Facilities (Apr 2015)

(viii) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).

(ix) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

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Part 12 Clauses (CONTINUED)

(x) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

(xi) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212)

(xii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xiii) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).

(xiv) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O 13627). Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O 13627).

(xv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

(xvi) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

(xvii) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).

(xviii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

(xix) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xx)(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

(xxi) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxiii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241 (b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS (DEC 2014) FAR

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

*****

Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (AUG 2020)

(a) * * *

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e. g., fiber optic, coaxial cable, Ethernet).

*****

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

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Part 12 Clauses (CONTINUED)

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

*** * * * ***

(b) Prohibition. (1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment. system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services arc covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use or covered telecommunications equipment or services, regardless of whether that use Is in performance of work under a Federal contract.

252.204-7009 LIMITATIONS ON THE USE OR DISCLOSURE OF THIRD-PARTY CONTRACTOR REPORTED CYBER INCIDENT INFORMATION (OCT 2016) DFARS

252.204-7012 SAFEGUARDING COVERED DEFENSE INFORMATION AND CYBER INCIDENT REPORTING (DEC Z019) DFAR5

252.232-7010 LEVIES ON CONTRACT PAYMENTS (DEC 2006) DFARS

52.247-34 F.O.B. DESTINATION (NOV 1991) FAR

52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013) FAR

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018) DFARS

(a) *Definitions*. As used in this clause-

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) *Electronic invoicing*. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall-

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.acguisjtion.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this web site.

(d) *WAWF training*. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/

(e) *WAWF methods of document submission*. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer

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Part 12 Clauses (CONTINUED)

Protocol.

(f) *WAWF payment instructions*. The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Contractor shall use the following document type(s).

Invoice and Receiving Report Combo

(Contracting Officer: Insert applicable document type(s).

Note: If a "Combo" document type is identified but not supportable by the Contractor's business systems, an "Invoice" (stand-alone) and "Receiving Report" (stand-alone) document type may be used instead.)

(2) Inspection/acceptance location. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

Destination

(Contracting Officer: Insert inspection and acceptance locations or "Not applicable.*)

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	SL4701
Issue By DoDAAC	SPE2DP
Admin DoDAAC	SPE2DP
Inspect By DoDAAC	N/A
Ship To Code	See Delivery Order
Ship From Code	N/A
Mark For Code	N/A
Service Approver (DoDAAC)	N/A
Service Acceptor (DoDAAC)	N/A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(*Contracting Officer: Insert applicable DoDAAC information or "See schedule" if multiple ship to/acceptance locations apply, or "Not applicable.")

(4) Payment request and supporting documentation. The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the wo performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in D FARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) WAWF email notifications. The Contractor shall enter the e-mail address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

[***]

(*Contracting Officer: Insert applicable email addresses or "Not applicable."*)

(g) *WAWF point of contact*.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

[***]

(*Contracting Officer: Insert applicable information or "Not applicable."*)

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

52.233-3 PROTEST AFTER AWARD (AUG 1996) FAR

252.244-7000 SUBCONTRACTS FOR COMMERCIAL ITEMS (JUN 2013) DFARS

52.253-1 COMPUTER GENERATED FORMS (JAN 1991) FAR

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PRIVATE OR CONFIDENTIAL.

Part 12 Clauses (CONTINUED)

252.204-7018 PROHIBITION ON THE ACQUISITION OF COVERED DEFENSE TELECOMMUNICATIONS EQUIPMENT OR SERVICES (DEC 2019) DFARS

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Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	State or Other Jurisdiction of Incorporation
Valneva UK Ltd	England and Wales
Valneva Austria GmbH	Austria
Valneva Canada Inc.	Canada
Vaccines Holdings Sweden AB	Sweden
Valneva France SAS	France
Valneva Scotland Ltd	Scotland
Valneva USA Inc.	Delaware
Valneva Sweden AB	Sweden