Table of Contents

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

As confidentially submitted to the Securities and Exchange Commission on October 20, 2021.
This 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)

Valneva USA, Inc.
910 Clopper Road, Suite 160S
Gaithersburg, MD 20878
+ 1 301 556 4500
(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:

David Boles **Marc Recht** **Divakar Gupta** **Katie Kazem** **Cooley LLP** **500 Boylston Street,** **14th Floor** **Boston, MA 02116** **+1 617 937 2300**	**Jean-Marc Franceschi** **Hogan Lovells Paris LLP** **17, avenue Matignon CS 30027** **75378 Paris Cedex 08, France** **+33 1 53 67 47 47**	**Robert E. Puopolo** **Edwin O'Connor** **Seo Salimi** **Goodwin Procter LLP** **100 Northern Avenue** **Boston, MA 02210** **+1 617 570 1000**	**Arnaud Duhamel** **Guilhem Richard** **Gide Loyrette Nouel** **A.A.R.P.I.** **15 rue de Laborde** **75008 Paris, France** **+33 1 40 75 60 00**

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: ☐

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 two ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby have been registered pursuant to a separate registration statement on Form F-6 (File No. 333-255301).
(2) Includes ordinary shares, which may be in the form of ADSs, which the underwriters have an option to purchase. See “Underwriting.”
(3) Includes additional ordinary shares that are being offered in the European private placement, 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.

Table of Contents

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 two ordinary shares, which we refer to as the "U.S. offering," and (ii) a concurrent private placement in Europe (including in France) of ordinary shares 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 private placement." We refer to the U.S. offering and the concurrent European private placement 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.

Our ADSs are listed on the Nasdaq Global Select Market under the symbol "VALN" and our ordinary shares are listed on Euronext Paris under the symbol "VLA."

The offering price is $ per ADS in the U.S. offering, corresponding to an offering price of € per ordinary share in the European private placement.

On , 2021, the last reported sale price of our ordinary shares on Euronext Paris was € per ordinary share and the last reported sale price of our ADSs was $ per ADS on the Nasdaq Global Select Market.

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 involves risks. See "Risk Factors" beginning on page 15 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 ordinary shares in the form of ADSs from us at the 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 private placement (including upon exercise of the underwriters' option to purchase, within 30 days from the date of this prospectus, additional 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 **Jefferies** **Guggenheim Securities** **Bryan, Garnier & Co.**

Prospectus dated , 2021.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

TABLE OF CONTENTS

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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. 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 $, which was the noon buying rate of the Federal Reserve Bank of New York on , 2021. 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.

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 undergoing clinical trials. VLA15 targets the six most prevalent serotypes, or variations, of Borrelia in the United States, where approximately 476,000 people are diagnosed with Lyme disease each year and in Europe, where at least a further 200,000 cases occur annually. Our clinical portfolio also includes VLA1553, targeting the chikungunya virus, which has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. VLA1553 is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data.

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 whole virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could be adapted to offer protection against mutations of the virus. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S), in terms of geometric mean titer, or GMT, for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222.

These Phase 3 topline results will allow us to finalize our rolling submission and review process with the UK's Medicines & Healthcare products Regulatory Agency, or MHRA, which we commenced in August 2021. We

expect to finalize our submission in November 2021 and believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the European Medicines Agency, or EMA. Further submissions to other regulatory agencies may take place in 2022.

We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand and Thailand, prevention of diarrhea caused by ETEC, the leading causes of travelers' diarrhea.

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

Company History and Team

We are a public company listed on the Nasdaq Global Select Market and Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior executive team has more than 100 years of combined experience spent working at industry leaders such as Novartis, Chiron, Acambis, GlaxoSmithKline and Daiichi Sankyo. 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

Our pipeline and key assets are summarized below:

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

Our clinical pipeline includes:

- **VLA15 –** a vaccine candidate against Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is the only vaccine undergoing clinical trials against Lyme disease. We have completed recruitment and reported initial results for 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 initiated in March 2021. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of $10 million. Together with Pfizer, we expect that our Phase 3 pivotal, placebo-controlled field efficacy trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the 2023 tick season. 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 VLA1553 is the only chikungunya vaccine candidate that has reported positive Phase 3 topline data. In our Phase 1 clinical trial, we observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants, which results were sustained after 12 months. VLA1553 advanced directly to a Phase 3 clinical trial, for which we reported positive topline results in August 2021. In the pivotal Phase 3 trial, we observed a seroprotection level of 98.5% 28 days after receiving the single administration. VLA1553 has received Fast Track and Breakthrough Therapy designation from the FDA and PRIME designation from the EMA. We have also received confirmation for our

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, we plan to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection, rather than executing a time- and cost-intensive field trial that observes natural rates of infection between trial participants receiving our vaccine and the placebo. The seroprotection rate observed in the pivotal Phase 3 trial exceeds the 70% surrogate of protection threshold agreed with the FDA. The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher, or PRV.

- **VLA2001** – a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of GMT for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. 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. We commenced our rolling submission and review process with the MHRA in August 2021 and expect to incorporate our positive Phase 3 topline results in November 2021. We believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022.

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

- **DUKORAL –** an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and, in Canada and other countries, heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. We acquired DUKORAL in 2015 and recorded €13.3 million and €31.5 million of revenues in the years ended December 31, 2020 and 2019, respectively. Sales in 2020 and 2021 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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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, Solna, 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 development program. 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, manufacture and commercialize a COVID-19 vaccine.
- The termination of the UK Supply Agreement has caused disruption to our VLA2001 development plans, and may continue to negatively affect our business.
- Our business has been and could continue to be materially adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic. Future outbreaks of disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, could materially affect our operations globally and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.
- We may fail to obtain regulatory approval for our products on a timely basis or comply with our continuing regulatory obligations after approval is obtained.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- We depend upon our existing collaboration partner, Pfizer, and other third parties to advance our business and may in the future depend on additional third parties. If we are unable to maintain such existing agreements or enter into additional arrangements, our business could be adversely affected.
- We are dependent on single source suppliers for some of the components and materials used in our products.

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- We rely primarily on our manufacturing facilities as the 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) December 31, 2026.

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.

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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.

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We 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.

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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 private placement. The total number of ordinary shares to be sold in the U.S. offering and European private placement is subject to reallocation between these offerings.
Offering price	The offering price is $ per ADS in the U.S. offering, corresponding to an offering price of € per ordinary share in the European private placement.
Option to purchase additional 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 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 two 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 ordinary share (corresponding to $ per ADS based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 2021, after

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	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 COVID-19, Lyme and chikungunya 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.
Nasdaq Global Select 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 99,760,077 ordinary shares outstanding as of June 30, 2021 and excludes:

- 40,625 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*), including 6,250 ordinary shares issued upon exercise of equity awards subsequent to June 30, 2021;
- 4,054,937 ordinary shares issuable upon exercise of outstanding stock options;
- 1,842,404 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,012,706 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 ADSs and no exercise of warrants, vesting of free ordinary shares or other equity awards or conversion of preferred shares subsequent to June 30, 2021.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated statement of income (loss) data for the years ended December 31, 2020 and 2019 have been derived from our audited consolidated financial statements as of and for the years ended December 31, 2020 and 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.

The following summary condensed consolidated statement of income (loss) data for the six months ended June 30, 2021 and 2020 and summary condensed statement of financial position data as of June 30, 2021 have been derived from our unaudited interim condensed consolidated financial statements as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 were prepared in accordance with IAS 34, Interim Financial Reporting, the standard of IFRS as issued by the IASB applicable to interim financial statements.

Our historical results and the results for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2021 or in any periods 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)	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Product sales	€ 31,762	€ 40,942	€ 65,938	€129,511
Revenues from collaboration, licensing and services	15,740	6,965	44,383	(3,315)
Total revenues	€ 47,502	€ 47,907	€110,321	€126,196
Cost of goods and services	(34,778)	(22,546)	(54,302)	(52,781)
Research and development expenses	(78,737)	(33,081)	(84,454)	(38,022)
Marketing and distribution expenses	(9,643)	(10,046)	(18,264)	(24,145)
General and administrative expenses	(20,904)	(10,615)	(27,539)	(18,398)
Other income and expenses, net	10,389	6,453	19,117	6,338
Operating profit (loss)	€(86,172)	€(21,928)	€(55,120)	€ (811)
Finance income	8,962	549	689	1,449
Finance expense	(8,431)	(6,109)	(10,738)	(3,082)
Result from investments in associates	(90)	90	(133)	1,574
Profit (loss) before income tax	€(85,730)	€(27,398)	€(65,302)	€ (870)
Income tax income (expense)	(668)	1,759	909	(874)
Profit (loss) for the period	€(86,399)	€(25,639)	€(64,393)	€ (1,744)
Earnings (losses) per share – basic	€ (0.91)	€ (0.28)	€ (0.71)	€ (0.02)
Earnings (losses) per share – diluted	€ (0.91)	€ (0.28)	€ (0.71)	€ (0.02)

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Consolidated Statement of Financial Position Data:

€ in thousands	As of June 30, 2021	
	Actual	As Adjusted(1)(2)
Cash and cash equivalents	€329,766	€
Total assets	745,107	
Total liabilities	668,037	
Total shareholders' equity	77,070	

(1) The as adjusted summary statement of financial position data reflects our issuance and sale of a total of ordinary shares (including ordinary shares represented by ADSs) in the global offering at an assumed offering price of € per ordinary share (corresponding to $ per ADS based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 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.

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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 €86.4 million and €25.6 million for the six months ended June 30, 2021 and 2020, respectively, and €64.4 million and €1.7 million for the years ended December 31, 2020 and 2019, respectively. As of June 30, 2021, we had an accumulated net loss of €319.9 million. We expect to continue to incur significant expenses and substantial operating losses over the next several years. Since inception, we have devoted a significant amount of our efforts to identifying, researching and conducting pre-clinical and clinical activities of our product candidates, building our manufacturing capabilities, building our commercial and sales infrastructure, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of our product candidates, VLA15, VLA1553, and VLA2001;
- initiate, conduct and complete any ongoing, anticipated or future pre-clinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- continue to commercialize our two products, DUKORAL and IXIARO (marketed as JESPECT in Australia and New Zealand), and commercialize any current or future product candidate for which we may obtain marketing approval;
- invest in our manufacturing facilities;
- market and distribute vaccines for third parties, such as Bavarian Nordic;
- seek to discover and develop additional product candidates;
- maintain, protect and expand our intellectual property portfolio;
- hire additional sales, clinical, regulatory, administrative and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and current and future commercialization efforts;
- experience delays or interruptions to pre-clinical studies, clinical trials, our receipt of services from third-party service providers or our supply chain due to the ongoing COVID-19 pandemic or otherwise; and
- incur ongoing and additional costs associated with operating as a public company on both Euronext Paris and Nasdaq.

Our ability to be profitable in the future will largely depend on our ability to generate sales of our commercial products and to obtain regulatory 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 manufacturing and commercialization of our approved products, the pace and amount of our future expenditures and our ability to obtain funding through milestone or royalty payments under our license and collaboration agreements, equity or debt financings, strategic collaborations and government grants and tax credits. Additionally, our future revenues will depend upon the size of any markets in which our products or

product candidates have received approval, and market acceptance, reimbursement from third-party payors and market share. We expect that our main sources of income for the near- and medium-term will be revenue from sales of our approved products and third-party products, revenue from licensing and service agreements and grants.

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

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve or maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

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

DUKORAL and IXIARO are aimed at diseases that largely threaten travelers. If international travel does not resume as quickly or as much as anticipated as a result of the ongoing COVID-19 pandemic, this will continue to significantly adversely affect the sale of these vaccines.

DUKORAL and IXIARO are aimed at diseases that largely threaten travelers to particular regions. Due to the ongoing COVID-19 pandemic, travel has significantly decreased worldwide, and many countries have instituted travel restrictions and advisories. As a result, sales of these vaccines have decreased significantly, adversely impacting our financial results. If international travel does not resume as quickly or as much as anticipated as a result of the ongoing COVID-19 pandemic, our revenues will be significantly adversely affected, and we may not be able to continue the development of one or more of our vaccine candidates without additional financing. Additionally, if our chikungunya vaccine candidate receives regulatory approval and international travel has not resumed to expected levels at that point in time, sales of this vaccine may be less than expected, because we anticipate that it would 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 June 30, 2021 and December 31, 2020, we had total assets of €745.1 million and €449.2 million, respectively, including cash and cash equivalents of €329.8 million and €204.4 million, respectively. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of June 30, 2021, 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 ongoing COVID-19 pandemic environment generally. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We will need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well

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as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing pre-clinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review and approval of our product candidates;
- the costs and timing of current and future commercialization activities, including product manufacturing, marketing, sales and distribution, for our current products and any of our product candidates for which we receive marketing approval;
- the revenue received from commercial sales of our products and any product candidates for which we receive marketing approval, and the continued impact of the COVID-19 pandemic on such revenues;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company in both France and the United States; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for our product candidates in development. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we may need or choose to seek additional financing to achieve our business objectives.

The ongoing COVID-19 pandemic continues to evolve rapidly and has already resulted in a significant disruption of global financial markets. 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."

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

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

We are pursuing a vaccine candidate, VLA2001, to address the ongoing COVID-19 pandemic caused by the virus SARS-CoV-2. Our testing and development of VLA2001 remains ongoing, and we may be unable to produce a successful vaccine in a timely manner and in sufficient quantities, if at all.

We are committing substantial financial resources, particularly research and development expenses and investment in our manufacturing facilities and personnel, to the development of a potential vaccine for COVID-19, which may cause delays in or otherwise negatively impact our other development programs. Following the September 10, 2021 notice from the UK Authority with respect to termination of the UK Supply Agreement, as defined below, we have had to, and will need to continue to, assume a greater degree of investment in the VLA2001 development program. While we believe investing in research and development and our manufacturing facilities is crucial to the potential success of VLA2001, such capital commitments plus any future commitments, in aggregate, may, in the future, exceed our available cash and cash equivalents and short-term investments. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs.

Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and constantly evolving, as a result of which our vaccine candidate may not be sufficiently effective or meet the current needs of potential customers and global demand. Alternatively, the threat of SARS-CoV-2 or of a particular strain of the virus could significantly change, including due to increasing rates of vaccination with approved vaccines, which could lead to a decrease in demand for our vaccine candidate. If we do not successfully develop VLA2001 and receive regulatory approval, or if we fail to successfully manufacture or commercialize VLA2001 if approved, we may not be able to achieve a return on our investment. As of the date of this prospectus, we do not have any customer agreements in place for the supply of VLA2001, if approved. We are continuing to negotiate a supply agreement with the European Commission but cannot guarantee that such an agreement will be executed at all or in a timely manner. Further, even if we enter into supply agreements with the European Commission and other customers, there is no guarantee that initial demand for VLA2001, if approved, will be sustained or that we will be able to remain competitive in geographies where we may initially sell VLA2001. Pursuant to a provision of the supply agreement, or the UK Supply Agreement, with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom, or the UK Authority, we may be required to pay the UK Authority low single-digit percentage royalties in respect of sales of VLA2001 to non-UK customers in an amount not to exceed €100 million.

The speed at which multiple stakeholders are moving to create, test and approve a vaccine for COVID-19 is highly unusual and may increase the risks associated with traditional vaccine development. Given this accelerated timeline, we and regulators, such as the MHRA and EMA, may make decisions more rapidly than is typical. Evolving or changing plans or priorities of governments and regulatory bodies, including based on new knowledge of COVID-19, how the disease affects the human body and the longevity of protection given by existing vaccines, the identification of potential side effects and the resulting choices regarding the deployment of specific vaccines in various countries or in various age groups, may significantly affect our plans and pathways for clinical development, regulatory approval, manufacturing and commercialization of VLA2001.

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These processes are interconnected and there can be no guarantee that evolutions in one process will not impact one or more of the others. For example, health authorities have started to shift attention to the need for a booster vaccine regimen, and the use of VLA2001 as a booster would require separate clinical data and regulatory approval. As of the date of this prospectus, we are seeking to collect our own data on the use of VLA2001 as a booster but cannot provide any assurance that these data will be positive. In addition, we may seek to adapt VLA2001 to target different variants of the virus as the global pandemic evolves. If the VLA2001 product is modified to address a variant of SARS-COV-2, we may need to redevelop our manufacturing process, including clinical trial material, which could result in additional time and expense and divert our manufacturing resources away from production of the existing VLA2001 product. The regulatory path and manufacturing requirements for adaptations of VLA2001 are uncertain and could require substantial investment that we may not ultimately recover through our commercial efforts.

We face certain risks relating to clinical trials of VLA2001. Our Phase 3 clinical trial, Cov-Compare, is ongoing in the United Kingdom. In September 2021, we learned that the MHRA had conducted an audit of Public Health England, our partner in the collection of clinical trial data, and identified a quality assurance issue relating to an assay used by Public Health England. Final assay validation for proof of data integrity remains ongoing pursuant to a plan agreed with the MHRA. Until this validation is completed, we will be unable to submit our Cov-Compare data for regulatory approval. Additionally, our Cov-Compare Phase 3 clinical trial compares our vaccine candidate to AstraZeneca's AZD1222 (ChAdOx1-S). If we wanted to seek regulatory approval for VLA2001 in a jurisdiction that has not yet approved AZD1222, notably the United States, we would have to redesign the regulatory strategy, and we may be unable to rely solely on the VLA2001-301 trial results as the pivotal trial in support of a regulatory submission. Additional clinical trial requirements could require significant investment and time. Furthermore, VLA2001 was one of the vaccines evaluated in the Cov-Boost study conducted by University Hospital Southampton NHS Foundation Trust in the United Kingdom. Cov-Boost studied seven different COVID-19 vaccines for use as potential boosters and is the first trial in the world to conduct this type of comparative study. Data from Cov-Boost are expected to be published in October 2021. The results from the Cov-Boost trial will not serve as the basis for any regulatory approval we may eventually seek, and we are in the process of collecting our own data on VLA2001's effectiveness as a booster. Even though the primary vaccination results from our own Cov-Compare trial were positive, the results of the Cov-Boost study or our own booster studies may be less satisfactory, or may not compare favorably to other vaccines that are authorized or in development.

We also face substantial risks and uncertainties in the manufacture of VLA2001. Manufacturing vaccines is a complex process and it is not uncommon for yields to vary materially from plans. We cannot guarantee that we will be able to timely and effectively produce VLA2001 in adequate quantities to meet global demand and contractual obligations. We may choose to outsource a substantial amount of production of VLA2001 to third parties in order to meet demand or specific customer requirements, and there are additional risks inherent in outsourcing vaccine production, particularly in the context of VLA2001. For further information about these risks, see "—Risks Related to the Manufacture of Our Products and Product Candidates."

Furthermore, other parties have developed and are developing vaccines for COVID-19, some of which have already received regulatory approval and been widely distributed 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, adjuvanted whole virus vaccine candidate and other parties may also develop 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. We may be unable to commercialize VLA2001 and establish a competitive market share before the COVID-19 pandemic is contained or significantly diminished. If our competitors are successful in producing a more efficacious vaccine or other treatments for COVID-19, including for variants of
the virus and in the context of boosters, or if our competitors are able to manufacture and distribute any such vaccines or treatments with greater efficiency, there may be a diversion of potential governmental and other funding away from us and toward such other parties. Finally, we received the biological material that would be

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used to manufacture certain variant-based vaccines from Public Health England and would need to acquire a license in order to commercialize any vaccines derived from this material. 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.

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

In September 2020, we entered into the UK Supply Agreement with the UK Authority, pursuant to which we were to develop, manufacture and supply a COVID-19 vaccine to the UK Authority in the United Kingdom of Great Britain and Northern Ireland, or the UK. The UK Supply Agreement also included an obligation for us to upgrade our manufacturing facilities in Scotland.

Following the close of business on September 10, 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. We never received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, in the event of termination of the UK Supply Agreement on this basis, the UK Authority could be entitled to recover damages and funding provided to us under the UK Supply Agreement. In a worst case scenario, it could be argued that our liability under the UK Supply Agreement could range up to as high as all sums paid to us. As of June 30, 2021, the UK Authority had placed orders and provided advance and funding payments related to the development and manufacture of VLA2001 of £310 million (€350 million), reported as refund/contract liability specified below. However, we believe that, even in the unlikely event that the UK Authority is able to successfully demonstrate that it suffered loss as a consequence of an alleged anticipatory breach by us, it is considered remote that we would be held liable for any damages, let alone damages of such a magnitude. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We have acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective on October 10, 2021. The UK Supply Agreement provides that, in the case of termination for convenience by the UK Authority, we shall not be obliged to refund or repay any amount paid by the UK Authority. A royalty on sales and other obligations, as described below, may survive termination in certain circumstances.

We were still, and still are, completing the construction of our new manufacturing facility, Almeida, at our site in Livingston, Scotland; this project was largely funded through certain advance payments made by the UK Authority pursuant to the UK Supply Agreement. Unless a satisfactory resolution can be secured, we may not be able to complete this construction.

The UK Authority's termination of the UK Supply Agreement has substantially disrupted our business and VLA2001 development plans, and the evolving situation regarding a possible settlement or litigation could cause further and substantial harm to our business, financial condition, prospects and results of operations. In addition, following our announcement on September 13, 2021 of the termination of the UK Supply Agreement, a number

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of law firms in the United States have announced the commencement of "investigations" for possible violations of U.S. federal securities laws. As of the date of this prospectus, we have not received notice of any actual claims. See "Business—Material Agreements—UK Supply Agreement" for further detail on the terms of this agreement and its termination provisions.

We consider that the event of termination is a non-adjusting subsequent event under IAS10, as it arose after the end of the reporting period and is not indicative of conditions existing as of June 30, 2021. As of June 30, 2021, we were not in breach of our delivery obligations, nor had we received any notification from the UK Authority indicating concern that such a breach had occurred or would occur. Therefore, no impact was recorded on our financial position and results as of and for the period ended June 30, 2021.

As of June 30, 2021, the significant assets and liabilities relating to the COVID-19 vaccine program that could be impacted by the termination of the UK Supply Agreement are the following:

- Property, Plant and Equipment of €43.9 million.
- Advance payments paid to suppliers for raw materials of €46.9 million.
- Inventories of €94.9 million.
- Refund liabilities of €14.1 million related to potential royalty payments.
- Contract liabilities of €335.6 million.

The final terms of the termination, which we are discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and our future results of operations. The impact is uncertain as of the date of issuance of our unaudited interim condensed consolidated financial statements as of June 30, 2021

- Inventories and advance payments for inventories may be revalued to net realizable value. As changes in our business plan resulting from the termination of the UK Supply Agreement may have an impact on our manufacturing plan, a write-down of raw materials, work in progress and advance payments of raw materials of up to €141.8 million may be necessary. This depends on concomitant changes to the supply plan, marketing authorization, commercial traction and ability to extend the current shelf life (expiry dates) of our existing inventory.
- We believe that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay us certain amounts in respect of commitments that we had made prior to termination. Nevertheless, a provision regarding related onerous supplier and lease agreements may be needed depending on the outcome of the negotiations with the UK Authority and our suppliers.
- We are currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If we were to cease to use our COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, acquired with funds advanced by the UK Authority, we may have certain obligations to the UK Authority, such as a partial reimbursement of funding received, in respect of those assets if they are sold, disposed or repurposed.
- Depending on the final outcome of discussions with the UK Authority, some or all of our contract liabilities may be recorded as revenue or other income for an amount that is unknown at this time.
- The termination of the UK Supply Agreement is considered to be an impairment indicator and therefore an impairment test of the Property, Plant and Equipment dedicated to the COVID-19 vaccine program and other assets used for the COVID-19 vaccine program and other products will be performed as part of the December 2021 accounting closing process.
- Under the terms of the UK Supply Agreement, we are required to pay the UK Authority a royalty in respect of sales of our UK-manufactured vaccine to non-UK customers. This requirement may survive termination of the UK Supply Agreement, and the aggregate maximum royalty payable to the UK Authority is €100 million, of which €14.1 million is recognized as refund liability as of June 30, 2021.

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

In February 2020, we entered into a debt financing agreement, or the Financing Agreement, with Deerfield and OrbiMed. The loan bears interest at 9.95% that, due to the quarterly interest calculation method applied, results in an aggregate annual interest paid of 10.09%. As of June 30, 2021, we had €54.1 million drawn down in two tranches under the Financing Agreement.

As a result of deferred recognition of revenues and the effects of COVID-19 on product sales, we were previously at risk of not meeting the minimum revenue covenant under the Financing Agreement. In July 2020, we reached an agreement with our lenders that this minimum revenue covenant 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, if we were unable to pay the full amount due in case of certain events of default, our lenders could exercise their rights to take possession and dispose of the collateral, which includes substantially all of our intellectual property, securing the Financing Agreement for their benefit. Our business, financial condition and results of operations could be substantially harmed if this occurs.

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 Commission, FDA, or applicable regulatory agency. The time required to conduct clinical trials and obtain approval or other marketing authorizations by the European Commission, FDA and other regulatory authorities is unpredictable and typically takes many years and depends upon numerous factors, including the substantial discretion of the regulatory authorities. While the timeline for receiving conditional approval of VLA2001 may be shorter, long-term approval of VLA2001 will require additional time and expense. 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.

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Prior to obtaining approval to commercialize any product candidate in the European Economic Area, or EEA, the United States or any other geographies, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the EMA, FDA or other regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from pre-clinical studies and clinical trials can be interpreted in different ways. Even if we believe that the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the European Commission, FDA and other regulatory authorities. The EMA, FDA or other regulatory authorities may also require us to conduct additional pre-clinical studies or clinical trials for our product candidates either prior to or post-approval or may object to elements of our clinical development program, requiring their alteration. Approval by one regulatory authority does not guarantee approval by another regulatory authority on the basis of the same data or at all.

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

Even if we eventually complete clinical testing and receive approval of a biologics license application, or BLA, or foreign marketing application for our product candidates, the European Commission, FDA or other comparable regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The European Commission, FDA or other comparable regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the European Commission, FDA or other comparable regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay, inhibit or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the European Commission, FDA or other comparable regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, successful commercialization will depend on a number of factors. We may still need to develop a commercial organization to support commercialization of the product or allocate additional resources to our existing commercial organizations. We will also need to establish a commercially viable pricing structure, obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities, and generate knowledge of and demand for our products. Additionally, our current marketing strategy includes partnering with third parties for the commercialization of approved products in certain geographies, and we cannot guarantee that we will be able to enter into or maintain such relationships. If we are unable to successfully commercialize our product candidates, including through contracting with third parties, we may not be able to generate sufficient revenue to continue our business.

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

Success in pre-clinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Pre-clinical and proof-of-concept studies and Phase 1 clinical trials are primarily designed to test safety, to study

pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results of clinical trials and regulatory approval. There can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in pre-clinical studies, successful advancement through earlier clinical trials, or initial data that we may publish, which may materially change as clinical trials progress. In particular, success in clinical trials of VLA2001, such as our initial data from our Cov-Compare clinical trial, may show promise against a particular strain of the virus that causes COVID-19, but these results may not be indicative of VLA2001's potential efficacy against different strains. In October 2021, we announced positive topline results from the Phase 3 Cov-Compare trial, in which VLA2001 met both co-primary endpoints of the trial; however, a final assay validation required by the MHRA to verify the integrity of the data remains ongoing. Although Cov-Compare presented some indication of protection against cases of COVID-19 caused by recent variants of the virus (e.g. the Delta variant), further analysis or studies may be required to confirm such protection.

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

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

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

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the European Commission, FDA or other comparable regulatory authority, and we may never receive such approvals. The time required to obtain approval by the European Commission, FDA and other comparable regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.

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We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

- inability to generate sufficient pre-clinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on the design or implementation of our clinical trials;
- regulators or institutional review boards and ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays or failures by us or our manufacturing partners to comply with current good manufacturing practices, or cGMP;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for follow-up or we may fail to recruit suitable subjects to participate in a trial;
- difficulty collaborating with investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- clinical trials of our product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment or the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, such as the possibility of using VLA2001 as part of a booster regimen, which may require new or additional trials;
- evolution of the COVID-19 pandemic, including the emergence or dissipation of different strains of the virus;
- decisions made by us or requirements imposed by regulators to conduct additional clinical trials or abandon product development programs; or
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease, which already caused us to delay initiation of the Phase 3 clinical trial for VLA1553 (chikungunya), and could cause other or additional disruptions.

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

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

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

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources.

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

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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 already in the market and ongoing clinical trials of competing vaccine candidates for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the trial. In addition, enrollment and retention of subjects in clinical trials could be disrupted by man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease. In addition, public perception of vaccine safety issues may adversely influence willingness of subjects to participate in clinical trials. Additionally, granted EUAs may saturate the marketplace prior to our advancement or commercialization, as allowed, for any of the vaccine areas in which we are developing products.

We may also face particular challenges in enrolling subjects in clinical trials of VLA15, as Lyme disease is a seasonal disease. We may only have a short window each year in which to fully enroll subjects in a VLA15 clinical trial, and failure to enroll an adequate number of subjects, or any other delays in enrollment, could cause substantial delay in our VLA15 clinical program, as it could force us to wait another year for the applicable enrollment window for this disease.

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

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

A core element of our business strategy is to expand our product pipeline. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenue for many reasons, including the following:

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

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

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

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

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

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

We currently focus our efforts on commercialization of our approved products, IXIARO and DUKORAL for prevention of Japanese encephalitis and cholera, respectively, as well as development of our product candidates for the prevention of Lyme disease, chikungunya and COVID-19. Our estimated market opportunity, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our products and product candidates. Our estimates with respect to market opportunity are based on our beliefs, assumptions and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. In addition, the disease for which we are developing a product vaccine may cease to be a public health concern. Likewise, the potentially addressable patient population for each of our products or product candidates may be limited or may not be receptive to receiving our vaccines or vaccine candidates, and new patients may become increasingly difficult to identify or access. This may be due in part to reputational challenges that the vaccine industry is facing related to the growing momentum of the anti-vaccine movement in some regions or a distrust of vaccines against certain diseases or of the adjuvants contained in our vaccines. For example, there has been some negative public perception of Lyme disease vaccines as a result of the Lyme disease vaccine LYMErix, which was marketed by Smith Kline Beecham Biologicals and discontinued due to lack of market access and safety concerns, although it was later proven to be safe by an FDA advisory

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

committee. If the market opportunities for our products or product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

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

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

- research and development;
- pre-clinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.
- principal competitive factors in our industry include:
- the quality and breadth of an organization's technology;
- management of the organization and the execution of the organization's strategy;
- the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;
- an organization's intellectual property portfolio;
- the capabilities of an organization throughout the product pipeline, from target identification and validation to discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

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

We are aware of companies with vaccine candidates for Japanese encephalitis vaccines, cholera, and COVID-19. If and when these vaccines are available in the markets in which we compete, sales of our vaccines will be adversely affected. Competition is the primary factor affecting our prices outside the United States. We are also

aware of companies with active vaccine development programs for Lyme disease, chikungunya and COVID-19. 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, applicable product tracking and tracing requirements, and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the product. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval. Regulators may also subsequently limit or revise the indicated uses for which the product was originally marketed, which could significantly impact our sales. For example, the agency supervising pharmaceutical products in Canada, which is our principal market for DUKORAL, contacted us in July 2021 to request further information in support of DUKORAL's indications and labeling. If DUKORAL's indications or labeling were to change significantly in Canada, this could have a significant negative impact on our sales which in turn could result in the product no longer being economically viable.

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

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

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend 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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

The European Commission's, FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, in the EEA, the United States or elsewhere.

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

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

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

In the United States, violations of the Federal Food Drug 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

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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;

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

- 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 European Commission, FDA, or other government regulators; is not used in accordance with cost-effective treatment methods as determined by the third-party payor; or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third-parties is the biggest driver of the prices of our products. In the United States, we may be significantly adversely affected if the federal pricing rules change requiring a greater discount than the current minimum of 24% compared to non-federal average manufacturer price for products listed on the federal supply schedule.

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

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

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

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

reimbursement, the commercial success of our vaccine products may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

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

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

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

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

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

To date, we have obtained product liability insurance with a coverage amount of €40 million per claim per year. Our product liability insurance will need to be adjusted in connection with the commercial sales of our products and our product candidates, and may be unavailable in meaningful amounts or at a reasonable cost. We do not currently have product liability insurance that would cover our vaccine candidate against SARS-CoV-2. 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. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate

and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

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

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

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

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

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

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

developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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 information regarding payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year; and
- similar healthcare laws and regulations in the EU and other jurisdictions, such as state anti-kickback and false claims laws, including the French "Bertrand Law", French Ordinance n° 2017-49 of January 19, 2017 and Decree No. 2020-730 of June 15, 2020 relating to benefits offered by persons manufacturing or marketing health products or services, and the UK's Bribery Act 2010, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers or any company providing services related to their products that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

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

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development,

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Valneva SE Pursuant to 17 C.F.R. Section 200.83**

manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal or administrative sanctions, including exclusions from U.S. government-funded healthcare programs.

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

In the United States, the European Union and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will

remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and through subsequent legislation will remain in effect through 2030. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through December 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 until January 1, 2023. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN interim final rule. In July 2021, the Biden administration

released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. President Biden may take additional steps to address pharmaceutical product pricing. For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition.

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

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. For example, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

In some countries, the proposed pricing for a biopharmaceutical product must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of biopharmaceutical product is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU member state may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could have an adverse effect on demand for our product candidates. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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

We are subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, and authorities in the European Union and the United Kingdom, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

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

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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 the EEA or the United States, or from selling or importing products that infringe our patents in and into the EEA or the United States or other jurisdictions.

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

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The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in EEA countries, the United States and other jurisdictions. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. For example, two of our patents have been limited in scope in opposition proceedings in Europe. One of these opposed patents relates to vaccine compositions comprising an aluminum component with low heavy metal and copper impurities, and covers IXIARO. The other opposed patent covers VLA84. These decisions are under appeal, and the patents could ultimately be revoked. We would not expect that the potential revocation of the opposed patent to have a significant impact on further commercialization of IXIARO, because other patents protecting IXIARO exist and have not been opposed. Revocation of the opposed patent relating to VLA84 could limit our ability to stop others from commercializing a similar product to VLA84 and could dissuade third parties from collaborating with us to develop VLA84. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

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

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

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

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by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

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

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

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

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

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

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk may increase that our product candidates may give rise to claims of infringement

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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;

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

- 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

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

- 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.

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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 ongoing COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

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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.

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

Finally, we use third-party investigators to assist with conducting clinical trials. All clinical trials are subject to strict regulations and quality standards. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations. In addition, the ongoing COVID-19 pandemic and government measures taken in response have also had a significant impact on our collaborators, and we expect that they will face further disruption which may affect our ability to initiate and complete our pre-clinical studies and clinical trials.

Risks Related to the Manufacture of Our Products and Product Candidates

We may be unable to successfully scale up 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. We may encounter unexpected challenges relating to manufacturing efficiency and are currently unable to guarantee consistent quantity manufactured across batches. Many factors, including but not limited to the virus strains being targeted and whether VLA2001 may be used as a booster, may affect our manufacturing capacity. The process of developing additional manufacturing capacity is complex and affected by multiple external factors, many of which are beyond our control. We may in the future outsource a substantial amount of the manufacturing of VLA2001 to third parties, which could result in delays, concerns about manufacturing consistency, or other manufacturing failures. Per the standard industry practice, we rather than the third party provider would bear the risk of such problems. Delays in manufacturing or our inability to manufacture sufficient doses of VLA2001 could adversely affect our business, financial condition, prospects and results of operations. If we, or any third party manufacturing partners, are unable to manufacture sufficient quantities of VLA2001, we may not be able to fulfill our obligations under our existing agreements or may be forced to forego additional partnerships or supply agreements which would be advantageous for our business. 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. Furthermore, supply agreements that we may enter into with governments may include obligations to refund part or all of any up-front payments received if we are unable to supply the agreed quantities in time. If we are required to make such refunds, this could result in a material adverse impact on our business, prospects, financial condition, and results of operations.

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

Our manufacturing facilities in Livingston, Scotland, and Solna, Sweden, are, and we expect will continue to be, significant factors in growing our revenues from product sales and maintaining control over production costs. Our manufacturing facility in Livingston, Scotland is the sole source of commercial quantities of our Japanese encephalitis vaccine, will be the sole source of clinical materials for our chikungunya vaccine candidate and is currently the primary source of clinical materials for our COVID-19 vaccine candidate. Our manufacturing

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facility in Solna, Sweden, is the sole source of commercial quantities of DUKORAL and will perform the fill-finish of VLA2001. The destruction of either of these facilities by fire or other catastrophic events would prevent us from manufacturing the relevant product and supplying our customers or clinical trial centers, which would result in a material adverse impact on our business, prospects, financial condition and results of operations.

We 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. Additionally, in the biopharmaceutical industry, supplier changes require lengthy validation and regulatory approval processes. A loss of any CMO or component supplier and delay in establishing a replacement could delay our clinical development and regulatory approval process.

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

Our manufacturing facilities are subject to ongoing regulation and periodic inspection by national authorities, including the competent authorities of EEA countries, FDA and other regulatory bodies to ensure compliance with cGMP when producing batches of our products and product candidates for clinical trials. CROs and other third party research organizations must also comply with GLP when carrying out regulatory toxicology studies. Any failure to follow and document our or their adherence to such GMP and GLP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our products.

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

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

Any of the foregoing actions could be detrimental to our reputation, business, financial condition or operating results. Furthermore, we or our key suppliers may not continue to be in compliance with all applicable regulatory

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requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing authorization in the EEA, the United States or other jurisdictions, our suppliers will have to pass an inspection by the applicable regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such inspections, and the inspections and any necessary remediation may be costly. Failure to pass such inspections by us or any of our suppliers would adversely affect our ability to commercialize our products or product candidates in the EEA, the United States or other jurisdictions. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our production costs may be higher than we currently estimate.

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

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

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

In addition, if we decide to manufacture VLA2001 in new or different ways, such as to target different strains of the virus or as a booster, we may face unexpected production costs that could ultimately affect profitability. Should any of these risks materialize, this could have a material adverse effect our business, prospects, financial condition and results of operations.

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

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

If we fail to comply with applicable regulations, particularly those applicable to our BSL 3 classification, 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

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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 delicate, particularly because the complexity of biological mechanisms leads to variability in industrial yields, and also because the biological material being manufactured is very vulnerable to contamination. The manufacturing of biological materials is also heavily regulated by the competent authorities of EEA countries, FDA and other regulatory authorities. 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

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us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

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

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

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

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

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

In addition, an acquisition could result in shareholder litigation, which could be costly and time consuming and divert management’s attention and resources. For example, following the merger between Vivalis SA and Intercell AG in 2013, certain former Intercell shareholders initiated legal proceedings to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used for the non-departing shareholders who received Valneva shares in the merger. On February 8, 2021, the judicial committee in charge of these proceedings appointed an expert and requested that he give an opinion

on the exchange ratio applied to this latter group. On October 6, 2021, we received the expert's opinion. With respect to the exchange ratio, the expert confirmed the prior calculation used but also recommended the calculation of safety margins. If the judicial committee adopts this recommendation, the expert will need to provide further guidance on how such calculations should be made. There is some risk that the exchange ratio to be applied could be challenged following the calculation of such safety margins, which could result in a liability for which we have not made specific reserves. Additionally, the expert addressed the cash compensation paid to departing shareholders and recommended an increase in such compensation. If this increase is approved by the court, it would result in a liability lower than our current litigation reserves, which pertain to this plaintiff group specifically. The 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, 2020 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 ongoing COVID-19 pandemic. Future outbreaks of disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, could materially affect our operations globally and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business has been and could continue to be materially adversely affected by the effects of pandemics or epidemics, including the current outbreak of the current COVID-19 pandemic and future outbreaks of the disease. The ongoing COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including government orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. As a result, a large part of our workforce has been working remotely since March 2020 and uncertainty remains about whether and to what extent the governments of the countries where we operate will impose further restrictions that will impact our ability to fully reopen our offices. The effects of government-imposed quarantines and our work-from-home policies, including the evolving nature of such policies, may negatively impact productivity and production, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

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

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

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

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

The global 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 September 30, 2021, we had 768 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.

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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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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,

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imprisonment of company officials and public censure), civil claims, litigation, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, operations and financial performance. With substantial uncertainty over the interpretation and application of these laws, regulations and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in our efforts to do so.

The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. For example, in May 2018 the European Union General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect in the European Economic Area, or EEA. The GDPR imposes stringent data protection requirements for processing the information of individuals in (i) the EEA and (ii) the United Kingdom as the GDPR continues to form part of law in the United Kingdom, or the UK GDPR, (by virtue of Section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations)), the United Kingdom, and to date, has increased compliance burdens on us, such as requiring the following: processing personal data only for specified, explicit and legitimate purposes for which personal data were collected establishing a legal basis for processing personal data creating obligations for controllers and processors to appoint data protection officers in certain circumstances; increasing transparency obligations to data subjects for controllers (including presentation of certain information in a concise, intelligible and easily accessible form about how their personal data is used and their rights vis-à-vis that data and its use); introducing the obligation to carry out so-called data protection impact assessments in certain circumstances; establishing limitations on collection and retention of personal data through "data minimization" and "storage limitation" principles; establishing obligations to implement "privacy by design"; introducing obligations to honor increased rights for data subjects (such as rights for individuals to be "forgotten," rights to data portability, rights to object etc. in certain circumstances); formalizing a heightened and codified standard of data subject consent; establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; introducing obligations to agree to certain specific contractual terms and to take certain measures when engaging third party processors and joint controllers; introducing the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authority or authorities and affected individuals; and mandating the appointment representatives in the United Kingdom and/or European Union in certain circumstances. The processing of sensitive personal data, such as health information, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR increases our obligations with respect to clinical trials conducted in Europe (including the EEA, United Kingdom and Switzerland) by expressly expanding the definition of personal data to include "pseudonymized" or key-coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators.

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

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the EEA, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards allowing U.S. companies to import personal data from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of

Commerce. However, the EU-U.S. Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU, in a case known colloquially as "Schrems II." Following this decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on the viability of the Swiss-U.S. Privacy Shield as a future compliance mechanism for Swiss-U.S. data transfers. The CJEU's decision in Schrems II also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or other third countries that are not the subject of an adequacy decision of the European Commission. While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle in Schrems II, it made clear that reliance on those Clauses alone may not necessarily be sufficient in all circumstances. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data. In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and/or applicable European law, the decision in Schrems II and subsequent draft guidance from the European Data Protection Board, or EDPB, would require the parties to that transfer to implement certain supplementary technical, organizational and/or contractual measures to rely on the Standard Contractual Clauses as a compliant "transfer mechanism." However, the EDPB recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data, adopted on November 10, 2020 conclude that no combination of such measures could be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data "in the clear" to recipients in countries where the power granted to public authorities to access the transferred data goes beyond that which is "necessary and proportionate in a democratic society" – which may, following the CJEU's conclusions in Schrems II on relevant powers of United States public authorities and commentary in that draft EDPB guidance, include the United States in certain circumstances (e.g., where Section 702 of the US Foreign Intelligence Surveillance Act applies). At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. However, the Court of Justice of the European Union recently invalidated the EU-U.S. Privacy Shield. The decision in Schrems II also affects transfers from the United Kingdom to the United States. As such, if we are unable to implement a valid solution for personal data transfers from Europe, including, for example, obtaining individuals' explicit consent to transfer their personal data from Europe to the United States or other countries, we will face increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to import personal data from the EEA, United Kingdom or Switzerland may also restrict our clinical trials activities in Europe; limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

The GDPR applies across the EEA and, by virtue of the UK GDPR in the United Kingdom, in a broadly uniform manner. However, the GDPR provides that EEA countries may make their own further laws and regulations to introduce specific requirements related to the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes and genetic information; as well as personal data related to criminal offences or convictions – in the United Kingdom, the United Kingdom Data Protection Act 2018 complements the UK GDPR in this regard. This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and/or United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use and share data in the context of our

EEA and/or United Kingdom establishments (regardless of where any processing in question occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

Further, the United Kingdom's vote in favor of exiting the European Union, often referred to as Brexit, and ongoing developments in the United Kingdom have created uncertainty with regard to data protection regulation in the United Kingdom. Following the United Kingdom's withdrawal from the European Union on January 31, 2020, pursuant to the transitional arrangements agreed to between the United Kingdom and European Union, the GDPR continued to have effect in law in the United Kingdom, and continued to do so until December 31, 2020 as if the United Kingdom remained a Member State of the European Union for such purposes. Following December 31, 2020, and the expiry of those transitional arrangements, the data protection obligations of the GDPR continue to apply to United Kingdom related to processing of personal data in substantially unvaried form and fashion under the UK GDPR. However, going forward, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and EEA. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains unclear. However, on June 28, 2021, the European Commission adopted an adequacy decision in relation to the United Kingdom. This decision permits personal data to flow freely from the EEA to the United Kingdom where it benefits from an essentially equivalent level of protection to that guaranteed under EU law. This adequacy decision has, however, a limited duration of four years, meaning that the decision will automatically expiry after this period. After expiry of the period, the adequacy decision will be renewed only if the United Kingdom continues to ensure an adequate level of data protection. Additionally, as noted above, the United Kingdom has transposed the GDPR into United Kingdom domestic law by way of the UK GDPR with effect from in January 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

It is possible that the GDPR or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations. Furthermore, other jurisdictions outside the 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 the EEA countries, the European Commission, EMA, FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in Europe, the United States and elsewhere and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

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

As a company with research and development activity, we benefit from certain tax advantages, including the Austrian Research and Development tax credit and the French Research Tax Credit (*Crédit Impôt Recherche*), which are tax credits aimed at stimulating research and development. Our Austrian Research and Development tax credits were €8.9 million and €4.4 million for the years ended December 31, 2020 and 2019, respectively. Our French Research Tax Credits were €1.1 million and €1.9 million for the years ended December 31, 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 €529.5 million and €457.0 million for the years ended December 31, 2020 and 2019, respectively. Applicable French law provides that, for fiscal years ending after December 31, 2012, the use of these tax losses is limited to €1.0 million, plus 50% of the portion of net earnings exceeding this amount. The unused balance of the tax losses in application of such rule can be carried forward to future fiscal years, under the same conditions and without time restriction. There can be no assurance that future changes to applicable tax law and regulation will not eliminate or alter these or other provisions in a manner unfavorable to us, which could have an adverse effect on our business, prospects, financial condition, cash flows or results of operations.

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

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

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

Furthermore, as part of Congress’ response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the CARES Act was enacted on March 27, 2020. Both

the FFCR Act and the CARES Act contain numerous tax provisions. Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately alter the impact of these laws on our business and financial condition.

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

Our business may be exposed to foreign exchange risks.

We operate internationally and are exposed to foreign exchange risks arising from various currencies, primarily with respect to the Euro (EUR), the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK) and the U.S. Dollar (USD). Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations. Because a substantial part of sales are generated in the United States for IXIARO, with production costs in GBP, and in Canada for DUKORAL, with production costs in SEK, we are exposed to foreign exchange risks, principally with respect to the USD, GBP, SEK and CAD. We have entered into currency option contracts to limit the risk of foreign exchange losses. However, our results of operations continue to be impacted by exchange rate fluctuations. For example, a substantial part of our sales are generated in the United States for IXIARO, with production costs in GBP, and in Canada for DUKORAL, with production costs in SEK. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. For example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euro at a reduced value. While we entered into currency option contracts in 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.

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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 ($ per ADS) in the net tangible book value after giving effect to the global offering at an assumed offering price of € per ordinary share (corresponding to $ per ADS in the U.S. offering based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 2021, 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 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.

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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 September 30, 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 Bank Europe SE 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 issued 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.

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

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

We are a European public company with limited liability (*Societas Europaea* or SE), with our 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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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;

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

- 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 years ended December 31, 2020 and 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. As of June 30, 2021, we had not yet completed remediation of these material weaknesses. 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 are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year. Accordingly, there is less publicly available information concerning our company than there would be if we were not a foreign private issuer.

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

As a foreign private issuer listed on Nasdaq, we are subject to Nasdaq's corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of its home country. Some corporate governance practices in France may differ significantly from Nasdaq corporate governance listing standards. We intend to continue to rely on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq corporate governance standards, to the extent possible. For example, neither the corporate laws of France nor our bylaws require a majority of our Supervisory Board members to be independent and although the corporate governance code to which we currently refer (the Middlenext code) recommends that, in a widely-held company like ours, a majority of the Supervisory Board members be independent (as construed under such code), this code only applies on a "comply-or-explain" basis and we may in the future either decide not to apply this recommendation or change the corporate code to which we refer. Furthermore, we could include non-independent members of the Supervisory Board as members of our nomination and compensation committee, and our independent Supervisory Board members would not necessarily hold regularly scheduled meetings at which only independent members of the Supervisory Board are present. Currently, we intend to continue to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. 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

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company. We would cease to be an emerging growth company upon the earliest to occur of (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates; (3) the issuance, in any three year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (4) December 31, 2026.

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

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made on June 30, 2022. In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our Management Board or Supervisory Board are residents or citizens of the United States, we could lose our foreign private issuer status. We estimate that following the closing of this global offering, approximately % 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 and all current holders of ADSs are residents of the United States).

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

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

Under the Code, a non-U.S. company will be considered a passive foreign investment company, or PFIC, for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the 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.

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We do not believe that we were characterized as 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

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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.

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- adverse results or delays in our or any of our competitors' pre-clinical studies or clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination or amendment of a strategic alliance, partnership or collaboration or the inability to establish additional strategic alliances, partnerships or collaborations;

- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- ordinary share and ADS price and volume fluctuations attributable to inconsistent trading volume levels of our ordinary shares and ADSs;
- price and volume fluctuations in trading of our ordinary shares on Euronext Paris;
- additions or departures of key management or scientific personnel;
- regulatory or legal developments in the United States, European Union and other countries;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent and other intellectual property protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

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

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

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

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

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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, pre-clinical studies and regulatory submissions;
- expected benefits of our approach to vaccine development, particularly with respect to our vaccine candidates in development;
- the potential safety and effectiveness of our vaccine candidates in development and, with respect to VLA2001, the potential for this vaccine candidate to complement other COVID-19 vaccines, particularly in special target populations, or to be used as a booster;
- our ability to successfully develop and advance our pipeline of product candidates;
- our expectations and forecasts for sales of our approved products;
- the present and future effects of the COVID-19 pandemic on our sales and operations, including our expectations and assumptions regarding the resumption of travel and the future demand for travel vaccines;
- the effectiveness and profitability of our collaborations and partnerships, our ability to maintain our current collaborations and partnerships and our ability to enter into new collaborations and partnerships;
- our expectations related to future milestone and royalty payments and other revenue under our collaborations and partnerships;
- our ability to safely and effectively scale up our manufacturing capabilities and supply a sufficient quantity of our products and product candidates, particularly with respect to our development of a COVID-19 vaccine;
- our ability to meet our obligations under our various collaboration, partnership and distribution arrangements;
- the potential impacts to us of the termination of the UK Supply Agreement, including impacts to our financial position;
- the timing or likelihood of regulatory filings and approvals, including the potential eligibility to receive a Priority Review Voucher for VLA1553;
- estimates of market opportunity for our approved products and vaccine candidates;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to obtain, maintain, protect and enforce our intellectual property rights and propriety technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- regulatory developments in the United States, Europe and other countries;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and stock performance;
- our expected use of proceeds of the global offering; and

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- 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.

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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 ordinary share (corresponding to $ per ADS based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 2021, after deducting estimated underwriting commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase additional 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 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 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 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 $ to fund further development of our COVID-19 VLA2001 vaccine candidate through ;
- approximately $ to fund further development of our Lyme VLA15 vaccine candidate through ;
- approximately $ to fund further development of our chikungunya VLA1553 vaccine candidate through ;
- approximately $ to invest in growing our preclinical pipeline; and
- any remaining amounts to fund working capital and 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 June 30, 2021, we had cash and cash equivalents of €329.8 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

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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.

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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.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2021 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 offering price of € per ordinary share (corresponding to $ per ADS based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 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 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 June 30, 2021**	
	Actual	**As Adjusted**
Cash and cash equivalents	€ 329,766	€
Liabilities—current portion	456,917	
Liabilities—non-current portion	211,119	
Total liabilities	€ 668,037	€
Share capital	14,986	
Share premium	328,688	
Other reserves	53,344	
Retained earnings (accumulated deficit)	(233,549)	
Profit (loss) for period	(86,399)	
Total shareholders' equity	€ 77,070	€
Total capitalization	€ 745,107	€

Each $1.00 (€) increase or decrease in the assumed offering price of $ per ADS (€ per ordinary share) 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 June 30, 2021 was €42.6 million ($50.5 million based on the exchange rate of €1.00 = $1.1848 as of June 30, 2021), or €0.43 per ordinary share (equivalent to $1.01 per ADS). 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 our ordinary shares outstanding as of June 30, 2021.

After giving effect to our sale of ordinary shares (including ordinary shares in the form of ADSs) in the global offering, based on an assumed offering price of € per ordinary share (corresponding to $ per ADS based on the exchange rate of €1.00 = $ as of , 2021), the last reported sale price of our ordinary shares on Euronext Paris on October , 2021, and after deducting estimated underwriting commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at June 30, 2021 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 June 30, 2021	
	Per Ordinary Share	Per ADS
Offering price	€	$
Historical net tangible book value per ordinary share or ADS	€0.43	$1.01
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 ADS (€ per ordinary share) 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 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

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 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 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 (including in the form of ADSs) purchased from us by our existing shareholders (translated into U.S. dollars at an exchange rate of €1.00 = $) as of June 30, 2021 and by new investors participating in this global offering based on an assumed offering price of € per ordinary share in the European private placement and $ per ADS in the U.S. offering, and before deducting estimated underwriting commissions and estimated offering expenses payable by us.

	Ordinary Shares (including in the form of ADSs) Purchased from Us		Total Consideration		Average Price per Ordinary Share
	Number	Percent	Amount	Percent	
Existing shareholders as of June 30, 2021	99,780,591	%	€ (1)	%	€
New investors		%	€	%	€
Total		**100.0%**	**€**	**100.0%**	

(1) Of which €100.6 million relates to consideration arising from the merger with Intercell AG in 2013.

If the underwriters exercise their option to purchase additional 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 99,760,077 ordinary shares outstanding as of June 30, 2021 and excludes:

- 40,625 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*), including 6,250 ordinary shares issued upon exercise of equity awards subsequent to June 30, 2021;
- 4,052,937 ordinary shares issuable upon exercise of outstanding stock options;
- 1,842,404 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,012,706 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.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated statement of income (loss) data for the years ended December 31, 2020 and 2019 have been derived from our audited consolidated financial statements as of and for the years ended December 31, 2020 and 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.

The following selected condensed consolidated statement of income (loss) data for the six months ended June 30, 2021 and 2020 and summary condensed consolidated statement of financial position data as of June 30, 2021 have been derived from our unaudited interim condensed consolidated financial statements as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 were prepared in accordance with IAS 34, Interim Financial Reporting, the standard of IFRS as issued by the IASB applicable to interim financial statements.

Our historical results and the results for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or for any periods in the future. You should read this selected 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)	**Six Months ended June 30,**		**Year ended December 31,**	
	2021	**2020**	**2020**	**2019**
Product sales	€ 31,762	€ 40,942	€ 65,938	€129,511
Revenues from collaboration, licensing and services	15,740	6,965	44,383	(3,315)
Total revenues	€ 47,502	€ 47,907	€110,321	€126,196
Cost of goods and services	(34,778)	(22,546)	(54,302)	(52,781)
Research and development expenses	(78,737)	(33,081)	(84,454)	(38,022)
Marketing and distribution expenses	(9,643)	(10,046)	(18,264)	(24,145)
General and administrative expenses	(20,904)	(10,615)	(27,539)	(18,398)
Other income and expenses, net	10,389	6,453	19,117	6,338
Operating profit (loss)	€(86,172)	€(21,928)	€(55,120)	€ (811)
Finance income	8,962	549	689	1,449
Finance expense	(8,431)	(6,109)	(10,738)	(3,082)
Result from investments in associates	(90)	90	(133)	1,574
Profit (loss) before income tax	€(85,730)	€(27,398)	€(65,302)	€ (870)
Income tax income (expense)	(668)	1,759	909	(874)
Profit (loss) for the period	€(86,399)	€(25,639)	€(64,393)	€ (1,744)
Earnings (losses) per share – basic	€ (0.91)	€ (0.28)	€ (0.71)	€ (0.02)
Earnings (losses) per share – diluted	€ (0.91)	€ (0.28)	€ (0.71)	€ (0.02)

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Consolidated Statement of Financial Position Data:

€ in thousands	**As of June 30, 2021**
Cash and cash equivalents	€ 329,766
Total assets	745,107
Total liabilities	668,037
Total shareholders' equity	77,070

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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 years ended December 31, 2020 and 2019 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. The audit report on the consolidated financial statements includes an explanatory paragraph referring to the adoption of IFRS 16 Leases.

Our unaudited interim condensed consolidated financial statements as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 were prepared in accordance with IAS 34, Interim Financial Reporting, the standard of IFRS applicable to interim financial statements.

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

Overview

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

Our clinical portfolio is composed of a number of highly differentiated vaccine candidates that are designed to provide preventative solutions to diseases with high unmet need. Our lead program, VLA15, is a Phase 2 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease, under development in collaboration with Pfizer, and it is the only active vaccine candidate against Lyme disease currently undergoing clinical trials. VLA15 targets the six most prevalent serotypes, or variations, of Borrelia in the United States, where approximately 476,000 people are diagnosed with Lyme disease each year and in Europe, where at least a further 200,000 cases occur annually. Our clinical portfolio also includes VLA1553, targeting the chikungunya virus, which has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. VLA1553 is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data.

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 whole virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could be adapted to offer protection against mutations of the virus.

In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S), in terms of geometric mean titer, or GMT, for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. We commenced our rolling submission and review process with the MHRA in August 2021 and expect to incorporate our positive Phase 3 topline results in November 2021. We believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022.

We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in 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 the Nasdaq Global Select Market and Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior executive team has more than 100 years of combined experience spent working at industry leaders such as Novartis, Chiron, Acambis, GlaxoSmithKline and Daiichi Sankyo.

Since our inception as Vivalis in 1998, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, establishing our commercial infrastructure, growing our commercial portfolio, establishing and advancing our manufacturing capabilities and conducting pre-clinical studies and clinical trials. As of June 30, 2021, we had €329.8 million in cash and cash equivalents.

Our operating losses were €55.1 million and €0.8 million for the years ended December 31, 2020 and 2019, respectively, and €86.2 million and €21.9 million for the six months ended June 30, 2021 and 2020, respectively. Our net losses were €64.4 million and €1.7 million for the years ended December 31, 2020 and 2019, respectively, and €86.4 million and €25.6 million for the six months ended June 30, 2021 and 2020, respectively. We expect to continue to incur significant operating expenses and net losses for the foreseeable future.

Factors Affecting Our Results

We believe that our financial performance has been and for the foreseeable future will continue to be primarily driven by the factors discussed below. While many of these factors present opportunities for our business, they also pose challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described under the heading "Risk Factors" included elsewhere in this prospectus.

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Revenues

We principally derive our revenues from the sale of our commercialized travel vaccines, DUKORAL and IXIARO, in their respective markets and from the sale of third-party products. We also derive revenues from partnerships related to our vaccine candidates, as well as from collaborations, services and licensing agreement and by offering our technologies and services to third parties. We report revenues under four segments: commercialized products, COVID, vaccine candidates and technologies and services, although the COVID segment has not generated any revenue yet. 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 56.0% and 99.5% of our revenues for the years ended December 31, 2020 and 2019, respectively, and 66.9% and 85.5% of our revenues for the six months ended June 30, 2021 and 2020, respectively. In 2019, total revenue included a negative revenue of €10.7 million related to the June 2019 mutual agreement to terminate our Strategic Alliance Agreement, or SAA, with GlaxoSmithKline Biologicals SA, or GSK, originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively) as further discussed below. We primarily sell IXIARO in the United States, Canada and Germany and DUKORAL in Canada.

In addition, we generate revenues by leveraging our existing sales and marketing infrastructure to sell third-party products. Revenues from sales of third-party products represented 3.8% and 3.1% of our revenues for the years ended December 31, 2020 and 2019, respectively, and 12.5% and 0.8% of our revenues for the six months ended June 30, 2021 and 2020, respectively.

In June 2020, we entered into a distribution agreement with Bavarian Nordic, pursuant to which we agreed to commercialize Bavarian Nordic's marketed vaccines for rabies and tick-borne encephalitis, leveraging our commercial infrastructure in Canada, the United Kingdom, France and Austria. This agreement had no material financial impact on the consolidated financial statement as of and for the year ended December 31, 2020. In the six months ended June 30, 2021, we recognized €4.7 million of revenue from sales of Bavarian Nordic's vaccines.

Sales trends in travel vaccines are primarily driven by travel volume to endemic regions, national travel advisories, awareness about the illness and the perception of risk by health practitioners and tourists. A COVID-19-driven travel reduction accounted for a material reduction in our revenues for the year ended December 31, 2020 compared to the year ended December 31, 2019. According to the United Nations World Tourism Organization or UNWTO, Asia and the Pacific, the first region to suffer the impact of the pandemic and the region with the highest level of travel restrictions still in place to date, experienced an 84% decrease in arrivals from international flights from January to December 2020.

While COVID-19 has adversely affected sales of our travel vaccines to the general public, sales of IXIARO to the U.S. Government Department of Defense, or DLA, which purchases our Japanese encephalitis vaccine for military personnel being deployed to endemic regions, have remained significant over the periods presented herein. In September 2020, DLA awarded us a new contract for the supply of IXIARO. The terms of the agreement contemplate an initial base year followed by two option years, each with a range of minimum and maximum potential dose orders. In September 2021, we announced that DLA exercised the first year option of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option which remains unchanged, compared to a minimum value of $135 million in the initial agreement. For the years ended December 31, 2020 and 2019, 52.6% and 37.0%, respectively, of our total product sales were from sales of IXIARO to the DLA. For the six months ended June 30, 2021 and 2020, 70.2% and 40.9%, respectively, of our total product sales were from sales of IXIARO to the DLA.

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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 June 30, 2021 and December 31, 2020, we have recognized €90.0 million and €81.9 million, respectively, as discounted refund liabilities. In addition, €5.6 million and €31.6 million was recognized as revenues from collaboration, licensing and services during the six months ended June 30, 2021 and the year ended December 31, 2020, respectively. As of June 30, 2021 and December 31, 2020, €3.0 million and €2.8 million, respectively, in contract costs were included in other assets, and €0.9 million and €0, respectively, were included in contract liabilities.

Revenues from Technologies and Services

We also derive revenues from our technologies and services. Revenues from our technologies consists of revenues from our EB66 cell line, which is derived from duck embryonic stem cells and provides an alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines, and our IC31 vaccine adjuvant, which is a synthetic adjuvant targeting antigens to improve immune response and has been licensed to several pharmaceutical companies. Services revenues consist of research and development services we provide to third parties, including process and assay development, production and testing of clinical trial material.

UK Supply Agreement Termination

In September 2020, we entered into a supply agreement, or the UK Supply Agreement, with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom, or the UK Authority, pursuant to which we were to develop, manufacture and supply a COVID-19 vaccine to the UK Authority in the United Kingdom of Great Britain and Northern Ireland, or the UK. As part of the UK Supply Agreement, it was agreed that a significant amount of the government advance funding to be provided by the UK Authority would be used to upgrade our manufacturing facilities in Scotland. Funding for UK-based clinical trials was agreed to in a separate, linked Clinical Trial Agreement. This Clinical Trial Agreement has not been terminated and we reported positive topline Phase 3 clinical trial results on October 18, 2021.

Following the close of business on September 10, 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. We never received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, in the event of termination of the UK Supply Agreement on this basis, the UK Authority could be entitled to recover damages and funding provided to us under the UK Supply Agreement. In a worst case scenario, it could be argued that our liability under the UK Supply Agreement could range up to as high as all sums paid to us. As of June 30, 2021, the UK Authority had placed orders and provided advance and funding payments related to the development and manufacture of VLA2001 of £310 million (€350 million), reported as refund/ contract liability specified below. However, we believe that, even in the unlikely event that the UK Authority is able to successfully demonstrate that it suffered loss as a consequence of an alleged anticipatory
breach by us, it is considered remote that we would be held liable for any damages, let alone damages of such a

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magnitude. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We have acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective on October 10, 2021. The UK Supply Agreement provides that, in the case of termination for convenience by the UK Authority, we shall not be obliged to refund or repay any amount paid by the UK Authority. A royalty on sales and other obligations, as described below, may survive termination in certain circumstances.

We were still, and still are, completing the construction of our new manufacturing facility, Almeida, at our site in Livingston, Scotland; this project was largely funded through certain advance payments made by the UK Authority pursuant to the UK Supply Agreement. Unless a satisfactory resolution can be secured, we may not be able to complete this construction.

We consider that the event of termination is a non-adjusting subsequent event under IAS10, as it arose after the end of the reporting period and is not indicative of conditions existing as of June 30, 2021. As of June 30, 2021, we were not in breach of our delivery obligations, nor had we received any notification from the UK Authority indicating concern that such a breach had occurred or would occur. Therefore, no impact was recorded on our financial position and results as of and for the period ended June 30, 2021.

As of June 30, 2021, the significant assets and liabilities relating to the COVID-19 vaccine program that could be impacted by the termination of the UK Supply Agreement are the following:

- Property, Plant and Equipment of €43.9 million.
- Advance payments paid to suppliers for raw materials of €46.9 million.
- Inventories of €94.9 million.
- Refund liabilities of €14.1 million related to potential royalty payments.
- Contract liabilities of €335.6 million.

The final terms of the termination, which we are discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and our future results of operations. The impact is uncertain as of the date of issuance of our unaudited interim condensed consolidated financial statements as of June 30, 2021:

- Inventories and advance payments for inventories may be revalued to net realizable value. As changes in our business plan resulting from the termination of the UK Supply Agreement may have an impact on our manufacturing plan, a write-down of raw materials, work in progress and advance payments of raw materials of up to €141.8 million may be necessary. This depends on concomitant changes to the supply plan, marketing authorization, commercial traction and ability to extend the current shelf life (expiry dates) of our existing inventory.
- We believe that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay us certain amounts in respect of commitments that we had made prior to termination. Nevertheless, a provision regarding related onerous supplier and lease agreements may be needed depending on the outcome of the negotiations with the UK Authority and our suppliers.
- We are currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If we were to cease to use our COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, acquired with funds advanced by the UK Authority, we may have certain obligations to the UK Authority, such as a partial reimbursement of funding received, in respect of those assets if they are sold, disposed or repurposed.

- Depending on the final outcome of discussions with the UK Authority, some or all of our contract liabilities may be recorded as revenue or other income for an amount that is unknown at this time.
- The termination of the UK Supply Agreement is considered to be an impairment indicator and therefore an impairment test of the Property, Plant and Equipment dedicated to the COVID-19 vaccine program and other assets used for the COVID-19 vaccine program and other products will be performed as part of the December 2021 accounting closing process.
- Under the terms of the UK Supply Agreement, we are required to pay the UK Authority a royalty in respect of sales of our UK-manufactured vaccine to non-UK customers. This requirement may survive termination of the UK Supply Agreement, and the aggregate maximum royalty payable to the UK Authority is €100 million, of which €14.1 million is recognized as refund liability as of June 30, 2021.

In 2020 and the six months ended June 30, 2021, no revenue was recognized as a result of this collaboration. As of June 30, 2021 and December 31, 2020, we booked €335.6 million and €87.0 million, respectively, in contract liabilities and €14.1 million and €20.9 million, respectively, in refund liabilities.

Key Cost Drivers

Research and Development

We generate a significant amount of research and development expenses due to the nature of our business. Research and development expenses were €84.5 million and €38.0 million for the years ended December 31, 2020 and 2019, respectively, and €78.7 million and €33.1 million for the six months ended June 30, 2021 and 2020, respectively. Research and development expenses generally track development of our underlying product candidate portfolio. Investment in research and development is required to support advancing programs through increasingly expensive stages of clinical development.

We have seen increased research and development costs in 2021 as we invest in development of our COVID-19 vaccine candidate (VLA2001), continue our Phase 3 clinical trial for our chikungunya vaccine (VLA1553) and commence our Phase 3 clinical trial for our Lyme vaccine candidate (VLA15). Under our agreement with Pfizer, we are obligated to contribute 30% of all ongoing and future Lyme vaccine candidate development costs through completion of the development program expected in 2025.

Marketing and Distribution

We have developed an established commercial infrastructure that is dedicated to promoting and selling our products and educating physicians and travelers about our products and the diseases they target. We are continually investing in our commercial infrastructure and have identified markets where we can increase our sales and marketing efforts and market penetration. We have also been able to leverage our commercial infrastructure for third-party product distribution.

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

Cost of Goods and Services

Historically, manufacturing costs have experienced limited cost increases. Manufacturing costs comprise site infrastructure, employees to operate the manufacturing and the bill of materials. Incremental cost increase is driven by the variable cost in the bill of materials. We plan to manufacture our chikungunya vaccine candidate at our facilities in Livingston. We anticipate we will need limited additional infrastructure and employees for this program, and that we will incur relatively low raw materials costs.

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Our facility in Livingston, Scotland is currently the primary manufacturer of our COVID-19 vaccine candidate, and fill-finishing activities will take place at our facilities in Solna, Sweden. As part of our broader COVID-19 response, we have invested in both of these manufacturing facilities, including through an expansion of the Livingston facility as part of the supply agreement with the United Kingdom.

General and Administrative Expenses

General and administrative expenses have increased as we have become a more complex organization, requiring more corporate support. We have also seen an increase in stock-based compensation expense as we have increased our headcount and the issuance of share based compensation to employees and the Management Board. Furthermore, stock-based compensation related social security expenses are driven by the development of our company's share price.

Grants

We seek grants from governmental agencies and non-governmental organizations to partially offset our increasing research and development costs. Grant income, which is recorded in other income, decreased from €3.0 million to €1.1 million for the six months ended June 30, 2021 as compared to the prior year period, in part due to recognition of €1.1 million of negative grant income in the six months ended June 30, 2021 related to our funding agreement with the Coalition for Epidemic Preparedness Innovations, or CEPI. Grant income increased from €1.9 million to €7.7 million for the year ended December 31, 2020 as compared to the prior year period. In the six months ended June 30, 2021 as well as the year ended December 31, 2020, we received grants related to the COVID-19 pandemic situation from various governments.

In July 2019, we entered into a funding agreement with the CEPI pursuant to which we are eligible to receive up to $23.4 million (paid in a series of six-month tranches) for vaccine manufacturing and late-stage clinical development of a single-dose live attenuated vaccine against chikungunya (VLA1553) in return for equitable access to project results. We are obligated to pay CEPI up to $7.0 million in commercial and related milestones. See "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, and proceeds in USD from our Nasdaq offering in May 2021, we are exposed to foreign exchange risks, principally with respect to the U.S. Dollar, or USD, GBP, SEK and the Canadian dollar, or CAD. We have entered into currency option contracts to limit the risk of foreign exchange losses. However, our results of operations continue to be impacted by exchange rate fluctuations.

Impact of COVID-19

The COVID-19 pandemic has had a number of significant impacts on our business since March 2020. Notably, we initiated development of a COVID-19 vaccine candidate and announced a COVID-19 vaccine partnership with the UK Government. However, COVID-19 has adversely impacted sales of our travel vaccines to the general public, with travel to endemic areas significantly reduced compared to 2019 and our sales and marketing team unable to travel. DUKORAL and IXIARO are aimed at diseases that primarily threaten travelers to particular regions. As a result, sales of these vaccines have decreased significantly, adversely impacting our financial results. We expect to remain impacted by the significant reduction in international travel following the onset of the global COVID-19 pandemic. Therefore, as a result of COVID-19, for the six months ended June 30,

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2021 and the year ended December 31, 2020, €4.3 million and €7.4 million, respectively, of the write-down we included in our income statement was due to lower sales expectations and limited shelf life of finished goods. As a result of a related manufacturing stoppage for IXIARO and DUKORAL in the third quarter of 2020, idle capacity costs were not capitalized.

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

For more information as to the risks associated with COVID-19, see 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.
- “**COVID**” — development, manufacturing and distribution related to our COVID-19 vaccine candidate, VLA2001.
- “**Vaccine candidates**” — proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding our COVID-19 vaccine candidate, VLA2001.
- “**Technologies and services**” — services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements.

Prior to January 1, 2021, we reported in three segments—commercialized products, vaccine candidates and technologies and services. With the transfer of the license of our VLA15 Lyme vaccine candidate to Pfizer in

December 2020, all related revenues and costs were moved from the vaccine candidates segment to the technologies and services segment for periods from January 1, 2021 onward.

As of January 1, 2021, given the materiality of our COVID-19 business in 2021, we introduced a "COVID" segment covering all activities related to the development, manufacturing and distribution of our COVID-19 vaccine candidate, VLA2001.

As of January 1, 2021, we changed our internal reporting process and amended the following allocation rule: general and administrative costs previously reported under "corporate overhead" have been fully allocated to the four operational segments based on three criteria (each equally weighted): (1) revenues, (2) research and development spend and (3) full-time equivalent personnel. The allocation of local general and administrative costs is based on the above criteria measured on the local level, whereas the allocation of global functional general and administrative costs is based on global key criteria. We also monitor our general and administrative expenses dedicated to corporate projects. Any project which (1) is material in spend, (2) is one-time in nature and (3) supports the entire business remains reported under Corporate Overhead. In 2021, the major item included in Corporate Overhead was costs related to our Nasdaq offering. Segment reporting information for earlier periods have been amended to conform to these changes. The change in segments had no impact on our historical consolidated financial position, results of operations or cash flows, as reflected in the reissued consolidated financial statements. The annual financial statements were restated only for the change in segment. This Management's Discussion and Analysis of Financial Condition and Results of Operations is revised from its previous presentation in our final prospectus filed with the Securities and Exchange Commission on May 7, 2021.

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, 2020 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

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of product sales from inventory produced in the prior year, idle production costs and costs related to expired and faulty products which have been written off. Cost of goods and services also include costs relating to our revenue-generating collaboration, services and licensing agreements.

Research and Development Expenses

The nature of our business and the primary focus of our activities generate a significant amount of research and development expenses. Research and development expenses include the costs associated with research and development conducted by us or for us by outside contractors, research partners or clinical study partners, and expenses associated with research and development carried out by us in connection with strategic collaboration and licensing agreements. Our research and development expenses are primarily incurred as a result of the following activities:

- discovery efforts leading to product candidates;
- clinical development efforts for our programs; and
- development of our manufacturing technology and infrastructure.

The costs of the above activities driving research and development expenses comprise the following categories:

- expenses related to our research and development personnel, including salaries, social security expense, share-based compensation expense, and other related expenses;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our pre-clinical studies and clinical trials, and in-licensing arrangements;
- costs of acquiring, developing and manufacturing materials for pre-clinical studies and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

The substantial majority of our direct expenses incurred for the six months ended June 30, 2021 and for the year ended December 31, 2020, 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 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. Both as of June 30, 2021 and December 31, 2020, we had capitalized research and development expenses recorded as intangible assets in an aggregate amount of €1.7 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. We have started to incur incremental costs for preparation of market access and launch activities of this vaccine, driven in part by the progression of our chikungunya vaccine candidate into Phase 3 clinical development in 2020.

General and Administrative Expenses

General and administrative expenses consist primarily of non-research and development personnel-related costs, including salaries, social security contributions, share-based compensation expense and other employee-related expenses for general management, finance, legal, human resources, investor relations and other administrative and operational functions, fees for professional services, such as consulting, legal and financial services, information technology and facility-related costs. These costs relate to the operation of our business and are unrelated to our research and development function or any individual product candidate program.

We anticipate that our general and administrative expenses will increase as we grow our support functions for the expected increase in our research and development and manufacturing activities. We also anticipate continued increased expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums and investor relations costs. In particular, we will incur additional accounting expenses to comply with the Sarbanes-Oxley Act of 2002 in the United States that will require us to test the effectiveness of our internal controls over financial reporting.

Other Income (Expenses)

Our other income results principally from grants and research tax credits. We expect to continue to be eligible for these tax credits and subsidies for so long as we incur eligible expenses.

Grants

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and that we will comply with all conditions. In 2019, we entered into a funding agreement with CEPI. Under this funding agreement, we are eligible to receive up to $23.4 million (paid in a series of six-month tranches) for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine against chikungunya (VLA1553). We will be obligated to repay up to $7.0 million to CEPI if and when certain commercial and related milestones are reached. See “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 per year. The Austrian research tax credit results in a cash inflow from the tax authorities paid to us and is not included in the determination of the corporate income tax.

We have concluded that research tax credits in both countries meet the definition of a government grant, as defined in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, and, as a result, it has been classified as other income within operating income in our statement of operations.

Finance Income (Expenses)

Finance income relates primarily to interest income received from cash and cash equivalents deposits. Our cash and cash equivalents have been deposited primarily into cash accounts and term deposit accounts with short maturities and therefore generate only a modest amount of interest income.

Finance expenses relate primarily to interest expense paid to banks and government agencies and on other loans as well as to interest expense on lease liabilities.

We also incur foreign exchange gains and losses related to our international operations, primarily with respect to the U.S. Dollar, the British Pound, the Swedish Krona, and the Canadian Dollar, which amounts are recorded as finance income or expenses. Furthermore, finance income or expenses include fair value gains or losses, respectively, on derivative financial instruments relating to various foreign currency option and forward contracts, which we entered into to limit the risk of foreign currency losses on expected future cash flows.

Results from Investments in Associates

We hold a 48.9% equity interest in BliNK Biomedical SAS, or BliNK, a private company not listed on a stock exchange. While we intend to retain a substantial ownership interest in the entity, BliNK is run as an independent

business by its own management team. We do not have control nor joint-control over BliNK, but rather hold a significant influence in BliNK in accordance with IAS 28.3, and therefore the investment is recorded using the equity method according to IAS 28.

Income Tax

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

Results of Operations

Overview

Results of Operations—Consolidated

Our results of operations for the six months ended June 30, 2021 and 2020 and the years ended December 31, 2020 and 2019 are summarized in the table below.

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Product sales	€ 31,762	€ 40,942	€ 65,938	€129,511
Revenues from collaboration, licensing and services	15,740	6,965	44,383	(3,315)
Total revenues	**€ 47,502**	**€ 47,907**	**€110,321**	**€126,196**
Cost of goods and services	(34,778)	(22,546)	(54,302)	(52,781)
Research and development expenses	(78,737)	(33,081)	(84,454)	(38,022)
Marketing and distribution expenses	(9,643)	(10,046)	(18,264)	(24,145)
General and administrative expenses	(20,904)	(10,615)	(27,539)	(18,398)
Other income and expenses, net	10,389	6,453	19,117	6,338
Operating profit (loss)	**€(86,172)**	**€(21,928)**	**€(55,120)**	**€(811)**
Finance income	8,962	549	689	1,449
Finance expense	(8,431)	(6,109)	(10,738)	(3,082)
Result from investments in associates	(90)	90	(133)	1,574
Profit (loss) before income tax	**€(85,730)**	**€(27,398)**	**€(65,302)**	**€(870)**
Income tax income (expense)	(668)	1,759	909	(874)
Profit (loss) for the period	**€(86,399)**	**€(25,639)**	**€(64,393)**	**€(1,744)**

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Results of Operations—By Segment

The following table presents our results of operations by segment for the six months ended June 30, 2021 and 2020:

€ in thousands	Commercialized products		COVID		Vaccine candidates		Technologies and services		Corporate overhead		Total	
	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020
Product sales	31,762	40,942	—	—	—	—	—	—	—	—	31,762	40,942
Revenues from collaboration, licensing and services	10	—	—	—	1,849	1,333	13,880	5,632	—	—	15,740	6,965
Revenues	**31,772**	**40,942**	—	—	**1,849**	**1,333**	**13,880**	**5,632**	**—**	**—**	**47,502**	**47,907**
Cost of goods and services	(19,326)	(18,148)	(4,156)	—	—	—	(11,295)	(4,397)	—	—	(34,778)	(22,546)
Research and development expenses	(878)	(1,514)	(46,105)	(1,548)	(29,513)	(29,568)	(2,241)	(451)	—	—	(78,737)	(33,081)
Marketing and distribution expenses	(7,086)	(9,817)	(444)	—	(2,037)	(179)	(75)	(50)	—	—	(9,643)	(10,046)
General and administrative expenses	(2,519)	(5,482)	(9,438)	—	(3,256)	(4,151)	(2,194)	(930)	(3,498)	(52)	(20,904)	(10,615)
Other income and expenses, net	2,126	71	4,690	307	2,952	5,835	900	107	(279)	133	10,389	6,453
Operating profit (loss)	**(4,089)**	**6,051**	**(55,454)**	**(1,241)**	**(30,005)**	**(26,730)**	**(1,025)**	**(89)**	**(3,776)**	**81**	**(86,172)**	**(21,928)**

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

€ in thousands	Commercialized products		COVID		Vaccine candidates		Technologies and services		Corporate overhead		Total	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Product sales	65,938	129,511	—	—	—	—	—	—	—	—	65,938	129,511
Revenues from collaboration, licensing and services	1	163	—	—	31,604	(10,516)	12,779	7,038	—	—	44,383	(3,315)
Revenues	**65,939**	**129,674**	—	—	**31,604**	**(10,516)**	**12,779**	**7,038**	**—**	**—**	**110,321**	**126,196**
Cost of goods and services	(41,830)	(47,789)	—	—	(3,305)	(1)	(9,167)	(4,991)	—	—	(54,302)	(52,781)
Research and development expenses	(2,711)	(3,928)	(18,962)	—	(62,140)	(32,864)	(640)	(1,229)	—	—	(84,454)	(38,022)
Marketing and distribution expenses	(17,554)	(22,930)	—	—	(638)	(895)	(72)	(261)	—	(59)	(18,264)	(24,145)
General and administrative expenses	(13,412)	(10,161)	(2,374)	—	(7,781)	(7,124)	(2,274)	(795)	(1,697)	(318)	(27,539)	(18,398)
Other income and expenses, net[1]	1,101	7	1,578	—	14,073	7,709	117	484	2,248	(1,861)	19,117	6,338
Operating profit (loss)	**(8,466)**	**44,873**	**(19,759)**	—	**(28,189)**	**(43,691)**	**743**	**245**	**551**	**(2,238)**	**(55,120)**	**(811)**

(1) For the year ended December 31, 2020, our other income and expenses, net in other corporate overhead consisted of €1.6 million of income derived from an early termination of a rental contract in Sweden and of €0.6 million COVID-19 pandemic related grants, which are not allocable to a segment. For the year ended December 31, 2019, our other income expenses, net in other corporate overhead of €1.9 million mainly related to the provision related to the merger litigation. For more information see Note 5.32.4 of to our consolidated financial statements as of and for the year ended December 31, 2020 included elsewhere in this prospectus.

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Revenue

Consolidated Revenue

Revenues decreased by €0.4 million, or 0.8%, to €47.5 million for the six months ended June 30, 2021 compared to €47.9 million for the six months ended June 30, 2020. The decrease was primarily due to a significant decrease in sales due to the impact of COVID-19 on the travel industry, resulting in a 36.3% decline in revenues from IXIARO and DUKORAL sales, partially offset by an increase in third party product sales from €0.4 million in the six months ended June 30, 2020 to €5.9 million in the six months ended June 30, 2021. The increase in third party product sales was driven by incremental sales related to our distribution agreement with Bavarian Nordic for their products in certain territories that commenced in 2021. Other revenues, including revenues from collaborations, licensing and services, amounted to €15.7 million for the six months ended June 30, 2021 compared to €7.0 million for the six months ended June 30, 2020. This increase was attributable to higher revenues related to the progress of our collaboration with Pfizer, incremental revenues related to our funding agreement with Instituto Butantan signed in January 2021 and higher revenues generated in the clinical trial materials manufacturing unit in Sweden.

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

The breakdown of revenue by operating segment is as follows.

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Commercialized products(1)	31,772	40,942	65,939	129,674
COVID	—	—	—	—
Vaccine candidates	1,849	1,333	31,604	(10,516)
Technologies and services	13,880	5,632	12,779	7,038
Total revenues	**47,502**	**47,907**	**110,321**	**126,196**

(1) During the six months ended June 30, 2021 and the year ended December 31, 2019, commercial products revenue included €10 thousand and €0.2 million of other services provided, which related to our commercialized products and therefore included in revenues from collaborations, licensing and services, respectively. For the six months ended June 30, 2020 and the year ended December 31, 2020, the full amount related to product sales.

Product Sales

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
IXIARO	25,394	28,406	48,480	94,144
DUKORAL	428	12,140	13,300	31,471
Third-party products	5,950	396	4,158	3,896
Total product sales	**31,772**	**40,942**	**65,939**	**129,511**

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Product Sales—Six Months Ended June 30, 2021 and 2020

Product sales decreased by €9.2 million, or 22.4%, from €40.9 million in the six months ended June 30, 2020 to €31.8 million in the six months ended June 30, 2021.

In the six months ended June 30, 2021, IXIARO product sales were €25.4 million, a decrease of €3.0 million, or 10.6%, compared to €28.4 million in the six months ended June 30, 2020. In the six months ended June 30, 2021, IXIARO product sales were largely driven by demand in the United States, mainly by military personnel through our supply agreement with the DLA. In the six months ended June 30, 2020, IXIARO product sales were driven by demand in the U.S. private and German market as well.

In the six months ended June 30, 2021, DUKORAL product sales were €0.4 million, a decrease of €11.7 million, or 96.5%, compared to €12.1 million in the six months ended June 30, 2020. In each of the six-month periods, DUKORAL product sales were driven by demand in Canada and, to a lesser extent, product sales to European countries.

Sales of IXIARO and DUKORAL continued to decrease in the 2021 period 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 six months ended June 30, 2021, third-party product sales were €6.0 million, an increase of €5.6 million, compared to €0.4 million in the six months ended June 30, 2020. This increase was primarily due to sales of Bavarian Nordic's marketed vaccines for rabies and tick-borne encephalitis under our distribution agreement, which began in 2021.

Product Sales—Years Ended December 31, 2020 and 2019

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

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

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

Sales of IXIARO and DUKORAL decreased primarily in 2020 as a result of the COVID-19 pandemic, as travel restrictions significantly reduced demand for travel vaccines in our main markets. The decreased demand for travel vaccines was partially mitigated by continued sales of IXIARO to the U.S. military.

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

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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	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
United States (military)	22,289	16,748	34,659	47,975
United States (non-military)	1,300	2,319	1,755	15,725
Canada	2,006	8,126	8,965	24,396
Germany	—	4,441	7,060	10,345
Nordics	897	2,691	2,866	11,027
Austria	3,006	324	3,333	2,668
United Kingdom	1,067	1,653	1,847	8,594
Other Europe	1,181	1,539	2,068	4,961
Rest of world	15	3,099	3,384	3,819
Total product sales	**31,762**	**40,942**	**65,938**	**129,511**

Total product sales in the United States increased by €4.5 million, or 23.7%, from €19.1 million in the six months ended June 30, 2020 to €23.6 million in the six months ended June 30, 2021. Sales in the United States increased primarily as a result of increased sales of IXIARO to the U.S. military. Product sales in Canada decreased by €6.1 million, or 75.3%, from €8.1 million in the six months ended June 30, 2020 to €2.0 million in the six months ended June 30, 2021, primarily as a result of decreased sales in DUKORAL due to the pandemic impact.

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

Revenues from Collaboration, Licensing and Services

The following table presents our revenue from collaboration, licensing and services, by segment, for the six months ended June 30, 2021 and 2020 and the years ended December 31, 2020 and 2019.

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Commercialized products	10	—	1	163
COVID	—	—	—	—
Vaccine candidates	1,849	1,333	31,604	(10,516)
Technologies and services	13,880	5,632	12,779	7,038
Total revenues from collaboration, licensing and services	**15,740**	**6,965**	**44,383**	**(3,315)**

In the six months ended June 30, 2021, total revenue from collaborations, licensing and services was €15.7 million, an increase of €8.8 million compared to €7.0 million in the six months ended June 30, 2020. In the

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six months ended June 30, 2021, our revenue from collaborations, licensing and services included €5.7 million related to service revenues from our Solna facility and contract manufacturing we perform for third parties, €5.6 million related to our Lyme research and development collaboration with Pfizer, €1.8 million related to our funding agreement with Instituto Butantan and €1.5 million related to our EB66 cell line. In the six months ended June 30, 2020, our revenue from collaborations, licensing and services included €3.6 million related to service revenues from our Solna facility and contract manufacturing we perform for third parties, €1.3 million related to our Lyme research and development collaboration with Pfizer, and €0.7 million related to our EB66 cell line.

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

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

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

Operating Income and Expenses

Cost of Goods and Services

Six Months Ended June 30, 2021 and 2020

Cost of goods and services, or COGS, increased by €12.2 million, or 54.3%, to €34.8 million with a gross margin on product sales of 39.2% for the six months ended June 30, 2021, as compared to COGS of €22.5 million and a gross margin on product sales of 55.7% for the six months ended June 30, 2020. The decline in gross margin was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €11.7 million were related to IXIARO sales, yielding a product gross margin of 54.1%. COGS of €3.6 million were related to DUKORAL sales, causing a negative product gross margin. Of the remaining COGS in the six months ended June 30, 2021, €4.1 million were related to the third-party product distribution business, €4.2 million to start-up costs of the COVID-19 business and €11.3 million to cost of services. In the six months ended June 30, 2020, overall COGS were €22.5 million, of which €18.1 million related to cost of goods and €4.4 million related to cost of services.

Years Ended December 31, 2020 and 2019

COGS increased by €1.5 million, or 2.9%, to €54.3 million with a gross margin on product sales of 36.6% for the year ended December 31, 2020, as compared to COGS of €52.8 million and gross margin on product sales of

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63.1% for the year ended December 31, 2019. The increase in COGS was primarily due to write-offs of excess stock driven by reduced demand resulting from the COVID-19 pandemic, idle capacity costs in both of our manufacturing sites and increased costs associated with our collaboration and manufacturing agreements with Hookipa Pharma Inc. and Batavia Biosciences. The increase in COGS was partially offset by a decrease in license fees and royalties due to lower sales and a reduction in raw materials and consumables used.

COGS was €54.3 million, or 32.8% of our total operating income (expenses), for the year ended December 31, 2020, of which €24.8 million related to IXIARO sales, yielding a product gross margin of 48.9%, and of which €14.3 million related to DUKORAL sales, yielding a product gross margin of minus 7.3%. Gross margin for IXIARO and DUKORAL sales were negatively impacted by decreased demand resulting from the COVID-19 pandemic, although gross margin for IXIARO sales was impacted to a lesser extent due to continued sales of IXIARO to the U.S. military. In 2020, COGS related to the third-party product distribution business was €2.8 million, and COGS related to cost of services was €12.5 million. COGS was €52.8 million, or 41.6% of our total operating income (expenses), for the year ended December 31, 2019, of which €31.1 million related to IXIARO sales, yielding a product gross margin of 67.1%. €14.0 million of COGS related to DUKORAL sales, yielding a product gross margin of 55.6%. Of the remaining COGS for the year ended December 31, 2020, €2.8 million related to the third-party product distribution business and €5.0 million related to cost of services.

Research and Development Expenses

Six Months Ended June 30, 2021 and 2020

Research and development expenses increased by €45.7 million, or 138.0%, to €78.7 million in the six months ended June 30, 2021 from €33.1 million in the six months ended June 30, 2020. This increase was mainly driven by €46.1 million in investments in our COVID-19 vaccine candidate, VLA2001, as well as Phase 3 clinical study costs for our chikungunya vaccine program, VLA1553. Excluding VLA2001, research and development investments amounted to €32.6 million in the six months ended June 30, 2021 compared to €31.5 million in the six months ended June 30, 2020.

For the six months ended June 30, 2021, research and development expenses consisted primarily of €11.8 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, €59.3 million external research and development services, including costs for clinical studies and external manufacturing, and €3.4 million of material consumptions. For the six months ended June 30, 2020, research and development expenses consisted primarily of €8.8 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, €20.0 million external research and development services, including costs for clinical studies and external manufacturing, and €1.9 million of material consumptions.

Years Ended December 31, 2021 and 2020

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

For the year ended December 31, 2020, research and development expenses consisted primarily of €19.9 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

compensation paid to employees in research and development functions, of €47.0 million external research and development services, including costs for clinical studies and external manufacturing as well as €6.8 million of material consumptions. For the year ended December 31, 2019, these expenses consisted primarily of €13.7 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development function, of €16.2 million external research and development services and €2.2 million of material consumptions.

Research and Development Expenses by Product or Development Program

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	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Lyme (VLA15)	(2,079)	(17,384)	(25,948)	(14,783)
Chikungunya (VLA1553)	(26,217)	(10,223)	(31,746)	(14,460)
COVID-19 (VLA2001)	(46,105)	(1,548)	(18,962)	—
hmPV	(1,007)	(798)	(1,327)	(2,052)
IXIARO	(485)	(790)	(1,373)	(1,904)
DUKORAL	(393)	(724)	(1,338)	(2,023)
Other research projects	(2,451)	(1,615)	(3,760)	(2,799)
Total research and development expenses	**(78,737)**	**(33,081)**	**(84,454)**	**(38,022)**

VLA15. Our research and development expenses related to our Lyme vaccine candidate program decreased by €15.3 million, 88.0%, to €2.1 million for the six months ended June 30, 2021 from €17.4 million in the prior year period. This decrease was primarily driven by the completion of our VLA15-201/202 studies. Our research and development expenses related to our Lyme vaccine candidate program increased by €11.2 million, or 75.5%, to €25.9 million in the year ended December 31, 2020 from €14.8 million in the prior year period. This increase was primarily driven by the advancement of VLA15 in our Phase 2 clinical trial.

VLA1553. Our research and development expenses related to our chikungunya vaccine candidate program increased by €16.0 million, or 156,5%, to €26.2 million for the six months ended June 30, 2021 from €10.2 million in the prior year period. This increase was primarily driven by the progression of our program into the Phase 3 clinical trial. Our research and development expenses related to our chikungunya vaccine candidate program increased by €17.3 million, or 119.5%, to €31.7 million in the year ended December 31, 2020 from €14.5 million in the prior year period. This increase was primarily driven by increased expenses related to our Phase 3 clinical trial.

VLA2001. Our research and development expenses related to our COVID-19 vaccine candidate program increased by €44.6 million to €46.1 million for the six months ended June 30, 2021 from €1.5 million in the prior year period. This increase was primarily driven by the progression into the Phase 2/3 clinical trial and related costs for manufacturing of clinical trial materials. Our research and development expenses related to our COVID-19 vaccine candidate program amounted to €19.0 million in the year ended December 31, 2020. 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 increased by €0.4 million, or 10.4%, to €4.3 million for the six months ended June 30, 2021 from €3.9 million in the prior year period. This increase was primarily driven by investments into pre-clinical vaccine candidates. Our research and development expenses related to our commercial products and the rest of our development pipeline decreased by €1.0 million, or 11.2%, to €7.8 million in the year ended December 31, 2020 as we chose to focus our research and development efforts on our clinical-stage programs.

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Marketing and Distribution Expenses

Six Months Ended June 30, 2021 and 2020

Marketing and distribution expenses decreased by €0.4 million, or 4.0%, to €9.6 million in the six months ended June 30, 2021 from €10.0 million in the six months ended June 30, 2020. Marketing and distribution expenses comprised 7.2% of our total operating income (expenses) for the six months ended June 30, 2021, compared to 14.4% of our total operating income (expenses) for the six months ended June 30, 2020. The decrease in the 2021 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 in the six months ended June 30, 2021 were a result of continued investments in our key markets as well as launch preparation costs of the chikungunya vaccine candidate and COVID-19 candidate. Notably, marketing and distribution expenses in the first half of 2021 included €2.0 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first half of 2020). For the six months ended June 30, 2021, marketing and distribution expenses consisted primarily of €4.7 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €1.3 million of advertising expenses, including media and public relations expenses, €0.7 million of warehousing and distribution costs and €1.4 million of costs related to third-party services. For the six months ended June 30, 2020, marketing and distribution expenses consisted of €4.2 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €1.8 million of advertising expenses, including media and public relations expenses, €1.2 million of warehousing and distribution costs and €0.9 million of costs related to third-party services.

Years Ended December 31, 2020 and 2019

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

These expenses in both 2019 and 2020 were a result of continued investments in our key markets, the United States and Canada. For the year ended December 31, 2020 marketing and distribution expenses consisted primarily of €8.8 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €2.5 million of advertising expenses, including media and public relations expenses, €1.9 million of warehousing and distribution costs and €1.8 million of costs related to third-party services. For the year ended December 31, 2019, marketing and distribution expenses consisted of €7.2 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses, €6.8 million of advertising expenses, including media and public relations expenses, €3.0 million of warehousing and distribution costs and €2.2 million of costs related to third-party services.

General and Administrative Expenses

Six Months Ended June 30, 2021 and 2020

General and administrative expenses increased by €10.3 million, or 96.9%, to €20.9 million for the six months ended June 30, 2021 from €10.6 million for the six months ended June 30, 2020. General and administrative expenses comprised 15.6% of our total operating income (expenses) for the six months ended June 30, 2021 compared to 15.2% of our total operating income (expenses) for the six months ended June 30, 2020. This

increase was primarily driven by increased costs to support corporate transactions and projects including increased resources in support of incremental COVID activities relating to research and development and manufacturing activities.

For the six months ended June 30, 2021, general and administrative expenses consisted primarily of €9.8 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees in general and administrative functions, and as well as of €9.9 million in costs and fees for professional services, such as consulting, legal and financial services including costs relating to the listing of our ADSs on Nasdaq in May 2021. For the six months ended June 30, 2020, general and administrative expenses consisted of €6.4 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 €3.4 million in costs and fees for professional services, such as consulting, legal and financial services.

Years Ended December 31, 2020 and 2019

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

For the year ended December 31, 2020, general and administrative expenses consisted primarily of €16.2 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees in general and administrative functions, and as well as of €9.5 million in costs and fees for professional services, such as consulting, legal and financial services. For the year ended December 31, 2019, general and administrative expenses consisted of €11.0 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees in general and administrative functions, and €5.0 million in costs and fees for professional services, such as consulting, legal and financial services.

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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	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Employee benefit expense other than share-based compensation(1)	(35,955)	(26,376)	(58,264)	(46,219)
Share-based compensation expense	(3,653)	(2,631)	(6,328)	(2,552)
Consulting and other purchased services	(76,213)	(27,860)	(65,212)	(29,840)
Raw materials and consumables used	(5,371)	(5,494)	(12,434)	(9,844)
Cost of services and change in inventory	(2,940)	2,257	(10,778)	(5,320)
Depreciation and amortization & impairment	(6,101)	(4,687)	(9,939)	(8,607)
Building and energy costs	(5,286)	(3,732)	(8,140)	(6,995)
License fees and royalties	(2,490)	(2,379)	(4,384)	(7,553)
Supply, office and IT-costs	(3,308)	(1,527)	(3,333)	(3,281)
Advertising costs	(1,318)	(1,810)	(2,496)	(6,801)
Warehousing and distribution costs	(745)	(1,219)	(1,898)	(3,013)
Travel and transportation costs	(126)	(419)	(529)	(1,921)
Other expenses	(554)	(410)	(822)	(1,399)
Operating expenses	**(144,062)**	**(76,288)**	**(184,558)**	**(133,345)**

(1) As of June 30, 2021, the position “employee benefit expense other than share-based compensations” includes an amount of €4.6 million of employer contribution fees, which are payable at the exercise of the share-based payment programs (June 30, 2020: €1.3 million). As of December 31, 2020 the position “employee benefit expense other than share-based compensations” includes an amount of €7.4 million of employer contribution fees, which are payable at the exercise of the share-based payment programs (December 31, 2019: nil).

The increase in operating expenses of €67.8 million in the six months ended June 30, 2021 compared to the prior year period, and the increase of €51.2 million in the year ended December 31, 2020 compared to the prior year, primarily resulted from the increased research and development expenses.

Other Income (Expenses)

The table below summarizes the other operating income (expenses) for the periods presented:

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Research and development tax credit	9,635	3,889	9,937	6,314
Grant income	1,145	2,995	7,680	1,886
Profit/(loss) on disposal of fixed assets and intangible assets, net	(21)	(7)	(10)	(92)
Profit/(loss) from revaluation of lease agreements	—	—	1,584	—
Taxes, duties, fees, charges, other than income tax	(133)	(116)	(168)	(146)
Miscellaneous income/(expenses), net	(237)	(308)	95	(1,623)
Total other operating income (expenses), net	**10,389**	**6,453**	**19,117**	**6,338**

Other operating income and expenses increased by €3.9 million, or 61.0%, to €10.4 million for the six months ended June 30, 2021 from €6.5 million for the six months ended June 30, 2020. This increase was mainly driven

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

by increased research and development tax credits directly resulting from increased qualifying research and development expenses. For the six months ended June 30, 2021 and 2020, of the research and development tax credit, €9.1 million and €3.3 million, respectively, related to research and development programs executed in Austria, mainly for COVID-19 and chikungunya vaccine candidates, whereas the remainder of €0.6 million and €0.6 million, respectively, related to France. In the six months ended June 30, 2021, a negative grant income of €1.1 million was recognized due to the increase of the probability of the PRV milestone under the CEPI funding agreement. This negative grant income was offset by €2.2 million of grants from government authorities related to the COVID-19 pandemic to cover fixed costs of the commercial activities.

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

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

Financial Income (Expense)

The table below summarizes our financial income (expense) for the periods presented:

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Finance income				
Interest income from other parties	228	74	119	199
Fair value gains on derivative financial instruments	—	475	397	—
Foreign exchange gains, net	8,735	—	173	1,250
	8,962	**549**	**689**	**1,449**
Finance expense				
Interest expenses on loans	(3,820)	(2,961)	(6,162)	(1,588)

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Interest expense on refund liabilities	(4,104)	(486)	(3,640)	(89)
Interest expenses on lease liabilities	(419)	(447)	(907)	(926)
Other interest expense	(88)	(16)	(30)	(30)
Foreign exchange losses, net	—	(2,200)	—	—
Fair value losses on derivative financial instruments	—	—	—	(449)
	(8,431)	**(6,109)**	**(10,738)**	**(3,082)**
Finance income/(expenses), net	**532**	**(5,560)**	**(10,049)**	**(1,633)**

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Finance income, net was €0.5 million for the six months ended June 30, 2021 compared to finance expense, net of €5.6 million for the six months ended June 30, 2020. This increase was mainly a result of foreign exchange gains amounting to €8.7 million in the six months ended June 30, 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss (net of gains on derivative financial instruments) of €1.7 million in the six months ended June 30, 2020. Interest charges increased to €8.4 million in the six months ended June 30, 2021 compared to €3.9 million in the prior year period. This growth was driven by increased interest charges related to refund liabilities as well as increased interest charges related to the financing agreement with U.S. healthcare funds Deerfield & OrbiMed entered into in 2020.

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

Income Tax

We recorded €0.7 million of income tax expense for the six months ended June 30, 2021 compared to an income tax benefit of €1.8 million for the six months ended June 30, 2020. Whereas the amount of €0.7 million for the six months ended June 30, 2021 are related to €0.3 million current income tax and €0.4 million deferred income tax, the income tax benefit of €1.8 million for the six months ended June 30, 2020 was primarily driven by effect from eliminated inter-company profits especially on the level of inventory held in the United States.

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

Profit/(Loss) for the Period

Our loss for the period for the six months ended June 30, 2021 was €86.4 million, increased from a loss of €25.6 million for the six months ended June 30, 2020. The increased loss in the six months ended June 30, 2021 as primarily driven by increased research and development expenses for our vaccine candidate programs, increased COGS and increased general and administrative expenses over the prior year period.

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

Liquidity and Capital Resources

Overview

Since our inception, we have financed our operations primarily through the issuance of equity and secured debt. As of June 30, 2021 and December 31, 2020, we had €329.8 million and €204.4 million, respectively, 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

In May 2021, we announced the closing of a global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares, after full exercise of the overallotment option granted to the underwriters. The public offering consisted of 2,850,088 ADSs, each representing two ordinary shares, in the United States at an offering price of $26.41 per ADS and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share. Gross proceeds of this global offering, after full exercise of the underwriters' option were €89.6 million, whereas related expenses of €11.1 million incurred.

As of June 30, 2021, we had borrowings and lease liabilities of €113.0 million, of which €55.1 million were other loans and €57.8 million were lease liabilities.

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

In February 2020, we entered into a debt financing agreement with Deerfield and OrbiMed. The intended use of proceeds was to repay existing borrowings from the EIB and allow us to continue to advance our Lyme and chikungunya development programs in the short term. Amortization payments will start in April 2023, while the loan will mature in February 2026. The loan bears interest at 9.95%. Due to the quarterly interest calculation method, the aggregate annual interest actually paid is an amount equivalent to 10.09%. The loan is secured by substantially all of our assets, including our intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. Furthermore, the loan agreement contains covenants, including a minimum liquidity in the amount of €35.0 million and minimum consolidated net revenue in the amount of €115.0 million on a consecutive twelve month basis. To avoid a breach of covenants due to the decline in revenues caused by the COVID-19 pandemic, the initial agreement was amended in July 2020, to postpone the application of the minimum revenue covenant until December 31, 2020 (included) in exchange for a minimum liquidity covenant of €75.0 million (instead of €35.0 million) during that period. On January 15, 2021, a new amendment was executed to (i) bring the minimum liquidity covenant to the amount of €50.0 million in 2021 and 2022 and €35.0 million thereafter and (ii) modify the minimum revenue covenant to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.8 million in 2022 and €115.0 million thereafter. If the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, Valneva would not be able to comply with the financial covenants in the financing agreement with Deerfield and OrbiMed, which could result in additional costs (up to additional 10%-points of interest over the duration of the default) and an early repayment obligation (payment of the principal increased by 8% and of an indemnity representing the interests expected until March 2023). We do not expect these limitations to affect our ability to meet our cash obligations. As of June 30, 2021 and December 31, 2020 $60.0 million (€54.1 million), respectively, was outstanding 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.

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Cash Flows

The table below summarizes our cash flows for the periods presented:

€ in thousands	Six Months ended June 30,		Year ended December 31,	
	2021	2020	2020	2019
Net cash generated from operating activities	84,247	113,219	137,738	5,529
Net cash used in investing activities	(39,902)	(1,831)	(19,340)	(10,685)
Net cash generated from/(used in) financing activities	78,743	24,468	21,740	(7,696)
Net change in cash and cash equivalents	**123,088**	**135,874**	**140,138**	**(12,852)**

Operating Activities

Net cash generated from operating activities was €84.2 million in the six months ended June 30, 2021, mainly derived by milestone payments related to the COVID supply agreement concluded with the UK Government in September 2020. The net cash generated by operating activities in the six months ended June 30, 2020 was €113.2 million, mainly derived from the $130 million upfront payment received from Pfizer related to the Lyme collaboration agreement.

Net cash generated from operating activities for the year ended December 31, 2020 was €137.7 million compared to €5.5 million for the year ended December 31, 2019. The increase was primarily due to the $130.0 million (€116.9 million) upfront payment we received from Pfizer and the £98.5 million (€107.7 million) payment we received from the UK Government, partially offset by €55.1 million of operating losses. The payment from Pfizer related to our Lyme research collaboration and license agreement and is reflected in working capital and non-current assets. The payment from the UK Government related to our agreement to develop and provide an inactivated COVID-19 vaccine and is reflected in working capital. Net cash generated from operating activities was €5.5 million for the year ended December 31, 2019. The major adjustments to reconcile our net loss to net cash generated from operating activities consisted of non-cash expenses, such as depreciation and amortization, accrued expenses and share-based payments, partly offset by cash outflows from working capital and income tax paid.

Investing Activities

Net cash used in investing activities was €39.9 million in the six months ended June 30, 2021 compared to €1.8 million in the six months ended June 30, 2020, mainly as a result of purchases of equipment related to the site expansion activities for COVID vaccine manufacturing in both Scotland and Sweden.

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

Financing Activities

Net cash generated from financing activities was €78.7 million in the six months ended June 30, 2021 which was mainly a result of proceeds from issuance of new shares in our U.S. initial public offering and European private placement in May 2021. Cash inflows in the six months ended June 30, 2020 were €24.5 million and mainly consisted of net proceeds from the financing arrangement with U.S. healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the EIB.

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Net cash generated from financing activities was €21.7 million for the year ended December 31, 2020 compared to €7.7 million used in financing activities for the year ended December 31, 2019. The increase was primarily due to the impact of borrowing activities. Net cash for the year ended December 31, 2020 consisted primarily of €48.8 million net proceeds from the financing arrangement with Deerfield and OrbiMed, partially offset by €20.0 million (carrying amount was €19.8 million) in repayments of our borrowings with the EIB. We had to pay an additional €0.6 million penalty for early repayment of the loan. Net cash used in financing activities was €7.7 million for the year ended December 31, 2019, driven primarily by the repayment of the Pharmakon Loan of €9.6 million in January 2019, offset by a €10.0 million tranche drawn against the €25.0 million term loan facility with the EIB. Payment of lease liabilities, interest paid and proceeds from issuance of common stock comprised the remainder of the financing activities.

Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. As of June 30, 2021 and December 31, 2020, we had accumulated a net loss of €319.9 million and €233.5 million, respectively. Our net loss was €86.4 million and €25.6 million for the six months ended June 30, 2021 and 2020, respectively, and €64.4 million and €1.7 million for the years ended December 31, 2020 and 2019, respectively. We expect to incur significant expenses and substantial operating losses over the next several years as we market our approved products, advance clinical development of our product candidates and continue our research and development efforts in the United States, Europe and endemic markets. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- invest in our vaccine candidate programs, including our VLA1553 and VLA2001 vaccine candidates, and our other pre-clinical and research programs; and
- invest in our working capital and general corporate purposes.

Our present and future funding requirements will depend on many factors, including, among other things:

- costs of continued commercial activities, including product sales, marketing, manufacturing and distribution, for our approved products;
- the scope, progress, timing and successful completion of our clinical trials of our current or future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- our ability to establish and maintain collaborations in favorable terms, if at all;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates; and
- the amount of revenues, if any, we may derive either directly, or in the form of royalty payments from any current or future collaboration agreements.

For more information as to the risks associated with our future funding needs, see 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

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Government, milestone and service payments from our collaboration with Pfizer regarding our Lyme vaccine, our existing liquidity and the proceeds of this 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 June 30, 2021 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 June 30, 2021 and the periods in which payments are due. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

€ in thousands	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Over 5 years	Total
Borrowings	7,107	32,171	33,267	2,250	74,795
Lease liabilities	4,013	29,052	5,219	12,899	64,035
Refund liabilities	12,163	84,035	30,018	—	126,216
Total	**23,283**	**145,258**	**68,504**	**15,149**	**265,046**

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

Borrowings

As of June 30, 2021, the outstanding amount of bank borrowings and other loans was €54.5 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%. Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €4.0 million and the CEPI loan in the amount of €2.3 million, which relates to advanced payments received which are expected to be paid back in the future.

As of June 30, 2020, the outstanding amount of bank borrowings and other loans was €55.1 million. Of this, €49.5 million related to the loan agreement with Deerfield and OrbiMed.

As of December 31, 2020, the outstanding amount of bank borrowings and other loans was €53.4 million. Of this, €46.2 million related to the loan agreement with Deerfield and OrbiMed. Part of the loan was used to fully repay the existing loan of €20.0 million with EIB. Other borrowings of €7.2 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).

As of December 31, 2019, the outstanding amount of bank borrowings and other loans was €26.3 million. This amount consisted of a loan agreement with EIB of €19.8 million with a variable interest rate and planned

repayments between 2021 and 2024, and other borrowings totaled €6.6 million and mainly related to financing of research and development expenses, fixed assets and CIR (research and development tax credit in France) and have various conditions (interest rates) and terms (maturities).

Lease Liabilities

As of June 30, 2021, the outstanding, discounted amount of lease liabilities was €57.0 million. Of this, €31.5 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. €24.5 million related the lease agreements 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 €1.0 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of June 30, 2020, the outstanding, discounted amount of lease liabilities was €57.8 million. Of this, €31.3 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. €25.4 million related the lease agreements 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 €1.0 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of December 31, 2020, the outstanding, discounted amount of lease liabilities was €52.1 million. Of this, €26.2 million related to the lease agreement for premises in Solna, Sweden, which we expect will terminate in 2037. Base rent will increase based on an inflation index. €24.9 million related the lease agreements for premises in Vienna, Austria. We expect 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).

As of December 31, 2019, the outstanding, discounted amount of lease liabilities was €58.9 million. Of this, €31.9 million was related to the lease agreement for premises in Solna, Sweden, which we expect will terminate in 2037. Base rent will increase based on an inflation index. €25.6 million was related to lease agreement for to the premises in Vienna, Austria. We expect 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).

Refund Liabilities

As of June 30, 2021, the carrying amount of refund liabilities was €111.4 million. Of this, €90.0 million (thereof €84.1 million non-current) related to the collaboration with Pfizer Inc., as Valneva will fund 30% of Phase 3 study costs performed by Pfizer Inc; €14.1 million (non-current) related to the agreement with UK Government to develop and commercialize a SARS-CoV-2 vaccine, €6.5 million (thereof €6.3 million non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 and €0.8 million related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products. Other releases mainly refer to changes in the refund liability related to changes in assumptions and estimates.

As of June 30, 2020, the carrying amount of refund liabilities was €75.8 million. Of this, €69.4 million (all non-current) related to the new collaboration with Pfizer Inc, as Valneva will fund 30% of Phase 3 study costs performed by Pfizer Inc; €6.2 million (thereof €6.2 million non-current) related to the expected payments to GSK

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Valneva SE Pursuant to 17 C.F.R. Section 200.83**

related to the termination of the strategic alliance agreements, signed in June 2019, and €0.2 million related to refund liabilities to customers related to rebate programs.

As of December 31, 2020, the carrying amount of refund liabilities was €111.4 million. Of this, €81.9 million (thereof €70 million non-current) related to the collaboration with Pfizer Inc. for development of our Lyme disease vaccine, as we are required to contribute 30% of Phase 3 clinical trial costs for this vaccine. €20.9 million (all non-current) related to the agreement with the UK Government to develop and commercialize a COVID-19 vaccine, €6.3 million (all non-current) related to expected payment to GSK related to the termination of the SAA with payments expected in 2024, and €2.3 million (all current) related to refund liabilities to customers related to rebate programs and right to return products.

As of December 31, 2019, the carrying amount of refund liabilities was €6.6 million (thereof €6.1 million non-current). This primarily comprised of the expected payment to GSK related to the termination of the SAA and €0.5 million (all current) related to refund liabilities to customers related to rebate programs and right to return products.

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 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 financial statements as of and for the year ended December 31, 2020 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

ongoing and future development costs through completion of the development program, as of December 31, 2020, €81.9 million have been recognized as discounted refund liabilities to reflect the requirement to pay 30% of Pfizer's research and development costs. The transaction price was determined taking into account our refund obligation. The agreement includes various performance obligations including: research and development and service performance obligations for which revenue is recognized over time, as well as a license performance obligation for which revenue was recognized at a point in time when Pfizer can benefit and use the license, which occurred in the fourth quarter of 2020. Judgement and estimates were applied when determining the transaction price (including the valuation of the refund liability) as well as at the allocation of the transaction price to the performance obligations. For the year ended December 31, 2020, €31.6 million was recognized as revenue from collaboration, licensing and services. €2.8 million costs to obtain a contract are included in other assets as of December 31, 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. The UK supply agreement also provided for up-front investments in the scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the collaboration. According to IFRS 15, this agreement 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 an option to sell an additional 90 million doses at the expected market price. For the six months ended June 30, 2021 and the year ended December 31, 2020, none of these performance obligations were satisfied, therefore no revenue was recognized in these periods. As of June 30, 2021 and December 31, 2020, we booked €335.6 million and €87.0 million, respectively, in contract liabilities, and €14.1 million and €20.9 million, respectively, was included in refund liabilities. Total expenses for research and development for the COVID-19 vaccine were €46.1 million and €19.0 million for the six months ended June 30, 2021 and the year ended December 31, 2020, respectively.

Following the close of business on September 10, 2021, we received notice of the UK Authority's decision to terminate the UK Supply Agreement. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us. First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly, at some time in the future, breach our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We have acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective on October 10, 2021. We consider that the event of termination is a non-adjusting subsequent event under IAS10, as it arose after the end of the reporting period and is not indicative of conditions existing as of June 30, 2021. As of June 30, 2021, we were not in breach of our delivery obligations, nor had we received any notification from the UK Authority indicating concern that such a breach had occurred or would occur. Therefore, no impact was recorded on our financial position and results as of and for the period ended June 30, 2021.

Accounting for Grants

In July 2019, we announced an agreement with CEPI, which includes performance obligations and refund obligations. Management's judgment is required to determine whether such components of an agreement are revenues from customers or fall within the standard of accounting for government grants. Since CEPI is an NGO partly funded by government and is acting in a way a government organization would, it was accounted for under IAS 20. In addition the valuation of the various components requires management's judgment.

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Valuation of Intangibles and Inventories / 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 cash generating units have been performed in December 2020, and an impairment test for DUKORAL was performed in the six months ended June 30, 2021. Management estimates are applied on the long range business plan – on the revenue as well as on the expense side. The impairment tests resulted in no impairment charges being taken. A reduction in revenues of 10.0% would result in no additional impairment loss in the six months ended June 30, 2021 or the year ended December 31, 2020. €9.2 million and €7.4 million of write-down of inventory is included in the income statements for the six months ended June 30, 2021 and the year ended December 31, 2020, respectively, due to lower sales expectations and limited shelf life of the finished goods.

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 €126.3 million as of December 31, 2020 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 recent years, we also established Phantom Stock Option Programs with terms and conditions similar to ESOPs, for employees who are U.S. citizens. In 2020, we established a Phantom Share Program with terms and conditions similar to the Free Ordinary Shares for certain employees.

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

While assumptions in measuring fair values on the share-based compensations have been taken into account, management has considered the likelihood of an event of change of control remote, therefore the accelerated vesting was not taken into account. Further information is explained in Note 5.22 to our consolidated financial statements as of and for the year ended December 31, 2020 included elsewhere in this prospectus.

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Leases

For any extension options of lease agreements, management applies judgement whether it is reasonably 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 years ended December 31, 2020 and 2019, three material weaknesses in our internal control over financial reporting were identified. The material weaknesses related to (i) a lack of formal, documented and implemented processes, controls and review procedures, (ii) insufficient controls on manual journal entries due to insufficient segregation of duties in the finance and accounting function and (iii) insufficient controls over the accuracy and completeness of information that is being processed and reported by third parties, used to recognize revenue and record inventory. These material weaknesses did not result in a material misstatement to our financial statements included 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.

Development and work on the remediation plan to address these material weaknesses and strengthen our controls in these areas remains ongoing. 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. As of June 30, 2021, we had not yet completed remediation of these material weaknesses. 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, 2020 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 (including cash held in GBP and USD) 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.

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

€ in thousands	Six Months ended June 30, 2021	Year ended December 31, 2020	2019
EUR/USD +10%	4,760	3,229	(3,134)
EUR/USD -10%	(5,818)	(3,947)	3,830
EUR/GBP +10%	(26,296)	(10,022)	(1,122)
EUR/GBP -10%	32,140	12,249	1,371
EUR/SEK +10%	(1,331)	(400)	114
EUR/SEK -10%	1,627	489	(140)
EUR/CAD +10%	(472)	(228)	(275)
EUR/CAD -10%	577	279	336

As of June 30, 2021, the changes in impact from an increase or a decrease in USD is mainly caused by a significant increase in refund liabilities denominated in USD.

As of June 30, 2021, the increase in the foreign currency exchange risk in GBP is caused by higher cash and cash equivalents and higher receivables within the group denominated in GBP relating to the COVID-19 vaccine.

As of December 31, 2020, the changes in impact from an increase or a decrease in USD is mainly caused by a significant increase in refund liabilities and borrowings denominated in USD.

As of December 31, 2020, the increase in the Foreign Currency Exchange Risk in GBP is caused by higher cash and cash equivalents and higher receivables within the group denominated in GBP relating to the COVID-19 vaccine

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 the first six months of 2021 and the full years 2020 and 2019, our investments at variable rates, as well as the borrowings at variable rates, were denominated in EUR, SEK, USD, CAD and in GBP. We analyze our interest rate exposure on a dynamic basis. Based on this analysis, we calculated the impact on profit and loss of a defined interest rate change. The same interest rate change was used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As of June 30, 2021 as well as December 31, 2020, no material interest risk was identified. In the event of increasing interest rates, the positive effect from cash in banks will be higher than the negative effect from variable interest bearing liabilities. In the event of decreasing interest rates there is expected to be no material negative impact on interest from cash as long as banks do not charge negative interest for deposits. As of December 31, 2019, the calculated impact on income before tax of a 0.25% shift was an increase or decrease of €0.1 million.

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 until December 31, 2026 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.

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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 the United States, where approximately 476,000 people are diagnosed with Lyme disease each year and in Europe, where at least a further 200,000 cases occur annually. Our clinical portfolio also includes VLA1553, targeting the chikungunya virus, which has spread to more than 100 countries and infected more than 3 million people in the Americas since first arriving there in 2013. VLA1553 is the first and only chikungunya vaccine candidate to report positive Phase 3 topline data.

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 whole virus vaccine, could offer benefits in terms of safety, cost, ease of manufacture and distribution compared to currently approved vaccines and could be adapted to offer protection against mutations of the virus. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S), in terms of geometric mean titer, or GMT, for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222.

We commenced our rolling submission and review process with the UK's Medicines & Healthcare products Regulatory Agency, or MHRA, in August 2021 and expect to incorporate our positive Phase 3 topline results in November 2021. We believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the European Medicines Agency, or EMA. Further submissions to other regulatory agencies may take place in 2022.

We have already successfully licensed and commercialized a portfolio of traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), indicated for the prevention of Japanese encephalitis in travelers and military personnel, and DUKORAL, indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand and Thailand, prevention of diarrhea caused by ETEC, the leading causes of travelers' diarrhea.

Our advanced clinical portfolio is supported by our significant development, manufacturing and commercial capabilities. We have a robust manufacturing and laboratory platform in place with facilities across Europe to

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meet our clinical and commercial needs, including BioSafety Level 3 manufacturing and R&D facilities. Additionally, sales of our proprietary products, IXIARO and DUKORAL, as well as products that we commercialize on behalf of third parties have given us the ability to reinvest in our research and development programs and to build the necessary infrastructure to support manufacturing of our product candidates.

We are a public company listed on the Nasdaq Global Select Market and Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior executive team has more than 100 years of combined experience spent working at industry leaders such as Novartis, Chiron, Acambis, GlaxoSmithKline and Daiichi Sankyo.

Our Portfolio and Pipeline

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

Our pipeline and key assets are summarized below:

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

Our clinical pipeline includes:

- **VLA15 –** a vaccine candidate against Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is the only vaccine undergoing clinical trials against Lyme disease. We have completed recruitment and reported initial results for 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 initiated in March 2021. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of $10 million. Together with Pfizer, we expect that our Phase 3 pivotal, placebo-controlled field efficacy trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the 2023 tick season. 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 VLA1553 is the only chikungunya vaccine candidate that has reported positive Phase 3 topline data. In our Phase 1 clinical trial, we observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants, which results were sustained after 12 months. VLA1553 advanced directly to a Phase 3 clinical trial, for which we reported positive topline results in August 2021. In the pivotal Phase 3 trial, we observed a seroprotection level of 98.5% 28 days after receiving the single administration. VLA1553 has received Fast Track and Breakthrough Therapy designation from the FDA and PRIME designation from the EMA. We have also received confirmation for our proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, we plan to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection, rather than executing a time- and cost-intensive field trial that observes natural rates of infection between trial participants receiving our vaccine and the placebo. The seroprotection rate observed in the pivotal Phase 3 trial exceeds the 70% surrogate of protection threshold agreed with the FDA. The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher, or PRV.
- **VLA2001** – a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. In October 2021, we announced positive Phase 3 topline results in which we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222 in terms of GMT for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. 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. We commenced our rolling submission and review process with the MHRA in August 2021 and expect to incorporate our positive Phase 3 topline results in November 2021. We believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022.

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.

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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 €48.5 million and €94.1 million in the years ended December 31, 2020 and 2019, respectively. Sales in 2020 and 2021 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. In September 2021, we announced that DLA exercised the first option year of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is now 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option of 250,000 doses, which remains unchanged.
- **DUKORAL –** an oral vaccine for the prevention of diarrhea caused by Vibrio cholera and, in Canada and other countries, heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. We acquired DUKORAL in 2015 and recorded €13.3 million and €31.5 million of revenues in the years ended December 31, 2020 and 2019, respectively. Sales in 2020 and 2021 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 two of 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 476,000 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, which, to our knowledge, is the only inactivated, adjuvanted, COVID-19 vaccine in clinical development in Europe. Following our announcement in April 2021 of initial positive data from the Phase 1/2 clinical trial showing high immunogenicity of VLA2001, we initiated a pivotal Phase 3 clinical trial and reported positive topline data from this pivotal Phase 3 trial in October 2021. These results will allow us to finalize our rolling submission and review process with the MHRA, which we commenced in August 2021. We expect to finalize our submission in November 2021 and believe we could receive MHRA approval by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022. We have also initiated further clinical trials to test VLA2001 in adolescent and elderly populations as well its use as a booster. In keeping with our specialized strategy, we believe our COVID-19 vaccine, if approved, could offer clear benefits compared to other vaccines, taking into account considerations such as safety, cost, ease of manufacture and distribution and could be adapted to offer protection against mutations of the virus. In addition to these advantages, we believe our flexible approach to the clinical and manufacturing development of VLA2001 will facilitate our ability to meet the needs of future customers.

- **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.

- **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.

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- **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. Vincent Dequenne, our Senior Vice President of Operations and Chief Operating Officer designee, has an extensive track record in the pharmaceutical and vaccines industry including roles with GSK and Eli Lilly. 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. Together with Pfizer, we announced the acceleration of the pediatric development of VLA15 with an additional Phase 2 clinical trial in approximately 600 participants between 5-65 years of age that began in March 2021. We announced further positive Phase 2 results, including a booster response, in September 2021. We intend to advance VLA15 into Phase 3 clinical trials in 2022 in adults, adolescents and children, with the potential to submit a BLA and a MAA in the second half of 2024.
- **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 advanced VLA1553 directly into various Phase 3 clinical trials and reported positive topline results of our pivotal Phase 3 trial involving over 4,000 healthy adults in August 2021. We expect to report final results from our pivotal Phase 3 clinical trial early in the first quarter of 2022 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 commercialization as early as 2023.

- **Advance VLA2001 through clinical development for the prevention of COVID-19.** We initiated clinical testing of VLA2001, an inactivated whole virus, adjuvanted SARS-CoV-2 virus vaccine, in December 2020. VLA2001 is a vaccine candidate developed from an inactivated whole virus, which is a type of vaccine that has proven effective against other viruses, including influenza. In April 2021, following our announcement of initial positive data from our ongoing Phase 1/2 clinical trial, we initiated a pivotal Phase 3 clinical trial in 4,012 healthy adults and announced positive topline results of this trial in October 2021. In this trial, VLA2001 met both co-primary endpoints by demonstrating superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of GMT for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. This Phase 3 clinical trial will form the basis for an initial conditional marketing authorization in the United Kingdom and European Union. 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 be adapted to offer protection against mutations of the virus. Further clinical trials will be required to broaden indications or obtain a final regulatory approval. We have already scaled our manufacturing capabilities and commenced initial 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 (hMPV), parvovirus B19, Epstein Bar Virus (EBV), Campylobacter and norovirus.

Background to Vaccine Development

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

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

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

- ***Live attenuated vaccines***. Live attenuated vaccines use a weakened, or attenuated, form of the virus or bacteria that causes a disease. Live attenuated vaccines typically provoke more durable immunological responses. However, they may not be safe for use in immunocompromised individuals, and on rare occasions can mutate to a virulent form and cause disease. Live attenuated vaccines protect against diseases such as measles/mumps/rubella, rotavirus, smallpox, chickenpox and yellow fever. Our chikungunya virus vaccine candidate is an example of a live attenuated vaccine.
- ***Inactivated vaccines***. Inactivated vaccines use a version of the disease-causing virus or bacteria that has been destroyed with chemicals, heat or radiation. Inactivated vaccines have a long history of use and are among the safest types of vaccine, with possibilities for use in special target populations, such as patients with weakened immune systems. We believe that the extensive knowledge and experience with the existing viral inactivation procedures for vaccine manufacture will continue to serve as a foundation of vaccinology for novel inactivated vaccines. Today millions of people are, and will be, protected worldwide with inactivated viral vaccines. Inactivated vaccines protect against diseases such as hepatitis A, flu, polio and rabies. Our vaccine against Japanese encephalitis and our SARS–CoV-2 vaccine candidate are both inactivated vaccines.
- ***Subunit, recombinant, polysaccharide and conjugate vaccines***. Subunit, recombinant, polysaccharide and conjugate vaccines use specific pieces of the virus or bacteria, such as its protein, sugar or casing, to generate an immune response. Rather than introducing an inactivated or attenuated microorganism to an immune system (which would constitute a “whole-agent” vaccine), a subunit vaccine uses a fragment of the microorganism to generate an immune response. Subunit vaccines can produce a long-lived immunity and are relatively safe since only parts of the virus are used and can be applicable to people with weakened immune systems. These vaccines protect against diseases such as Hib (Haemophilus influenza type b), hepatitis B, HPV (human papillomavirus), whooping cough (part of the DTaP combined vaccine), pneumococcal disease, meningococcal disease and shingles. Our clinical development and manufacturing technology have allowed us to develop our VLA15 vaccine candidate, a multivalent, protein subunit vaccine for prevention of Lyme disease.
- ***Toxoid vaccines***. Toxoid vaccines use a toxin made by the virus or bacteria that causes a disease. These vaccines are used to protect against diseases such as diphtheria and tetanus.

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

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

In addition to the vaccine’s primary component, such as an inactivated virus, vaccines may contain adjuvants, which are used to improve the immune response to the vaccine, for example through producing more antibodies. Adjuvants used in human vaccines include alum (potassium aluminum sulphate) and other types of aluminum

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salts. Adjuvants have a proven safety record based on more than 60 years of use. Effective use of adjuvants requires expertise around vaccine formulation and development. We have utilized adjuvants in a number of our clinical stage vaccine candidates, including VLA15 and VLA2001.

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

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

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

Our Clinical Development Pipeline

VLA15—Our vaccine 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 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 476,000 people in the United States are diagnosed with Lyme disease each year and at least a further 200,000 cases occur in Europe. Research suggests that Lyme disease cases may rise 92% by 2100 in the United States due to climate change. Although most patients recover from Lyme disease, 10-20% have persistent symptoms, which for some are chronic and disabling. Studies indicate that Lyme disease costs up to approximately $1.3 billion each year in direct medical costs in the United States alone. The global market for a Lyme disease vaccine is estimated to reach $1 billion by 2030.

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

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

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

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VLA15 Approach

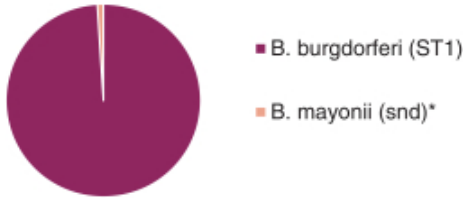
VLA15 provides a potential prophylactic solution to Lyme disease by generating antibodies that target the OspA protein on the surface of Borrelia, killing the bacteria before it can be transmitted from the infected tick to the human host. Third-party studies have shown that antibodies against OspA, which are immunoglobulin G, or IgG, antibodies, in the blood of an animal bitten by an infected tick are transmitted to the tick during feeding and kill the Borrelia in the tick's gut before it can migrate to the tick's salivary glands and be transmitted to the animal. VLA15 is a recombinant protein subunit vaccine that is designed to achieve this protective effect using a truncated form of the OspA protein to generate IgG antibodies against the OspA protein through a process summarized in the table below.

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

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

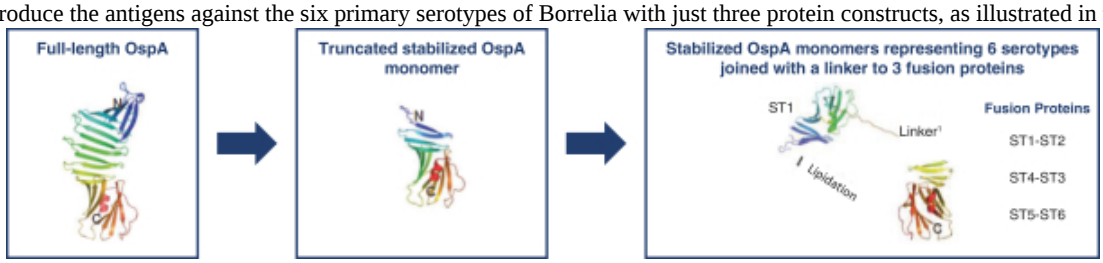
Europe

United States



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

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



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Phase 1 Clinical Trial and Results

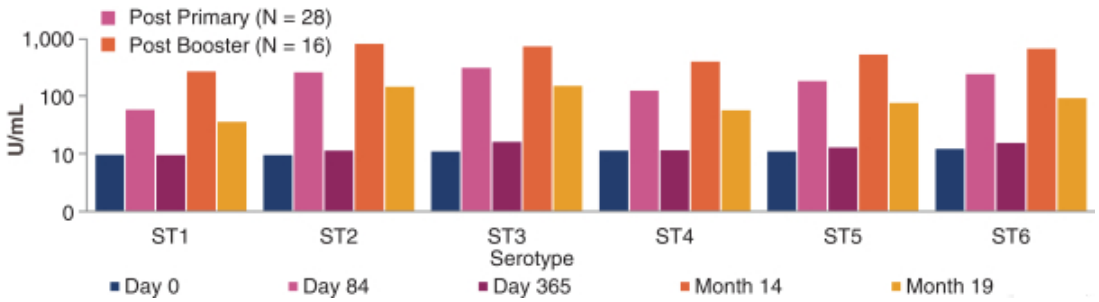
We evaluated VLA15 in a partially randomized, multi-center dose escalation Phase 1 clinical trial conducted in Belgium and the United States in 179 healthy adults below 40 years of age. The first 24 subjects were included in an open-label trial in which they participated in a staggered dose escalation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

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

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

For some vaccines, immunity begins to decline after a certain period of time, at which point a “booster” dose is needed to raise immunity levels. To evaluate the benefit of a booster dose, 64 subjects across the two higher dose groups (48 µg and 90 µg, both with and without alum) from the Phase 1 trial received a booster in the period 12 to 15 months after their initial dose in the primary immunization. Safety and immunogenicity of VLA15 was evaluated up to month 19, with an interim analysis at month 14. This booster dose resulted in a significant anamnestic response, yielding OspA antibody titers at levels from 2.7-fold for ST2 and ST3 to 5.8- fold for ST1 over the initial titers observed at Day 84. This potent immunogenic response against all six OspA variants can be observed in the figure below. Additional data about a booster dose follow in the Phase 2 discussion below.

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



Phase 2 Clinical Trials and Results

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

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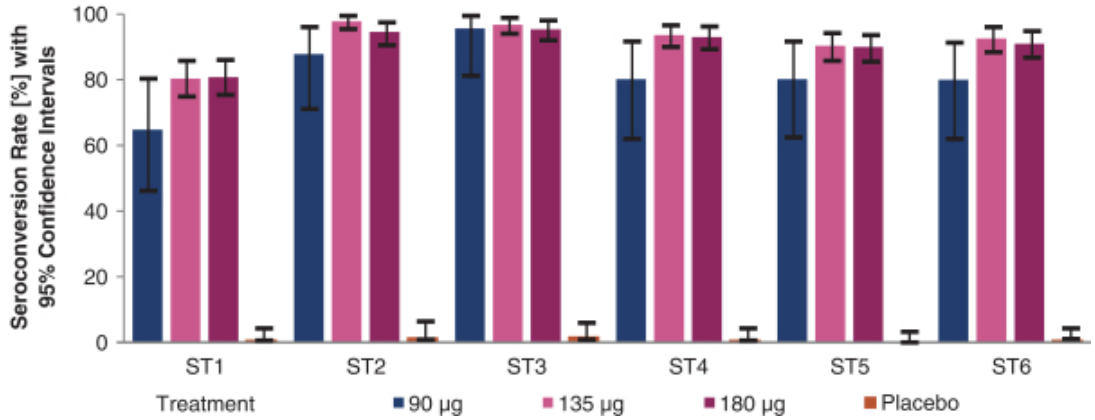
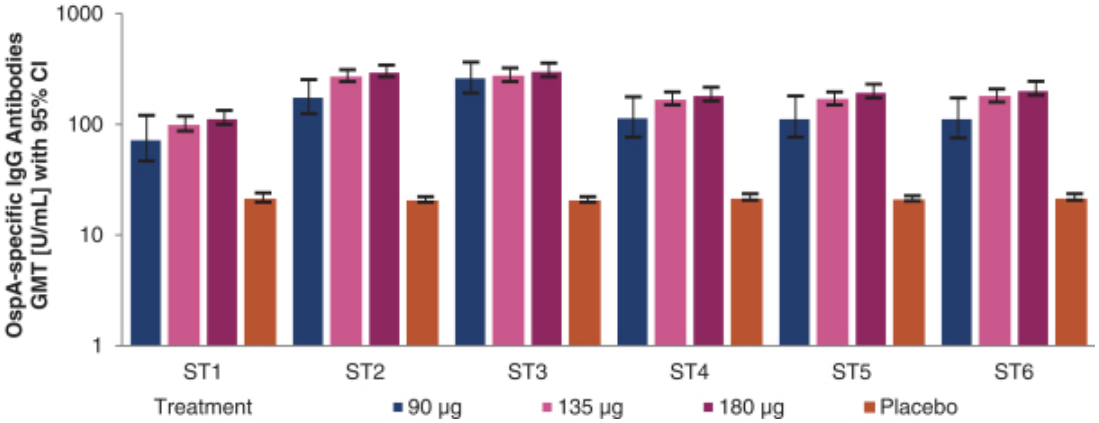
VLA15-201 Clinical Trial and Results

Our first Phase 2 clinical trial, VLA15-201, was a randomized, observer-blind, placebo-controlled, multi-center Phase 2 clinical trial conducted in Belgium, Germany and the United States, consisting of a "run-in phase" and a "main study phase." In the run-in phase, a total of 120 subjects aged 18-40 were randomized into one of four groups: a placebo group and three groups at different dosage levels of VLA15 with alum (90 µg,135 µg or 180 µg). The subjects received intramuscular injections on Days 1, 29 and 57. Based on the elicited higher antibody responses across all serotypes observed from the run-in phase, we selected the two higher VLA15 dose levels to be evaluated in the main study phase. A total of 452 subjects aged 18-65 were randomized 2:2:1 to receive one of two VLA15 doses (135 µg or 180 µg) or placebo, and received intramuscular injections on Days 1, 29 and 57. The primary endpoint for the trial was GMTs for IgG against each OspA serotype ST1 to ST6. GMT calculates the average antibody across a set of subjects. Secondary endpoints examined SCR, geometric mean fold rise, or GMFR, and occurrence of adverse events.

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



The figure below shows VLA15 201 GMT for OspA-specific IgG for Serotypes 1-6 on Day 85. No statistically significant differences between 135 µg and 180 µg treatment groups were observed.



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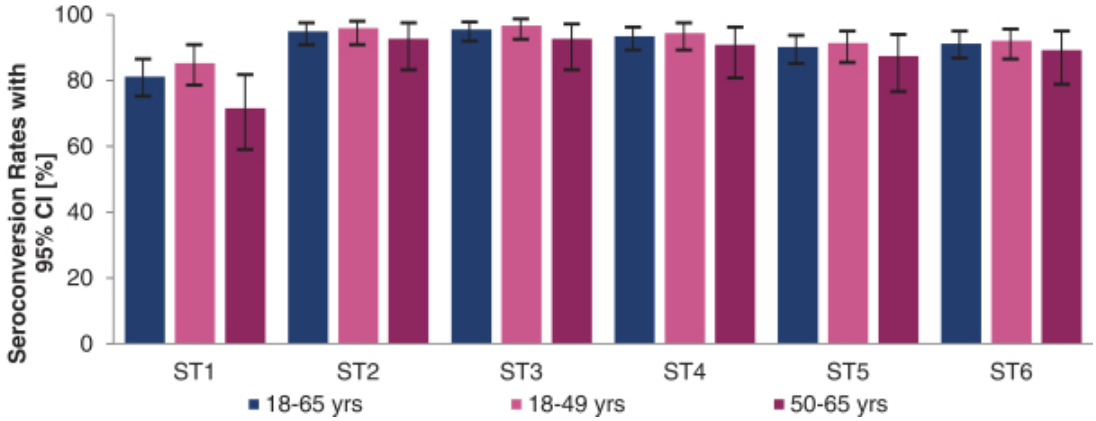
In the age group comparable to the age group investigated in the Phase 1 clinical trial (18-39 years), SCRs ranged from 85.6% to 97%. The immunological response in older adults (50-65 years), one of the main target groups for a Lyme vaccine, had SCRs ranging from 71.9% to 93%. Results indicated that prior exposure to *Borrelia burgdorferi sensu lato* (Bb sl), the bacteria that causes Lyme disease (baseline Bb sl sero-positivity) did not have an impact on immunogenicity or safety. The figure below shows SCRs measured at Day 85 of VLA15-201 for OspA-specific IgG antibodies per serotype and age group.



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

VLA15-202 Clinical Trial and Results

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

On October 20, 2020, we reported statistically significant interim results from VLA15-202. Compared to VLA15-201, immunogenicity was further enhanced using an immunization schedule of vaccinating at zero, two and six months. SCRs, after completion of the primary vaccination series, showed similar responses and ranged from 93.8% (ST1) to 98.8% (ST2, ST4). Antibody responses were comparable in the two dose groups tested, as illustrated in the figure below, which shows SCRs as of Day 208.

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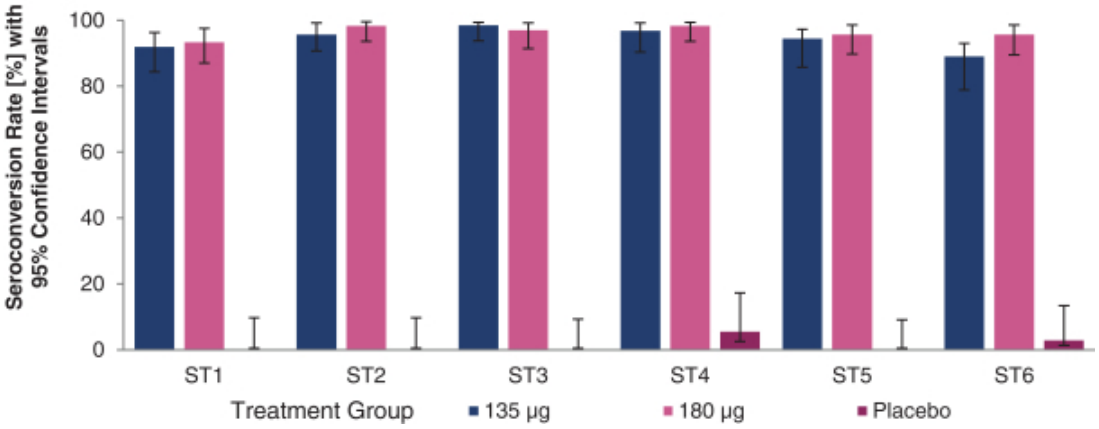
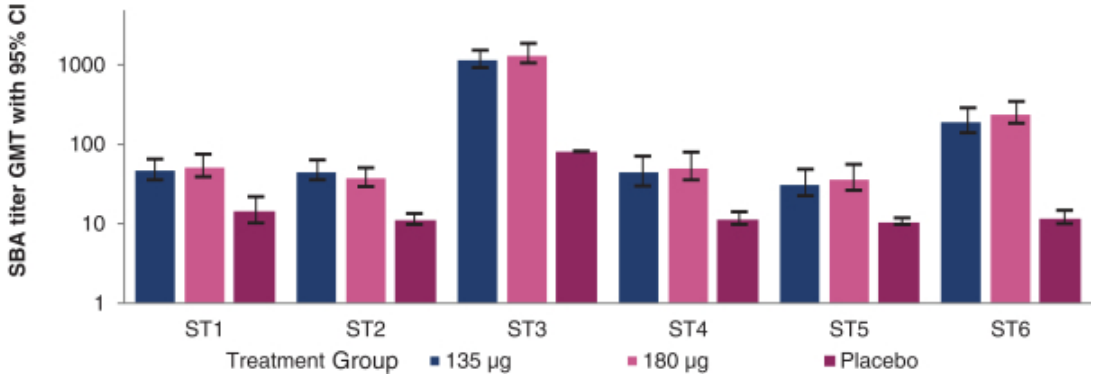


Antibody responses were comparable in the two dose groups tested. The immunological response in older adults, one of the main target groups for a Lyme vaccine, was consistent with our observations in VLA15-201. Furthermore, results did not indicate that prior exposure to *Borrelia burgdorferi sensu lato*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

Unlike our previous trials, we also performed a Serum Bactericidal Assay, or SBA, assessing the functional immune response against Lyme disease after vaccination with VLA15. Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses. Over the course of our trial, the SBAs demonstrated functionality of antibodies against all OspA serotypes. The figure below shows the GMT for OspA-specific SBA Titer, per serotype at day 208.



VLA15 was generally well tolerated across all doses and age groups tested in VLA15-202. The tolerability profile including fever rates was comparable to what has been observed in trials of other lipidated recombinant vaccines or lipid containing formulations. Overall, 232 of 246 participants (94.3%) reported any adverse event, solicited or unsolicited, up to Day 208. Rates of participants who experienced adverse events were similar in the VLA15 treatment groups: 96.9% (135 µg group) and 99.0% (180 µg group), compared with 80.4% in the placebo group. Most adverse events were mild or moderate in severity and no related serious adverse events were reported. A total of 6.1% of participants experienced severe related adverse events; 5.7% of participants experienced at least one severe solicited Grade 3 reactogenicity event, and as such, were considered to be related, including 6.2% in the 135 µg group, 7.1% in the 180 µg group, and 2.0% in the placebo group. One participant in

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the 135 µg group experienced a severe unsolicited adverse event of ventricular extrasystoles 13 days after the second vaccination, which was assessed as possibly related to the study vaccine by the investigator. The participant had a history of benign premature ventricular contractions, was treated with propranolol and recovered after 39 days. Six unrelated serious adverse events were reported: 3.1% in the 135 µg group (invasive ductal breast carcinoma, prostate cancer, and vertigo) and 2.0% in the 180 µg group (intervertebral disc protrusion, osteoarthritis). One case of Lyme disease (135 µg group) was reported as an adverse event of significant interest: erythematous rash, developed approximately two weeks after the first vaccination.

On September 28, 2021, we announced further positive results from VLA15-202. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all dose groups, remaining above baseline and confirming the need for a booster strategy. Participants who received a complete primary vaccination series with the 180 µg dose of VLA15 were invited to continue the trial in a booster extension phase and were randomized 2:1 to receive an additional 180 µg dose of VLA15 or placebo at Month 18. VLA15's acceptable safety profile was confirmed through one-month post-booster. No related serious adverse events were observed in any treatment group. Administration of the booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (GMT) in anti-OspA IgG antibody titers compared with titers observed after primary immunization (Figure 1). All participants seroconverted to anti-OspA IgG after the booster dose, meaning SCRs were 100% for all OspA serotypes (Figure 2). SCR was defined as the rate of subjects that changed from seronegative at baseline to seropositive. Additionally, subjects who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by SBA, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The trial is continuing to monitor persistence of antibody responses.

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

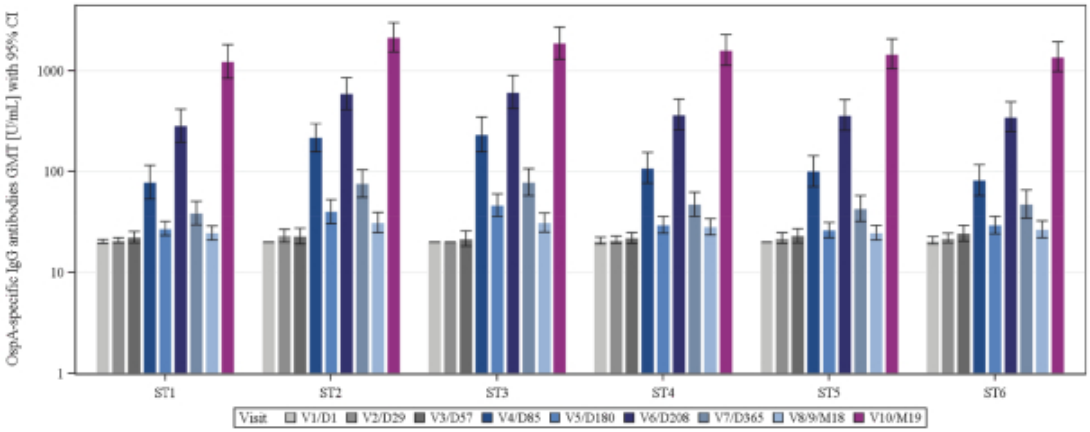

Figure 2. Seroconversion Rate (SCR)* for OspA-specific SBA Titer, per Serotype, at Month 19 (Booster PP Population)

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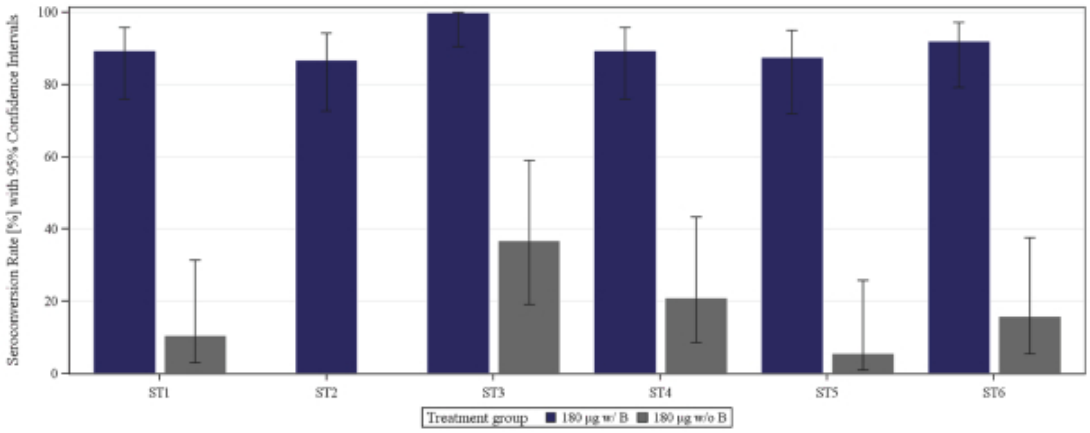

Note: No bar is shown if there is no seroconverted subject for a serotype in the respective treatment group.

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

VLA15-221 Clinical Trial

On December 2, 2020, we announced the acceleration of the pediatric development of VLA15. The Phase 2 clinical trial VLA15-221, which commenced in March 2021 is the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old. We announced completion of recruitment for VLA15-221 in July 2021, and we expect to report topline data in the first half of 2022.

VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 clinical trial. A total of 625 participants, 5 to 65 years of age, have been randomized to receive VLA15 at Month 0-2-6 or Month 0-6 (approximately 200 volunteers each) or placebo at Month 0-2-6 (approximately 200 volunteers). The trial is conducted at sites in the US which are located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with *Borrelia burgdorferia* as well as *Borrelia burgdorferi*-naïve volunteers. Participants receive VLA15 at a dose of 180µg, which was selected based on data generated in the two previous Phase 2 clinical trials. The main safety and immunogenicity readout will be performed approximately one month after completion of the primary vaccination schedule (i.e. at Month 7), when peak antibody titers are anticipated. A subset of participants will receive a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed for three additional years to monitor antibody persistence. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3 clinical development.

The dosing of the first subject in this trial triggered 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, Canada and countries in the European Union. The pivotal field efficacy trial will evaluate the ability of a VLA15 vaccine regimen to prevent Lyme disease compared to a placebo regimen. We anticipate that this trial will start in the third quarter of 2022, subject to feedback from regulatory authorities. 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 in the second half of 2024.

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The planned Phase 3 clinical trial will include adults, adolescents, as well as pediatric participants at least five years of age, enrolling approximately 18,000 participants in total. Participants will be randomized 1:1 to receive either VLA15 180µg or placebo, with alum, at the primary immunization schedule as determined by our VLA15-221 trial. A booster vaccination will be given to all participants 12 months after receiving the last dose of the primary vaccinations. The planned primary endpoint for the Phase 3 clinical trial will be the efficacy of VLA15 compared to placebo in preventing confirmed Lyme disease during the first tick season after completing the primary series vaccination (i.e., April to October 2023). In case this endpoint is not met after the first tick season, efficacy of VLA15 in preventing confirmed Lyme disease in the second Lyme disease season after participants also receive the 12-month booster dose (i.e., April to October 2024) will be the basis for potential vaccine licensure. Enrollment in this trial is expected to begin in the third quarter of 2022 and primary vaccinations are expected to be completed by March 2023, prior to start of the tick season.

VLA1553—Our vaccine candidate targeting the chikungunya virus

VLA1553 is a vaccine candidate for chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further through infected travelers who carry the virus to their home countries. The risk of a significant outbreak is increasing particularly in the southern United States and Europe, where tiger mosquitoes, which are particularly associated with the spread of the disease, are established. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat. The global market for a chikungunya vaccine is estimated to exceed $500 million annually by 2032.

In our Phase 1 clinical trial, we observed that VLA1553 led to the development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants in the trial and that these levels were sustained after 12 months. Based on this Phase 1 dataset we were able to advance directly into Phase 3 clinical development and are conducting a pivotal Phase 3 trial in over 4,000 healthy adults. VLA1553 has received Fast Track and Breakthrough Therapy designation from the FDA and PRIME designation from the EMA. We have also received confirmation for our proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, we plan to seek licensure of VLA 1553 based on a surrogate of protection agreed with the FDA. The surrogate of protection is an immune response that predicts protection against clinical endpoints and is reasonably likely to predict protection from chikungunya infection. This eliminates the need to execute a time-intensive and costly field trial where a group of patients receiving a placebo is compared to groups of patients receiving VLA1553. The rates of infection are observed and compared at various points in time across each of the various trial groups. The topline Phase 3 clinical trial data that we announced in August 2021 indicated a seroprotection rate of 98.5% compared to the 70% threshold surrogate of protection (for non-acceptance) agreed with the FDA.

The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a PRV. We reported positive topline results for our Phase 3 clinical trial in August 2021 and expect to report final trial results in early 2022. 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, which has been approved by the local regulatory agency, ANVISA. 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 can cause a significant economic

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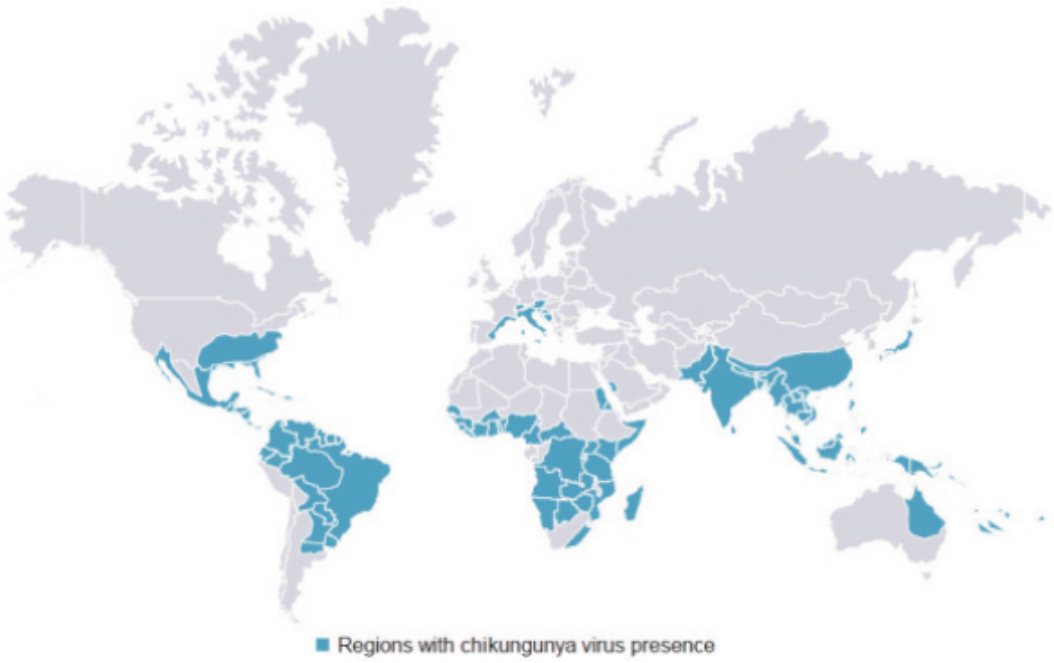
impact. There have been more than 3 million reported cases in the Americas since the virus first arrived there in 2013. In 2020, there were approximately 95,000 suspected cases reported in the Americas and well as approximately 32,000 suspected cases in India and 11,000 in Thailand. The true incidence 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:



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

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

No vaccine to prevent chikungunya infection has been approved. The current standard of care to treat individuals who have become infected with chikungunya is the application of non-steroidal anti-inflammatory drugs to relieve symptoms. To date, preventive measures rely on avoiding mosquito bites. Effective mosquito control has proven challenging, even in higher income countries.

In addition to VLA1553, there are three third-party advanced chikungunya vaccine candidates. The first is a measles-vectored vaccine candidate developed by Merck, which has completed Phase 2 clinical testing with positive results, but has not publicly announced initiation of Phase 3 clinical trials. The second is an inactivated vaccine candidate manufactured by Bharat Biotech of India, which has initiated a seamless Phase 2/3 clinical trial. The third is a virus-like particle vaccine candidate developed by Emergent BioSolutions, which has announced initiation of Phase 3 clinical trials in October 2021. We believe that all of these potential vaccine candidates may face limitations relative to VLA1553, including VLA1553 being designed to only require a single administration, while Bharat's, Merck's and potentially Emergent BioSolution's vaccine candidates are likely to require multiple shots to either reach or maintain high levels of effectiveness.

VLA1553 Approach

VLA1553 is a live-attenuated chikungunya vaccine candidate based on the East, Central and Southern African, or ESCA, strain which has spread across the Indian Ocean. It is cross-reactive with other strains, meaning that it is designed to protect against those as well, including the strain of Asian lineage which is rapidly spreading across the Americas as observed in pre-clinical studies. Additionally, given that we have engineered VLA1553 as a live-attenuated vaccine, we believe it may confer life-long immunity.

VLA1553 is engineered using a strain of chikungunya, where specific segments of the virus have been deleted, thereby weakening, or attenuating, the virus. This approach enables VLA1553 to catalyze the patient's immune system into generating the antibodies necessary to provide protection against the virus while the weakened strain does not cause the patient to develop significant symptoms. In our pre-clinical studies, growth of this strain on Vero cells resulted in a viral titer 35 times lower than observed with the original unattenuated strain, demonstrating the attenuation of our chikungunya strain. The deleted segment also remained absent following replication of the virus in the Vero cells, suggesting that the weakness of the virus is sustained.

Pre-Clinical Data

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

- It was highly immunogenic and induced a strong and long-lasting neutralizing antibody response in non-human primates, or NHPs, models after a single administration.
- It was protective in NHPs that received a high-dose of wild-type, or WT, chikungunya virus after vaccination.

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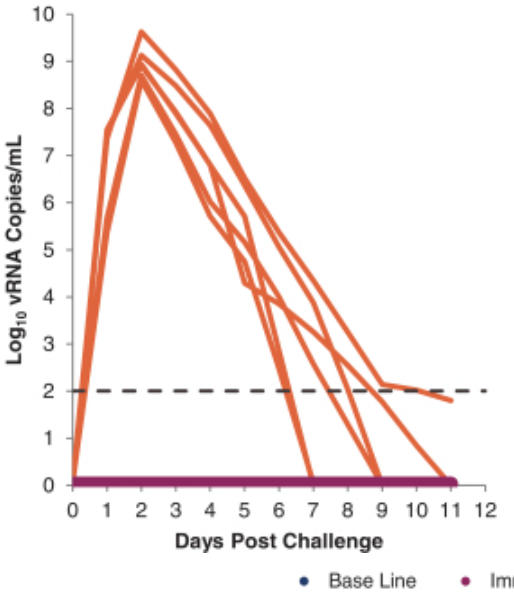
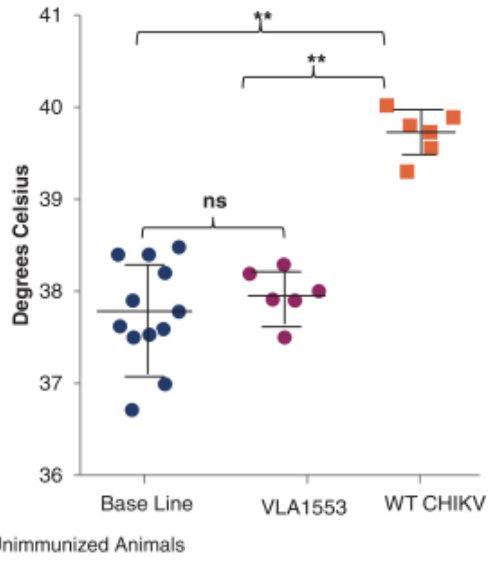
- It was not observed to cause any of the clinical manifestations such as viremia, fever and rash that NHPs typically develop after infection with the WT chikungunya virus, and caused lower and delayed virus titers compared to an infection with the WT virus.

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.

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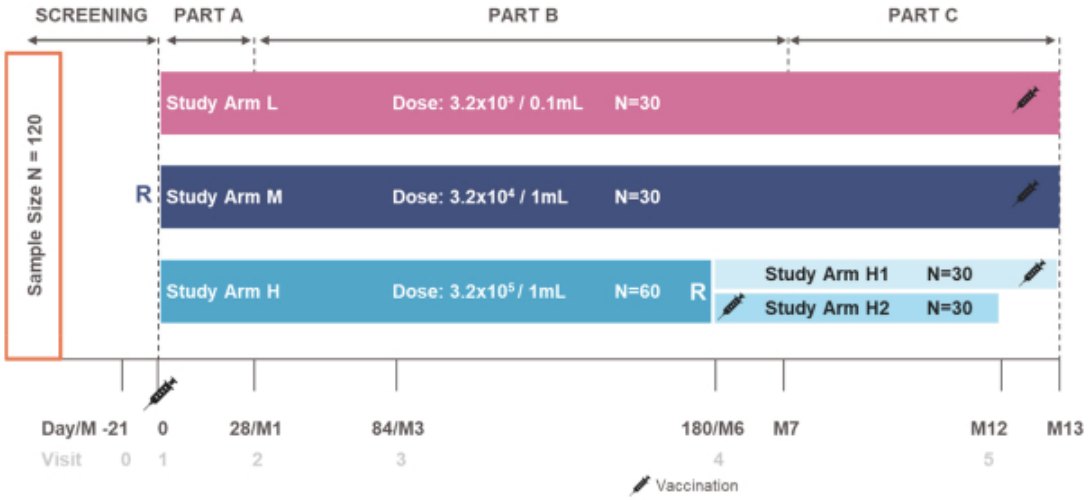
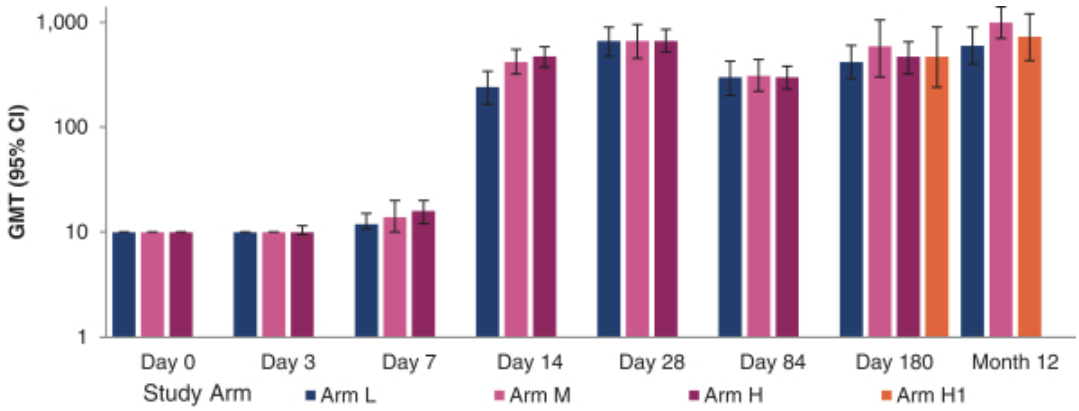
Phase 1 Clinical Trial and Results

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.

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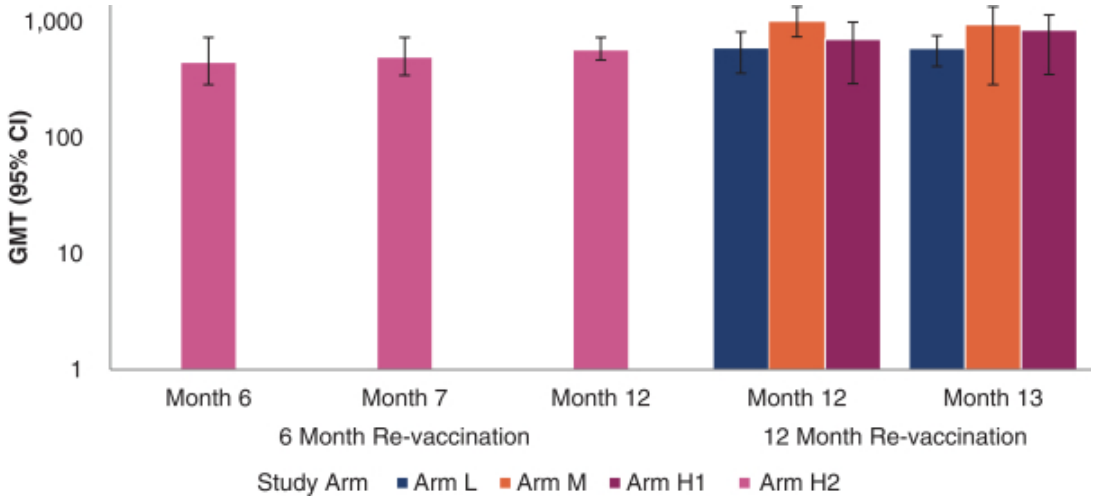
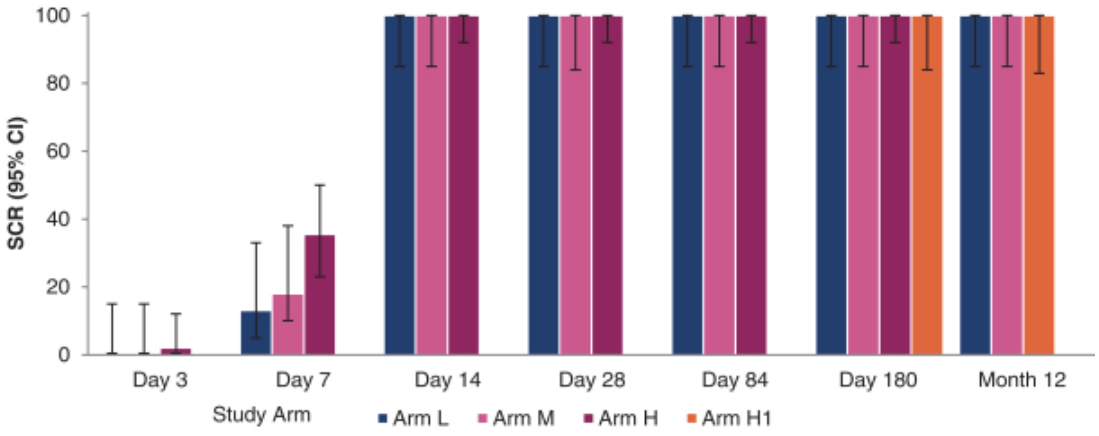


The titer of these neutralizing antibodies was assessed by determining how far the antibodies in the plasma could be diluted and still reduce *in vitro* viral infection by 50%, a commonly used parameter referred to as the neutralization titer or NT_{50}. Seroconversion was defined as having an NT_{50}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



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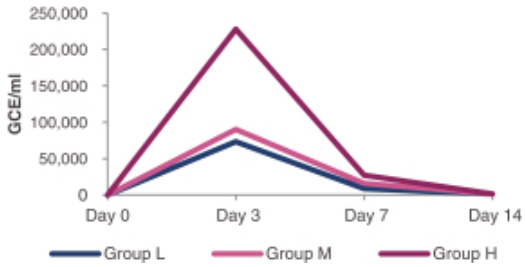
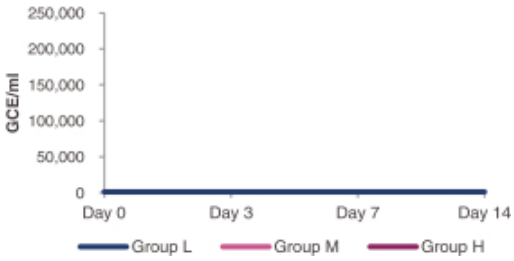
Plasma of the trial volunteers was screened for viremia, which peaked at day three in all groups and was lower in the low-dose and medium-dose groups. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

Viremia after Single Vaccination



Viremia After Re-Vaccination with VLA1553



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

We have received concurrence from the FDA on our proposal to utilize the accelerated approval pathway, which will enable us to potentially submit a BLA for this candidate based on clinical trial data on an immunological surrogate of protection, rather than observing natural rates of infection between trial participants receiving our vaccine and the placebo 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 Clinical Trials

VLA1553-301 Clinical Trial

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

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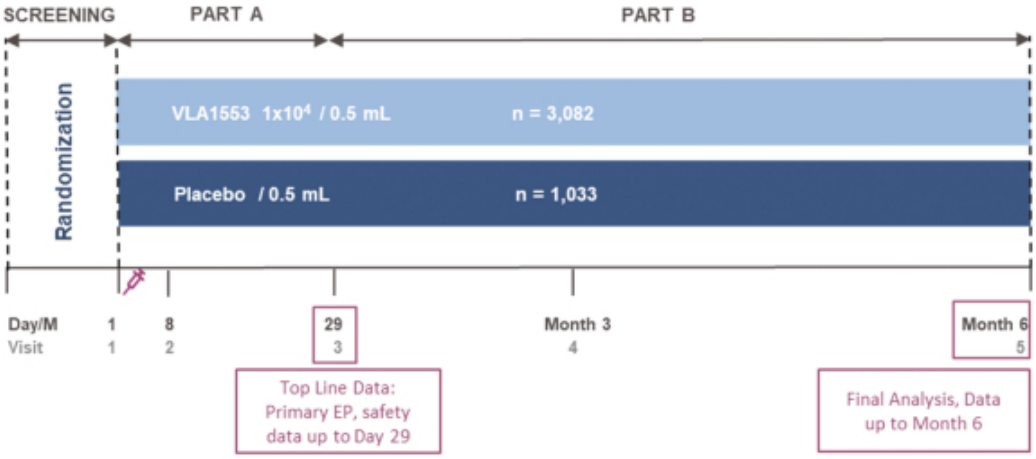
The graphic below shows the design of the Phase 3 clinical trial.

Design of the VLA1553 Phase 3 Trial



The primary endpoint was safety and immunogenicity 28 days after a single vaccination with VLA1553. The trial met its primary endpoint, inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 96.2-99.6). The seroprotection rate result of 98.5% exceeded the 70% threshold (for non-acceptance) agreed with the FDA (Figure 3). The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission for approval of VLA1553 under the accelerated approval pathway. VLA1553 was highly immunogenic, with a GMT of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 clinical trial (Figure 4).

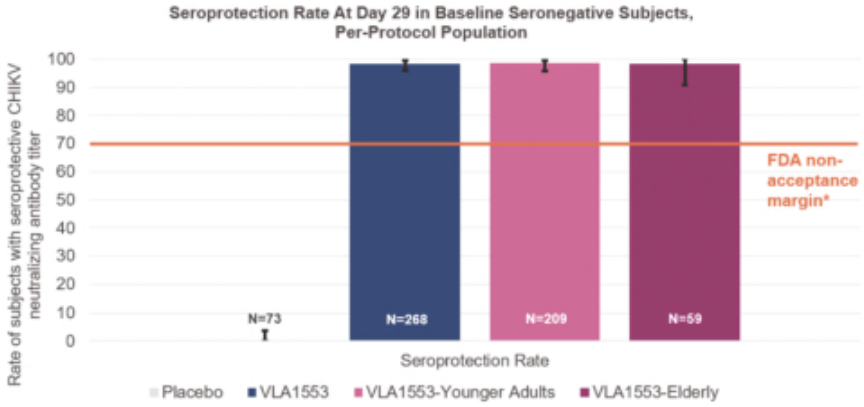


Figure 3. Seroprotection Rate at Day 29 in Baseline Seronegative Subjects, PP Population, for All Subjects Receiving VLA1553 Combined and Stratified by Age Group.

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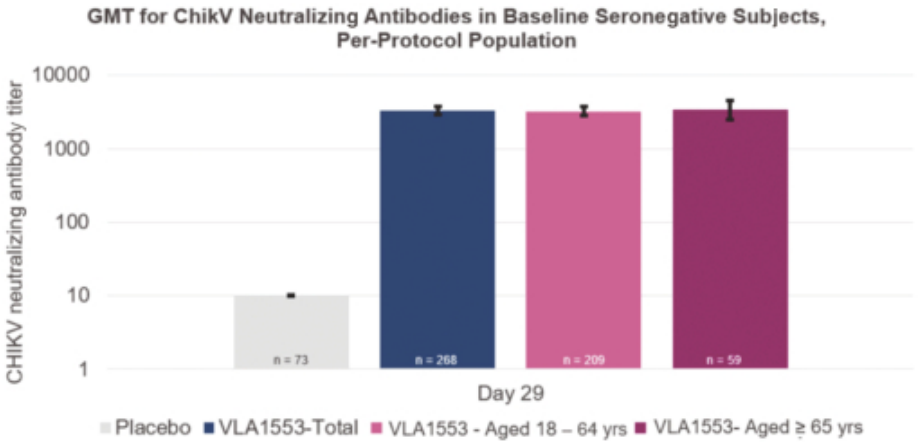

Figure 4. Geometric Mean Titers for CHIKV Neutralizing Antibodies at Day 29 in Baseline Seronegative Subjects, PP Population, for All Subjects Receiving VLA1553 Combined and Stratified by Age Group.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. The topline data safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of trial participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

Additionally, VLA1553 was highly immunogenic in elderly study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553-301 will continue towards final analysis including the 6-month safety data. We expect to report final trial results in early 2022.

VLA1553-302 Clinical Trial

We also initiated a lot-to-lot consistency Phase 3 trial, VLA1553-302, in February 2021 in 410 subjects aged 18 to 45 to show manufacturing consistency of VLA1553. We announced completion of recruitment for this trial in June 2021 and expect to receive data from this trial in late 2021. VLA1553-302 will continue to run in parallel to VLA1553-301.

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

Trial volunteers will be followed for a total of six months and overall, the trial is expected to last approximately ten months.

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VLA1553-303 Clinical Trial

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

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 initiated a pivotal Phase 3 clinical trial of VLA2001 in April 2021 and reported positive topline data from this trial in October 2021. In this trial, we observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of geometric mean GMT for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. We observed that VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. The results of the pivotal Phase 3 clinical trial will be included in our initial rolling submission to the MHRA in the United Kingdom and we believe that we may expect a potential conditional marketing authorization by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022.

While a number of vaccines against COVID-19 have already been approved for use and multiple candidates remain in late stage development, VLA2001 currently is the only inactivated, whole virus vaccine candidate in clinical trials in Europe. We believe VLA2001, 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 be adapted to offer protection against mutations of the virus.

Overview of COVID-19

COVID-19 is a disease caused by infection with SARS-CoV-2, a strain of coronavirus. Respiratory illness is the most common symptom associated with COVID-19 with a severity ranging from mild disease to life-threatening acute respiratory distress syndrome. Patients with advanced age, comorbidities such as obesity, diabetes and cardiovascular disease, or an immunocompromised state are at increased risk for poor outcomes. COVID-19 has been declared a pandemic by the World Health Organization, or WHO. As of October 8, 2021, there have been more than 236 million confirmed cases of COVID-19, including over 4.8 million deaths, reported to the WHO. As of October 6, 2021, more than 6.2 billion vaccine doses have been administered worldwide.

Several therapies are currently being investigated or have been approved or authorized to treat or prevent COVID-19. These include therapies being developed to directly target SARS-CoV-2 such as small molecules, oral antiviral, and monoclonal antibody therapies. For example, the FDA has granted emergency use authorization to Gilead's 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.

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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. As of October 1, 2021, four vaccines have been approved by US or European regulatory authorities. Although there have been preliminary data released on the ability of some of these vaccines to generate neutralizing antibodies that can prevent severe COVID-19 disease, no data on their potential to prevent mild or asymptomatic infection or the transmission of the virus to others have been publicly presented. We believe that the worldwide need for an effective vaccine to prevent COVID-19 will not be adequately addressed by first-wave vaccines and product candidates alone as governments must take into consideration safety, cost, ease of manufacture and distribution and indications for specific populations of each vaccine while trying to vaccinate as many people as possible.

VLA2001 Approach

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

We have entered into a collaboration with Dynavax Technologies to evaluate the use of their adjuvant CpG 1018, a component of their FDA- and EMA-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 pronounced induction of protective antibody titers with CpG 1018 compared to alum. We believe that the use of alum and CpG 1018 could further enhance the broader immune response that we expect from VLA2001 as an inactivated whole virus vaccine.

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 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 supported our research efforts and the expansion of our Livingston production facility.

We commenced in-human clinical trials for VLA2001 in December 2020 and announced initial positive results from our Phase 1/2 clinical trial in April 2021. We initiated our pivotal Phase 3 clinical trial shortly thereafter and announced positive topline Phase 3 data in October 2021, in which VLA2001 met both of the co-primary endpoints of the trial. These topline results of the pivotal Phase 3 clinical trial will be included in our rolling submission to the MHRA in the United Kingdom and we believe that we may expect an initial approval from the MHRA by the end of 2021. We are also preparing to commence a rolling submission process with the EMA. Further submissions to other regulatory agencies may take place in 2022.

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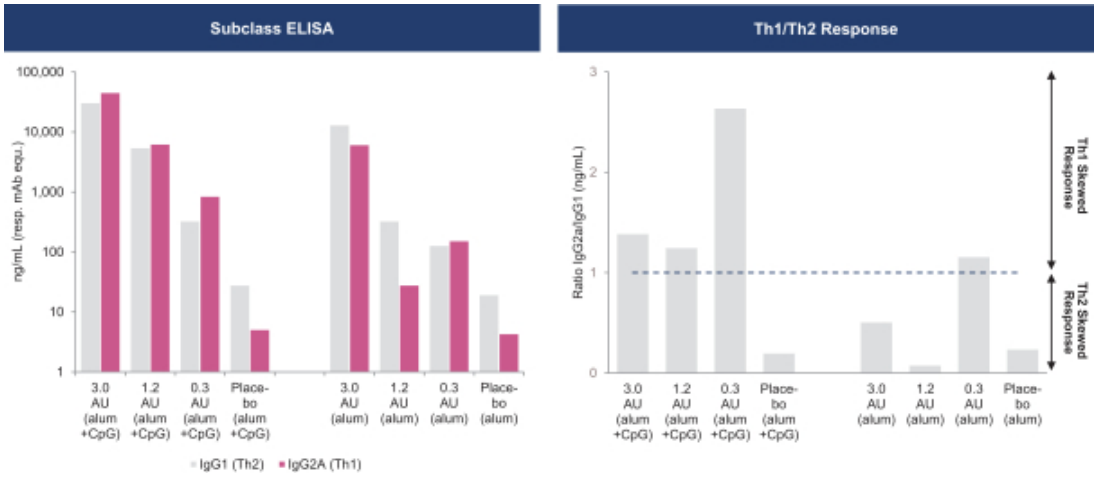
Pre-clinical Trial and Results

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

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

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

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



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

VLA 2001 Phase 1/2 Clinical Trial and Results

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

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

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

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

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

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

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

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

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

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

Additionally, the VLA2001-201 protocol was amended to include study participants who have completed the primary immunization schedule (two vaccinations) and were invited to participate in a Booster Phase of the trial to investigate the immunogenicity and safety of a booster dose of VLA2001 administered at approximately 6-7 months after completing the primary immunization schedule. We announced in September 2021 that we have started to provide boosters to volunteers in the VLA2001-201 trial. This planned expansion of VLA2001 clinical trials will support future clinical development strategies and allow for potential approval and label expansions.

Phase 3 Clinical Trials

VLA2001-301 (Cov-Compare) Clinical Trial

Trial Design

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

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

Topline Results

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

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

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

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

Adolescent Recruitment

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

VLA2001-304 Clinical Trial

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

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

Additional Planned Clinical Trials

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

With respect to the ongoing Cov-Compare Phase 3 clinical trial, we are planning an amendment of the trial to evaluate VLA2001 as a booster. We estimate this booster phase would involve approximately 400 participants from the Cov-Compare trial aged 18 years and above.

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

In addition, we are considering a Phase 3 clinical trial to further evaluate VLA2001 as a booster approximately six months after people had a primary vaccination with a number of other licensed vaccines or who have had COVID-19. The estimated sample size for this trial is 200-300 participants, aged 12 years and above.

Anticipated Next Steps

We announced on August 23, 2021 that we had commenced rolling submission for initial approval of VLA2001 with the MHRA in the United Kingdom. We are also planning to commence a rolling submission to the EMA. Further submissions to other regulatory agencies may take place in 2022.

VLA1601—Our Zika virus development program that remains on hold

We have developed VLA1601, a highly purified inactivated vaccine candidate which we developed using the same manufacturing platform as IXIARO, our approved Japanese encephalitis vaccine. We have concluded the Phase 1 trial and the results obtained will allow us to design a Phase 2 clinical trial if we choose to continue this program. We currently have this program on hold, as cases of Zika have significantly declined since 2016. We have chosen to prioritize our development programs to focus on viruses that are currently a greater health crisis, but we may choose to reactivate this program in the future if warranted.

VLA84—Our Clostridium difficile vaccine candidate that remains on hold

We have developed VLA84, a vaccine candidate against *Clostridium difficile*, a leading cause of life-threatening, healthcare-associated infections worldwide. We completed Phase 2 development of VLA84 and could advance into Phase 3 if we choose to reactivate this program and find a suitable partner.

Our Pre-clinical Portfolio

In addition to our clinical portfolio, we are advancing a series of pre-clinical assets. Each of the assets included in our pre-clinical pipeline aligns with our strategy of leveraging our vaccine development expertise and capabilities to develop prophylactic solutions for diseases with high unmet need and limited available preventative and effective therapeutic treatment options.

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

VLA1554—Our vaccine candidate targeting Human MetaPneumoVirus (hMPV)

Human metapneumovirus, or hMPV, is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection in the pediatric population. hMPV is also a common cause of worldwide morbidity and mortality in immunocompromised patients and older adults. Repeated infections occur often, demonstrating a heavy medical burden. However, there is currently no hMPV-specific prevention treatment.

We are currently in pre-clinical proof of concept studies and we 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.

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Epstein-Barr Virus (EBV) program

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

Campylobacter program

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

Parvovirus B19 program

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

Norovirus program

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

Our Commercial Portfolio

Our commercial portfolio is composed of two vaccines both of which are marketed as traveler vaccines in that they are targeted to people traveling to the regions where the diseases they prevent are endemic. Our vaccines serve a wide range of potential travelers, from business and leisure travelers to government and military personnel traveling on behalf of their government. These vaccines have generated meaningful revenues, much of which we have reinvested in our research and development capabilities in order to advance our clinical assets and drive future growth.

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IXIARO—Our Japanese encephalitis vaccine

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

Japanese encephalitis virus, or JEV, is spread by mosquitos and is the most important cause of viral encephalitis in Asia and the Western Pacific. IXIARO sales were €48.5 million and €94.1 million in the years ended December 31, 2020 and 2019, respectively and €25.4 million and €28.4 million in the six months ended June 30, 2021 and 2020, respectively. Sales in 2020 and 2021 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. In September 2021, we announced that DLA exercised the first option year of this agreement. Due to the ongoing impact of the COVID-19 pandemic on Department of Defense operations, the option terms were amended such that the minimum number of doses for the first option year is now 200,000 with an approximate value of $28.8 million. This brings the total minimum value of the agreement to approximately $118 million, assuming the exercise of the second year option of 250,000 doses, which remains unchanged. See “—Material Agreements—Department of Defense Contracts” for more information about this agreement.

Japanese encephalitis background

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

Other than IXIARO, there is currently no other treatment for Japanese encephalitis except symptomatic support. In 2017, approximately 30 million people traveled from Europe and North America to the countries where JEV is endemic. Vaccination remains the single most important control measure against Japanese encephalitis worldwide.

IXIARO Overview

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

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

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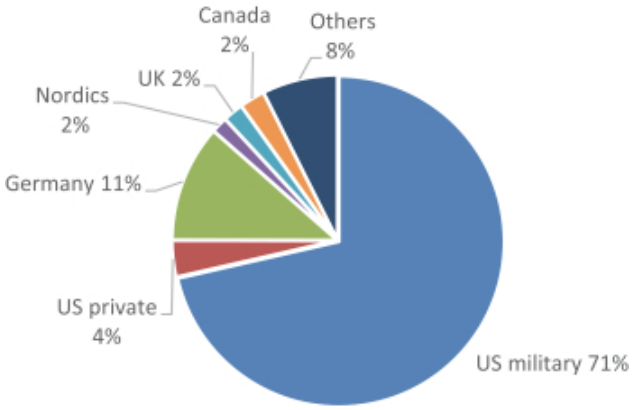
Sales of IXIARO

IXIARO was first approved by the FDA and European Commission in 2009, and since then sales for IXIARO grew to €94.1 million during the year ended December 31, 2019. Due to travel restrictions in light of the ongoing COVID-19 pandemic, sales for IXIARO declined to €48.5 million during the year ended December 31, 2020. 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.



FY2020 product sales analysis €48.5m

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

DUKORAL—Our vaccine for cholera and ETEC

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

Cholera disease background

Cholera is an acute diarrheal disease caused by ingestion of food or water contaminated with the bacterium *V. cholerae.* Cholera remains a global threat to public health and an indicator of inequity and lack of social

development. Researchers have estimated that every year, there are roughly 1.3 to 4.0 million cases, and 21,000 to 143,000 deaths worldwide due to cholera. Cholera is an extremely virulent disease that can cause severe acute watery diarrhea. It takes between 12 hours and five days for a person to show symptoms after ingesting contaminated food or water. Cholera affects both children and adults and can kill within hours if untreated.

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

ETEC disease background

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

DUKORAL Overview

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

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

Sales of DUKORAL

DUKORAL was granted marketing authorization throughout the European Union in 2004, having previously been licensed in Sweden and Norway in 1991 through national licensure processes. DUKORAL was approved in Canada in 2003. Sales of DUKORAL were €13.3 million and €31.5 million in the years ended December 31, 2020 and 2019, respectively, of which Canada represented approximately €6.8 million and €18.3 million, respectively, of global sales due to the strong overlap between Canadian travelers to regions of high ETEC prevalence and the vaccine's approved indication. In the six months ended June 30, 2021 and 2020, sales of DUKORAL were €0.4 million and €12.1 million, respectively. Similar to other travel vaccines, sales in 2021 continue to be significantly impacted by ongoing COVID-19 travel restrictions.

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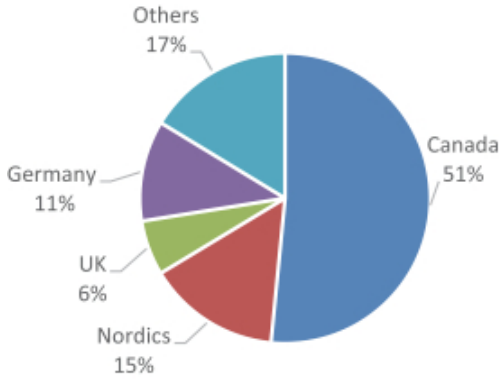

FY2020 product sales analysis €13.3m

Sales and Marketing

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

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

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Commercial operations in key markets

Based on 2020 product sales, we manage approximately 82% 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 2020, North America accounted for 78% of worldwide IXIARO sales, comprising 71% generated by the U.S. military, 4% generated by U.S. private, and 2% in Canada.

In 2020, sales of DUKORAL in Canada represented about 51% 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 commercialize two differentiated vaccines in Austria. We entered into a marketing and distribution partnership with Bavarian Nordic in 2020 to commercialize their Rabipur and Encepur brands in Austria, the UK, France, Belgium, The Netherlands and Canada.

Manufacturing

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

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

We operate three manufacturing sites augmented by contract manufacturing partners. Our manufacturing network has been operating and producing licensed vaccines for more than 10 years. We have a highly experienced management team and workforce operating our production network. We have the expertise and capability to produce most types of viral or bacterial vaccines.

Livingston (Edinburgh), Scotland, UK

Our fully owned property, comprising approximately 65,000 square feet of currently operational manufacturing space, operates under a Manufacturers License from MHRA. The site is qualified to meet required quality standards of several regulatory bodies including FDA, the European Commission, EMA, TGA and Health Canada. We employ currently around 250 staff on the site. The site is a multi-product, FDA-registered manufacturing site and viral vaccines center of excellence.

The Livingston site operates dedicated bulk production units for IXIARO and a BioSafety Level 3 multi-purpose unit used for VLA1553 Phase 3 clinical supply and future commercial manufacturing, currently dedicated to the commercial production of our COVID vaccine candidate VLA2001.

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

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Solna (Stockholm), Sweden

Our Solna facility can operate on a multi-product basis and comprises approximately 12,000 square meters. The site is qualified to meet required standards of several regulatory bodies including the competent Swedish authorities, Health Canada and TGA. Our Solna site has a heritage and history from more than 100 years in vaccines operations. It is currently our center of excellence for fill-finish operations. With around 200 employees, the site operates as a dedicated and integrated production unit for DUKORAL as well as a Clinical Trial Manufacturing Unit currently operating as a contract manufacturing business. As part of our COVID vaccine business we are currently expanding our existing fill-finish capacity by fitting out a nearby site for formulation, filling and packaging of our COVID vaccine candidate, VLA2001. 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 European Commission in April 2020 for protection against cholera only. It has not yet been commercially launched in Europe.

Competition related to our product pipeline

Lyme disease

Companies such as GlaxoSmithKline, Sanofi and Baxter had clinical programs that advanced thorough pre-clinical all the way to market. LYMErix, from GSK, achieved approval in the US and was later taken out of the market due to lack of market access and potential safety concerns, although it was later proven to be safe by a FDA advisory committee. Sanofi and Baxter were not successful and stopped their programs before requesting a marketing authorization. Other companies like Takeda Pharmaceuticals, Inovio Pharmaceuticals and Euroimmun are developing antibody-mediated treatment and are in pre-clinical and/or Phase 1/2 clinical stage. Apart from vaccines, we are also aware of potential treatments to prevent Lyme disease that are in early clinical development. We are also aware of companies developing mRNA such as Moderna Therapeutics, or therapeutic antibiotic drug candidates such as Ixodes; however, these remain in the very early stages of clinical development.

Chikungunya

We are aware of companies such as Merck, NIAID, Emergent, Barath Biotech, Moderna Therapeutics, Inovio, DRDE, Indian Immunological, UAB developing clinical stage vaccine candidates with neutralizing antibodies

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mechanism of action for chikungunya. Companies such as Takeda Pharmaceuticals, Profectus, Nanotherapeutics, Medigen, Vaxart, Ti Pharma, Arbovax, GlaxoSmithKline, GenPhar are developing vaccine candidates with similar mechanism of action although they are currently at pre-clinical stage of development.

COVID-19

A number of companies are actively advancing COVID-19 vaccines through the clinic. Pfizer and BioNtech, Moderna Therapeutics, AstraZeneca and Johnson & Johnson 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, Novavax, Inovio Pharmaceuticals are currently developing vaccine candidates into Phase 2 and Phase 3 clinical stage development. Developers of COVID-19 vaccines are also investigating adaptions of their vaccines to protect against new variants of the virus.

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 base year had a minimum value of approximately $53 million for 370,000 doses, and the first option year, which DLA has exercised, has a minimum value of approximately $28.8 million for 200,000 doses. The second option year, if exercised, has a minimum value of approximately $36 million for 250,000 doses. Like most governmental contracts, these contracts can be terminated by DLA for convenience at any time.

We will also provide additional inventory after September 2023 to mitigate the potential impact of unused stock that may expire. This replacement inventory will be provided without cost to DLA and recognized as deferred revenue of up to $9 million beginning in fiscal year 2021.

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

Pfizer License Agreement

In April 2020, we entered into a research collaboration and license agreement, or the Pfizer License, with Pfizer. In connection with the Pfizer License, we granted to Pfizer (a) an exclusive, worldwide, sublicensable license under certain patents, know-how, and materials and (b) a non-exclusive, worldwide, sublicensable license under all patents, know-how or other intellectual property rights controlled by us, in each case to use, have used, develop, have developed, manufacture, have manufactured, commercialize, have commercialized and otherwise exploit VLA-15 and related products for all therapeutic, diagnostic and prophylactic human and veterinary use. Under the Pfizer License, we also obtained, during the development term, a non-exclusive, royalty-free, fully paid-up, worldwide license with the right to sublicense to subcontractors under certain patents and know-how controlled by Pfizer and patents and know-how developed under the Pfizer License to perform development activities relating to VLA15 and related products.

We are obligated to grant licenses or sublicenses that are consistent with the Pfizer License directly to affiliates of Pfizer upon Pfizer’s written request. Each party also granted the other a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up worldwide license for research purposes with the right to sublicense to affiliates under its know-how, materials and confidential information disclosed under the agreement.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 £98.5 million ($134.6 million based on the exchange rate as of December 31, 2020) under the UK Supply Agreement.

Under the UK Supply Agreement, we were obligated to use commercially reasonable efforts to develop the vaccine candidate to secure marketing authorization (and to prosecute the application for minimum viable marketing authorization) in the UK, to conduct assigned activities in accordance with the facility and manufacturing plans and to perform other activities, including working with third parties to maintain sufficient manufacturing capacity. Pursuant to the terms of the UK Supply Agreement, the UK Authority placed an initial order for 60 million doses to be delivered in 2021 and was granted an option for a further 40 million doses to be delivered in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. In January 2021, the UK Authority exercised its option to order 40 million doses for delivery in 2022. 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 Supply Agreement requires the UK Authority to pay us advance payments to fund certain manufacturing-related expenses over the life of the project, subject to our continued supply of product in accordance with the terms of the UK Supply Agreement. 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.

Following the close of business on September 10, 2021, we received notice of the UK Authority’s decision to terminate the UK Supply Agreement. We never received any indication from the UK Authority, prior to this time, of the UK Authority’s intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for us.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that we would allegedly , at some time in the future, our obligations regarding the delivery schedule under the UK Supply Agreement. We strongly dispute the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and do not consider such termination to be valid. However, in the event of termination of the UK Supply Agreement on this basis, the UK Authority could be entitled to recover damages and funding provided to us under the UK Supply Agreement. In a worst case scenario, it could be argued that our liability under the UK Supply Agreement could range up to as high as all sums paid to us. As of June 30, 2021, the UK Authority had placed orders and provided advance and funding payments related to the development and manufacture of VLA2001 of £310 million (€350 million), reported as refund/contract liability specified below. However, we believe that, even in the unlikely event that the UK Authority is able to successfully demonstrate that it suffered loss as a consequence of an alleged anticipatory breach by us, it is considered remote that we would be held liable for any damages, let alone damages of such a magnitude. In any event, the UK Authority has not notified us of any specific claim for damages in connection with the purported termination nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. We have acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and, as such, the termination became effective on October 10, 2021. The UK Supply Agreement provides that, in the case of termination for convenience by the UK Authority, we shall not be obliged to refund or repay any amount paid by the UK Authority. A royalty on sales and other obligations, as described below, may survive termination in certain circumstances.

We were still, and still are, completing the construction of our new manufacturing facility, Almeida, at our site in Livingston, Scotland; this project was largely funded through certain advance payments made by the UK Authority pursuant to the UK Supply Agreement. Unless a satisfactory resolution can be secured, we may not be able to complete this construction.

As of June 30, 2021, the significant assets and liabilities relating to the COVID-19 vaccine program that could be impacted by the termination of the UK Supply Agreement are the following:

- Property, Plant and Equipment of €43.9 million.
- Advance payments paid to suppliers for raw materials of €46.9 million.
- Inventories of €94.9 million.
- Refund liabilities of €14.1 million related to potential royalty payments.
- Contract liabilities of €335.6 million.

The final terms of the termination, which we are discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and our future results of operations. The impact is uncertain as of the date of issuance of our unaudited interim condensed consolidated financial statements as of June 30, 2021:

- Inventories and advance payments for inventories may be revalued to net realizable value. As changes in our business plan resulting from the termination of the UK Supply Agreement may have an impact on our manufacturing plan, a write-down of raw materials, work in progress and advance payments of raw materials of up to €141.8 million may be necessary. This depends on concomitant changes to the supply plan, marketing authorization, commercial traction and ability to extend the current shelf life (expiry dates) of our existing inventory.
- We believe that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay us certain amounts in respect of commitments that we had made prior to termination. Nevertheless, a provision regarding related onerous supplier and lease agreements may be needed depending on the outcome of the negotiations with the UK Authority and our suppliers.

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

- We are currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If we were to cease to use our COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, acquired with funds advanced by the UK Authority, we may have certain obligations to the UK Authority, such as a partial reimbursement of funding received, in respect of those assets if they are sold, disposed or repurposed.
- Depending on the final outcome of discussions with the UK Authority, some or all of our contract liabilities may be recorded as revenue or other income for an amount that is unknown at this time.
- The termination of the UK Supply Agreement is considered to be an impairment indicator and therefore an impairment test of the Property, Plant and Equipment dedicated to the COVID-19 vaccine program and other assets used for the COVID-19 vaccine program and other products will be performed as part of the December 2021 accounting closing process.
- Under the terms of the UK Supply Agreement, we are required to pay the UK Authority a royalty in respect of sales of our UK-manufactured vaccine to non-UK customers. This requirement may survive termination of the UK Supply Agreement, and the aggregate maximum royalty payable to the UK Authority is €100 million, of which €14.1 million is recognized as refund liability as of June 30, 2021.

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 combination of the Antigen and Dynavax's adjuvant. We obtained an exclusive (even as to Dynavax), worldwide, fully-paid-up, sublicensable (including through multiple tiers), transferable, royalty free license under these joint patents to make, use, develop, sell, and otherwise commercialize the Product or biosimilar versions thereof. The Dynavax Agreement 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 sold, disposed or repurposed. 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

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Valneva SE Pursuant to 17 C.F.R. Section 200.83**

increased outbreak preparation need. This includes maintaining at our cost a one-year rolling safety stock comprised of not less than 200,000 doses of chikungunya vaccines, referred to as the Safety Stock. In case the Safety Stock is used to address an outbreak or increased outbreak preparation need, and CEPI wishes to replenish such Safety Stock, CEPI shall pay us the related production costs.

Either party may terminate the CEPI Agreement upon an uncured material breach of the agreement or insolvency of the other party. CEPI may also terminate the agreement if we are unable to discharge our obligations, for safety, regulatory or ethical issues, if we do not satisfy specified criteria for funding, if there are material changes to the development plan without CEPI's prior written consent, or during the term any affiliate to whom we have assigned or transferred the agreement ceases to be our affiliate. We may also terminate the agreement (in whole or with respect to certain markets) for convenience at any time after 10 years following the grant of U.S. marketing approval for the product, at any time after 3 years following the grant of U.S. marketing approval for the product if we are unable to sell the product at a viable price, or if CEPI transfers or assigns the agreement other than to specified entities. Following the last to occur of (a) the granting of U.S. marketing approval for the product and (b) such approval in the first low income country, in the event we undergo a change of control or sell the entire chikungunya business, we may also terminate the agreement. In each of these terminations by Valneva, we have obligations to collaborate with CEPI for 2 years to find a third party supplier to whom our obligations under the CEPI Agreement will be assigned and to transfer the drug substance and drug product technology and related intellectual property (with the exception of trademarks) to such third party supplier. In lieu of such transfer, after 2 years following termination, the CEPI Agreement will be suspended, except for certain continuing obligations, until we and CEPI agree to continue the program appropriate to the circumstances.

In connection with our obligations under the CEPI Agreement, and following the execution of a binding term sheet in May 2020, in January 2021 we entered into definitive agreements with Instituto Butantan, a Brazilian public institute, and Fundacao Butantan, a Brazilian non-profitable private foundation of the Instituto Butantan, which we refer to jointly as Butantan, engaged in the research, development, manufacture and commercialization of vaccines in Brazil, pursuant to which we and Butantan intend to collaborate to transfer our drug product technology to Butantan, to enable Butantan to develop, manufacture and commercialize our chikungunya vaccine in low and middle income countries and obtain WHO prequalification. In turn, Butantan will provide certain clinical and Phase 4 observational studies that we will use to meet regulatory requirements with the FDA. Butantan will also have to comply with certain CEPI requirements, among others, equitable access to the product and outbreak related obligations, including maintaining a Safety Stock.

GSK Distribution Agreement

In December 2015, we entered into a distribution agreement, or the GSK Distribution Agreement, with GlaxoSmithKline GmbH (as a successor in interest to Novartis Vaccines and Diagnostics, Inc.), or GSK, pursuant to which we granted GSK an exclusive right to import, market, promote, distribute and sell IXIARO in Germany, including sub-distribution rights in accordance with the terms of the GSK Distribution Agreement. 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

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

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.

Bavarian Nordic Distribution Agreements

In November 2020, Valneva Austria GmbH, or Valneva Austria, entered into a distribution agreement, or the IXIARO Distribution Agreement, with Bavarian Nordic A/S, or BN, pursuant to which Valneva Austria granted BN an exclusive right to import, market, promote, distribute and sell IXIARO in Germany. In parallel, Valneva Sweden AB, or Valneva Sweden, entered into a distribution agreement, or the DUKORAL Distribution Agreement, with BN pursuant to which Valneva Sweden granted BN an exclusive right to import, market, promote, distribute and sell DUKORAL in Germany. The IXIARO Distribution Agreement and the DUKORAL Distribution Agreement together are referred to as the BN Distribution Agreements.

The BN Distribution Agreements include sub-distribution rights. Each of Valneva Austria and Valneva Sweden has a co-exclusive right to deliver, distribute, market, sell, promote, and import IXIARO and DUKORAL, as applicable, in Germany solely with respect to certain non-profit organizations. Pursuant to the BN Distribution Agreements, BN is required to use reasonable commercial efforts to promote, sell and distribute IXIARO and DUKORAL in Germany and is required to purchase an agreed upon minimum quantity of IXIARO and DUKORAL doses during each year of the BN Distribution Agreements. The BN Distribution Agreements shall commence on January 1, 2022 and continue until December 31, 2024. Unless terminated earlier this initial term will automatically extend by two years to terminate on December 31, 2026.

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

As of September 30, 2021, we had a portfolio of over 424 issued patents, including over 83 granted in Germany, France, United Kingdom, Spain and Italy, over 30 issued in the United States, over 160 pending patent applications, including 19 pending in Europe and 16 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, as of September 30, 2021, we own a patent family which includes two issued U.S. patents and two European patents as well as 21 foreign patents and 7 patent applications with claims covering the composition of matter of VLA15. We further own a second patent family which includes two issued U.S. patents and one granted European patents as well as 15 foreign patents and 4 patent applications with claims covering the composition of matter of VLA15. Patent applications, if issued, and patents in these families are expected to expire in 2033 and 2035, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

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

As of September 30, 2021, we also own 3 International patent applications with claims directed to compositions comprising OspA fusion proteins including uses thereof and to improved methods for producing a vaccine. Patent applications claiming priority to these patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

VLA1553—Chikungunya vaccine candidate

In regards to our chikungunya vaccine candidate, VLA1553, as of September 30, 2021, 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.

As of September 30, 2021, we also own two pending PCT applications with claims covering formulations and manufacturing processes of VLA1553. Patent applications claiming the benefit of these PCT applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

VLA2001—SARS-CoV-2 vaccine candidate

In regards to our SARS-CoV-2 vaccine candidate, VLA2001, as of September 30, 2021, we own one International patent application and 7 foreign patent applications with claims relating to the antigen and processes preparing the antigen of VLA2001, furthermore we co-own together with Dynavax 2 International patent and 3 national patent applications with claims related to adjuvant formulation and processes of preparing the formulation of VLA2001. These patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

VLA84—Clostridium difficile candidate

In regards to our *C. difficile* candidate VLA84, as of September 30, 2021, we own a patent family with three granted U.S. patents with claims covering the composition of matter of VLA84 and methods of use thereof, 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.

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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, as of September 30, 2021, 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. We have recently received a third party observation against the European patent application of the above case.

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 September 30, 2021 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
IXCHIQ	1

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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83**

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 September 30, 2021, we hold 68 domain names (reserved or in the process of being reserved).

Government Regulation

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

Regulatory Approval in the United States

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

- completion of extensive pre-clinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;

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

Pre-clinical Studies

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

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed

and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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

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

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

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

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

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The

manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic does not undergo unacceptable deterioration over its shelf life.

FDA Review Processes

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

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

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

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

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety, purity, and potency of the product candidate. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is

not bound by recommendations of an advisory committee, but it generally considers such recommendations carefully when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. A CRL or deferred action on the application may also occur where FDA is unable to complete required pre-approval inspections due to travel restrictions and the COVID-19 pandemic. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing in order for FDA to reconsider the application. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months from receipt, depending on the type of information included. Even if data and information are submitted in response to the deficiencies identified in a CRL, the FDA may decide that the BLA does not satisfy the criteria for approval.

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

Orphan Drug Designation

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

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

Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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

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FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

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

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

Additional Controls for Biologics

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

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

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission

of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted.

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

Post-Approval Requirements

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

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

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

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;

- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are consistent with the provisions of the FDA-approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, issuance of warning or untitled letters, requirements to issue corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict the manufacturer's communications on the subject of off-label use of their products, as well as actions taken on behalf of the manufacturer, such as sponsored scientific and educational activities conducted by a third party.

Biosimilars and Reference Product Exclusivity

The ACA, signed into law in 2010, includes a subtitle called The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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

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

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

Regulatory Approval in the EU

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

Clinical Trial Approval

Pursuant to the 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 EU 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 EU Member States 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 EU 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 EU Member States and further detailed in applicable guidance documents.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. The new Clinical Trials Regulation entered into force on January 31, 2021 with a three-year transition period for certain aspects of on-going clinical trials. The Clinical Trials Regulation, which will be directly applicable in all the EU Member States, will repeal the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

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

to be governed by the national law of the concerned Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

Orphan Drug Designation and Exclusivity

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

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

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

Marketing Authorization

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

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products

with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients authorization through, the centralized procedure is optional on related approval.

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

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

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

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

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

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

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

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

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

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Data and Market Exclusivity

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

Regulatory Requirements after Marketing Authorization

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

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

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

Advertising Regulation

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

Regulatory Approval in the United Kingdom

On January 31, 2020, the United Kingdom left the EU (commonly referred to as "Brexit") and accordingly is no longer an EU Member State. A transition period began on February 1, 2020, during which EU pharmaceutical

law remained applicable to the United Kingdom, however this period ended on December 31, 2020. Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from EU regulations, Brexit has materially impacted, and could further materially impact, the regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as United Kingdom legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long-term. As the United Kingdom is no longer an EU Member State, the United Kingdom's participation in the European Medicines Regulatory Network has ceased and the United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA") has assumed the functions that were previously undertaken by the EU institutions for human medicines on the United Kingdom market (with the exception of Northern Ireland, which, pursuant to the Protocol on Ireland/Northern Ireland has remained aligned with EU regulations). The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time.

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

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

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International Regulation

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

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

U.S. Healthcare Laws and Regulations

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

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- The Health Insurance Portability and Accountability Act, or HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit

program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates 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 payments and other 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.

U.S. Legislative Reform

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

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

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established the Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow-on biologic products.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for the purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects.

In addition, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021. 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 until January 1, 2023. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. We expect that additional U.S. federal healthcare reform measures will be adopted in the future.

European Healthcare Laws and Regulations

In the EEA, pharmaceutical companies, products and distributors are also generally subject to extensive governmental price controls and other market regulations. In many EERA countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits.

In various EEA countries, continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper products as an alternative apply. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including countries representing major markets. The HTA process, which is currently governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EEA Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EEA level for joint clinical assessments in these areas. In June 2021, the European Parliament and Council reached a provisional agreement on the draft regulation. Entry into application of the Regulation could impose stricter and more detailed procedures to be followed by MAHs concerning conduct of HTA in relation to their products which may influence related pricing and reimbursement decisions.

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Coverage and Reimbursement

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

Third-party payors decide which therapies they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, biological, and vaccine products, or formulary, generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of such product by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. In addition, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

Third-party payors are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the EMA, FDA, or other government regulators; is not used in accordance with cost-effective treatment methods as determined by the third-party payor; or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third-parties is the biggest driver of the prices of our products.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced pharmaceutical pricing or reimbursement rates for medical products. For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care organizations, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of various laws including the ACA, that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on drugs (including vaccines) sold to certain Medicare Part D beneficiaries in the coverage gap (the so-called "donut hole").

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 five 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, a 10,763 square feet office and warehouse facility on a two year lease from December 2021 and a 27,695 square feet office and warehouse facility.

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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 September 30, 2021, we had a total of 768 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	253
Valneva Canada Inc.	5
Valneva SAS	3
Valneva Scotland Ltd	266
Valneva SE Lyon	5
Valneva SE Nantes	45
Valneva Sweden AB	171
Valneva UK Ltd	5
Valneva USA, Inc.	15
Total	**768**

Of these employees, 53% were primarily engaged in manufacturing, 24% in research and development, 19% in general and administrative functions and 5% in commercial operations.

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

Pursuant to local laws, including the laws of France and Austria, some of our employees are covered by collective bargaining agreements. We consider our relationship with our employees to be good.

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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 October 1, 2021.

Name	Age	Position
Management Board Members		
Thomas Lingelbach	59	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	57	General Counsel, Corporate Secretary
Supervisory Board Members		
Frédéric Grimaud	57	Chairman of the Supervisory Board
James Sulat	71	Vice Chairman of the Supervisory Board
Anne-Marie Graffin	60	Member of the Supervisory Board
Sharon Tetlow	62	Member of the Supervisory Board
Johanna Willemina Pattenier	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.

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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, M.D., has served as our Chief Medical Officer and as a member of our Management Board since October 2020. Prior to joining us, Dr. Jaramillo served as Senior Vice President, Market Access & Medical Affairs and then as Senior Vice President, Head of Global Market Access & Pricing at Daiichi Sankyo, GmbH from April 2013 to September 2020. Prior to Daiichi Sankyo, Dr. Jaramillo served as Senior Vice President, Medical Affairs & Clinical Development at Grünenthal, Inc. and prior to that held a variety of positions at GlaxoSmithKline plc. Dr. Jaramillo received his M.D. and B.S. in Pre-Medicine from Universidad Central Del Este.

Frédéric Jacotot has served as our Vice President of Legal & IP and General Counsel since 2013 and has served on our Management Board since April 2017. Prior to joining us, he served as counsel at Abbott Laboratories from 2010 to 2013. Mr. Jacotot received his *Diplôme d'études approfondies* in business law from Paris 1 Panthéon-Sorbonne University.

Supervisory Board

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

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

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

James Sulat has served on our Supervisory Board since 2013 and is currently Vice Chairman of our Supervisory Board. Prior to that, he served on the Supervisory Board of Intercell AG from 2005 until its

merger with Vivalis SA in 2013. From 2009 to 2013, Mr. Sulat served as Chief Executive Officer and Chief Financial Officer of Maxygen, Inc., and as a member of Maxygen's Board of Directors from 2003 to 2013. From 2005 to 2009, Mr. Sulat served in a variety of roles at Memory Pharmaceuticals Corp., including as President and Chief Executive Officer from 2005 to 2008 and as a member of Memory's Board of Directors from 2005 to 2009. Previously, Mr. Sulat served as Chief Financial Officer for Chiron Corporation and Stanford Health Services. Mr. Sulat has served on the Board of 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 has served on the supervisory board of Nanobiotix S.A. (Nasdaq: NBTX) since 2013. Ms. Graffin received her MBA from ESSEC Business School Paris. We believe Ms. Graffin's experience in the vaccine space and her experience advising biotech companies qualifies her to serve on our Supervisory Board.

Sharon Tetlow has served on our Supervisory Board since June 2020. She founded and has served as Managing Partner of Potrero Hill Advisors, which provides strategic and operational financial support to life science companies, since January 2016. Prior to that, she 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 and DICE Therapeutics, Inc. (NASDAQ:DICE) since November 2020, where she serves as Chair of the Audit Committee and a member of the Nominating and Corporate Governance Committee. Ms. Tetlow received her M.B.A. from Stanford University and her B.A. in Psychology from the University of Delaware. We believe Ms. Tetlow's expertise in corporate finance and strategic planning in the biotechnology and pharmaceutical industries and her public company board experience qualifies her to serve on our Supervisory Board.

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

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.

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Supervisory Board Committees

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

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

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

Audit and Governance Committee

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

Our Supervisory Board has determined that Mr. Sulat and Ms. Tetlow are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. We expect that within one year of our listing on Nasdaq in May 2021, Mr. Grimaud will resign from the audit and governance committee and will be replaced by an independent director; at that point, all members of the audit and governance committee will be independent. Our Supervisory Board has further determined that Mr. Sulat is an “audit committee financial expert” as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

The principal responsibility of our audit and governance committee is to monitor the existence and efficacy of our financial audit and risk control procedures on an ongoing basis.

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

- oversight of the statutory auditors’ work in relation to their review of the interim condensed consolidated financial statements, and their audit of the annual Company and consolidated financial statements;
- oversight of the statutory auditors and monitoring of the independence of the statutory auditors; and
- oversight of internal audit procedures and monitoring the efficiency of internal and risk management procedures.

Nomination and Compensation Committee

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

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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 continue to follow French corporate governance practices in lieu of Nasdaq listing requirements for each of the foregoing.

These exemptions do not modify the independence requirements for the audit and governance committee, and we intend to comply with the requirements of the Sarbanes-Oxley Act and the Nasdaq listing rules, which require that our audit and governance committee be composed of at least three independent members. Rule 10A-3 under the Exchange Act provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. Under Rule 10A-3, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or our shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by our shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least 33 1/3% of the outstanding shares of the company's ordinary voting shares. We intend to continue to follow our French home country practice, rather than complying with this Nasdaq rule. Consistent with French law, when first convened, general meetings of shareholders may validly convene only if the shareholders present or represented hold at least (i) 20% of the voting shares in the case of an ordinary general meeting or of an extraordinary general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium (the ordinary general meeting shall make its decision on a majority of half of the votes cast by the shareholders present or represented), or (ii) 25% of the voting shares in the case of any other extraordinary general meeting (the general meeting shall make its decision on a majority of two thirds of the votes cast by the shareholders present or represented). If such quorum required by French law is not met, the meeting is adjourned. There is no quorum requirement under French law when an ordinary general meeting or an extraordinary general meeting is reconvened where shareholders are voting on a capital increase by

capitalization of reserves, profits or share premium, but the reconvened meeting may consider only questions that were on the agenda of the adjourned meeting. When any other extraordinary general meeting is reconvened, the required quorum under French law is 20% of the shares entitled to vote. If a quorum is not met at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Code of Ethics

We have adopted a Code of Conduct, available on our website, which is applicable to all of our employees and members of our Management Board and Supervisory Board. 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 February 2021, 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

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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	€ 30,498
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 was a member of the Supervisory Board until March 2021 but 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.

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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 partial waiver of fixed remuneration for 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**	

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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 partial waiver of fixed remuneration for 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**	

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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 partial waiver of fixed remuneration for 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**	

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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	€3,300	€1,100 per month as per Dr. Jaramillo's Management Agreement. Prorated amount taking into account the starting date of Dr. Jaramillo's office as Management Board member.
– 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	**€114,396.32**	

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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 acting CFO.

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 partial waiver of fixed remuneration for Q2 2020. Amount taking into account an exchange rate from £ to € of 0.88471.
Termination indemnities	€776,197.65	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	**€1,146,033.53**	

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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 partial waiver of fixed remuneration for 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	€6,431.95 – €2,572.78 (Valneva SE) – €3,859.17 (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	**€478,213.18**	

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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 have obtained insurance coverage for liability under the Securities Act. We also have entered into agreements with our Management and Supervisory Board members to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified Management and Supervisory Board members.

These agreements may discourage shareholders from bringing a lawsuit against our Management and Supervisory Board members for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our Management and Supervisory Board members, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our Management and Supervisory Board members pursuant to these insurance agreements.

Equity Incentives

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our Management Board and Supervisory Board members and our employees, including stock options, Free Convertible Preferred Shares, 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.

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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 June 30, 2021:

Plan name	BSA 27
General Meeting date	June 30, 2016
Grant decision date	December 7, 2017
BSAs issued by the Management Board	87,500
Subscription price per share	€ 2.574
BSAs lapsed as of June 30, 2021	15,625
BSAs exercised as of June 30, 2021	31,250
Outstanding BSAs as of June 30, 2021	40,625
Valneva SE ordinary shares potentially resulting from exercise of the warrants remaining as of June 30, 2021	40,625

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.

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The following table sets forth the stock options outstanding as of June 30, 2021:

Plan name	ESOP 2013	ESOP 2015	ESOP 2016	ESOP 2017	ESOP 2019
General Meeting date	June 28, 2013	June 26, 2014	June 30, 2016	June 30, 2016	June 28, 2018
Grant date	October 2, 2013	July 28, 2015	October 7, 2016	December 7, 2017	September 30, 2019
Subscription price	€2.919	€3.92	€2.71	€2.85	€3.05
Option/share conversion ratio	1: 1.099617653 (then rounded-up for each beneficiary)	1: 1	1: 1	1: 1	1: 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	1,052,950	712,000	584,250	1,269,500	2,671,510
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 June 30, 2021	0	0	363,050	427,025	0
Shares resulting from exercise of stock options	0	0	363,050	427,025	0
Outstanding stock options as of June 30, 2021	642,200	528,000	36,200	559,725	2,224,760
Of which outstanding stock options held by corporate officers	*210,000*	*100,000*	*0*	*0*	*0*
Shares potentially resulting from stock option exercise after June 30, 2021	706,252	528,000	36,200	559,725	2,224,760
Stock options having lapsed as of June 30, 2021	410,750	184,000	185,000	282,750	446,750

Free Ordinary Shares

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

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

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

The following table shows the free ordinary shares outstanding as of June 30, 2021:

Plan name	Free ordinary share plan 2019-2023
General Meeting date	June 27, 2019
Management Board decision	December 19, 2019
Free ordinary shares granted by the Management Board	2,191,947 allocated in three tranches, each amounting to one third of the total individual allocation. If one third is not a whole number, the number of free ordinary shares will be rounded down for the first two tranches and rounded up for the third tranche.
Duration of vesting period	The first tranche 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 June 30, 2021	0
Free ordinary shares being vested as of June 30, 2021	1,842,404 (including 856,807 by corporate officers)
Free ordinary shares lapsed as of June 30, 2021	349,543
Performance and employment conditions	Concerning non-corporate officers employees, the vesting of each tranche will be contingent upon the beneficiary's performance in the Relevant Year having been rated not lower than "Meets Expectations" (regardless of any qualifying sign), as assessed by his/her supervisor under the Company's employee performance appraisal rules. Concerning corporate officers, the vesting of each tranche will be contingent upon the level of achievement of the Management Board member's collective and individual goals in the Relevant Year (as defined below), as assessed by the Supervisory Board, starting above 60% (60% = no vesting) and increasing in a linear way, so that 80% goal achievement will result in vesting of 50% of the relevant tranche and 100% goal achievement will result in vesting of 100% of the relevant tranche. ***Relevant Year*** means 2021 for the first tranche, 2022 for the second tranche and 2023 for the third tranche. If a vesting period expires before the performance has been assessed for the Relevant Year, the vesting of the relevant tranche will be postponed until all Participants have been assessed. Additionally, each of the beneficiaries must continuously remain a Management Board member, corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting, subject to the retirement exception below. 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

Plan name	Free ordinary share plan 2019-2023
Provisions relating to retirement	Beneficiaries who will retire in accordance with the age requirements of their applicable retirement regime before complete vesting will remain entitled to a prorated amount of shares, for each unvested tranche, based on the period from the initial grant date until retirement, as compared to the total duration of the tranche in question (2, 3 or 4 years); provided, however, that the performance condition stated above was met in the performance appraisal immediately preceding the retirement. For Management Board members (including the CEO), the level of performance will also affect the amount of shares kept.
Provisions relating to a change of control	If (a) a Change of Control (as defined below) occurs not earlier than December 19, 2023, and (b) the performance condition stated above was met for the calendar year immediately preceding the year of Change of Control (or for the year of Change of Control if already assessed), all tranches will vest immediately. For Management Board members (including the CEO), their level of performance will also affect the amount of shares that will be the subject of accelerated vesting. If a Change of Control takes place before December 19, 2021, and Article L. 225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however to the above-mentioned performance conditions, and for the Management Board (including the CEO), to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free ordinary shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable plan rules will apply to this calculation, *mutatis mutandis.* ***Change of Control*** means that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L 233-3 of the French Commercial Code.

Free Convertible Preferred Shares

In December 2017, we granted 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.

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The following table shows the Free Convertible Preferred Shares outstanding as of June 30, 2021:

Plan name	Free Convertible Preferred Share program 2017-2021
General Meeting date	June 29, 2017
Management Board decision	December 7, 2017
FCPS granted by the Management Board	34,017 (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 June 30, 2021	0
FCPS being vested as of June 30, 2021	32,463 (including 14,898 by corporate officers)
FCPS lapsed as of June 30, 2021	1,554
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/her convertible preferred shares within 3 months from expiry of the 4 years' period mentioned above, his/her 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 recent years, we established Phantom Stock Option Programs with terms and conditions similar to the then-existing ESOPs described above, for employees who are U.S. citizens.

The Phantom Stock Option Programs are based on our share price and entitle the participants to a potential cash bonus if there has been an increase in our share price compared to the entry price at the grant date. The Phantom Shares Program does not have any dilutive effect on our shareholders, as the phantom shares do not constitute or qualify for our ordinary shares.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

The overall objectives of the Phantom Stock Option Programs are (i) to retain certain employees who are U.S. citizens, (ii) to create long-term incentive for the participants and (iii) to align the interests of our employees who are U.S. citizens and our employees eligible for the ESOPs. Each employee participating in the program has phantom stock options potentially giving right to a certain number of phantom shares, which will be settled in cash instead of equity.

The entry price per phantom share for each program is calculated on the basis of the volume-weighted average closing price of our shares on Euronext Paris during a period of 20 trading days prior to the grant of options under the parallel ESOP. Current entry prices are set in a range from €2.71 to €3.92. The phantom shares will be settled in cash between 2023 and 2030 by subtracting the entry price per share from the market price per share and multiplying the result by the total number of granted phantom shares, but only if our market price per share at that date exceeds the entry price. The market price per share will be based on the closing price of our shares on Euronext Paris on the date of receipt of the exercise notice.

In 2020, we established a Phantom Free Share Plan for the benefit of senior managers who could not receive free ordinary shares under the free ordinary share plan 2019-2023 because they were not members of the Management Committee. This plan includes vesting and performance conditions similar to those of the free ordinary share plan 2019-2023, but provides for a settlement in cash instead of equity.

As of June 30, 2021, the Phantom Stock Option Programs consisted of an aggregate of 845,200 phantom shares.

The liability for the phantom plans is measured (at the end of each reporting period) at the fair value of the share options rights (determined using the Black Scholes valuation model), by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

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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.

Participation in our Nasdaq Offering

In May 2021, Bpifrance Participations SA purchased 1,514,576 of our ordinary shares at the public offering price of €11.00 per share, for an aggregate purchase price of €16.7 million.

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, €193.1 thousand excluding tax in 2020 and €101.1 thousand excluding tax in the six months ended June 30, 2021.

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

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

Related Person Transaction Policy

We comply with French law regarding approval of transactions with related parties. In May 2021, our Supervisory Board adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and the amount involved in the transaction exceeds $120,000, with the exception of usual transactions concluded under normal conditions. A related person is any member of the Management Board or Supervisory Board or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to the Supervisory Board for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our Management Board and Supervisory Board and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

In addition, under our Code of Conduct, our employees and Management and Supervisory Board members have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, the Supervisory Board, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on the independence of a member of the Management Board or Supervisory Board in the event that the related person is a member of the Management Board or Supervisory Board, immediate family member of a member of the Management Board or Supervisory Board or an entity with which a member of Management Board or Supervisory Board is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, the Supervisory Board must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as the Supervisory Board determines in the good faith exercise of its discretion.

All of the transactions described above were entered into prior to the adoption of the written policy, but our Supervisory Board evaluated and approved all transactions that were considered to be related party transactions under French law at the time at which they were consummated.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

PRINCIPAL SHAREHOLDERS

The following table and accompanying footnotes sets forth, as of October 1, 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 October 1, 2021, approximately 13,204,676 shares, or 13% of our ordinary shares outstanding at that date, were held of record by 16 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 October 1, 2021 and options and warrants that are currently exercisable or exercisable within 60 days of October 1, 2021. Ordinary shares subject to free ordinary shares, options and warrants currently exercisable or exercisable within 60 days of October 1, 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 99,915,188 ordinary shares issued as of October 1, 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 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Valneva SE, 6 rue Alain Bombard, 44800 Saint-Herblain, France.

	Number of Ordinary Shares Owned Before Global Offering	Percentage of Ordinary Shares Beneficially Owned	
		Before Global Offering	After Global Offering
5% Shareholders:			
Groupe Grimaud La Corbière SAS(1)	13,704,831	13.7%	%
Bpifrance Participations SA(2)	8,971,361	9.0	
Management Board and Supervisory Board Members:			
Thomas Lingelbach(3)	357,953	*	
Franck Grimaud(4)	601,519	*	
Juan Carlos Jaramillo	—	—	
Frédéric Jacotot(5)	23,541	*	
Frédéric Grimaud(6)	13,975,326	14.0	
James Sulat	27,242	*	
Anne-Marie Graffin(7)	11,125	*	
Sharon Tetlow	—	—	
Johanna Willemina Pattenier	—	—	
All members of our Management Board and Supervisory Board as a group (9 individuals)(8)	**14,996,707**	**15.0**	

* Represents beneficial ownership of less than 1%.

(1) Consists of 13,704,831 ordinary shares held by Groupe Grimaud La Corbière SAS (“Groupe Grimaud”). The majority shareholder of Groupe Grimaud is La Financiere Grand Champ, a French company. Voting and investment control over the shares is held in Groupe Grimaud La Corbière by a strategic shareholders committee (*Comité Stratégique des Actionnaires*) comprised of Frédéric Grimaud, Joseph Grimaud, Claire Grimaud-Mandin, Odile Grimaud-Chateigner, Patrick Neaume, Unigrains (represented by Nicolas Mulle), Idia Participations (represented by Manuel Leal) and Bpifrance Participations (represented by Louis Molis). The principal business address of Groupe Grimaud and La Financiere Grand Champ is 3 La Corbière – Roussay – 49450 Sevremoine, France. Frédéric Grimaud, a member of our Supervisory Board, is the President and Chief Executive Officer of Groupe Grimaud.

(2) Bpifrance Participations SA (f/k/a Fonds Stratégique d’Investissement, “Bpifrance”) is a French public investment fund specializing in the business of equity financing via direct investments or fund and a wholly owned subsidiary of Bpifrance S.A., a French financial institution (“Bpifrance S.A.”). Caisse des Dépôts (“CDC”) and EPIC Bpifrance (“EPIC”) each hold 49.2% of the share capital of Bpifrance S.A. and jointly control Bpifrance S.A. CDC is principally engaged in the business of long-term investments. EPIC is principally engaged in the business of banking finance. Bpifrance holds directly 8,971,361 ordinary shares. As of the date hereof, neither Bpifrance S.A., CDC nor EPIC holds any ordinary shares directly. Bpifrance S.A. may be deemed to be the beneficial owner of 8,971,361 ordinary shares, indirectly through its sole ownership of Bpifrance. CDC and EPIC may be deemed to be the beneficial owners of 8,971,361 ordinary shares, indirectly through their joint ownership and control of Bpifrance S.A. The board of directors of Bpifrance holds voting and investment power over these shares and is comprised of Bpifrance’s chief executive officer, three directors appointed by the French State, three directors appointed by CDC and three independent directors. The current members of the board of directors of Bpifrance are Nicolas Dufourcq, Carole Abbey Duval, Antoine Saintoyant, Frederic Saint-Geours, Constance Valigny, Chloe Mayenobe, Victoire Aubry, Sophie Stabile, Romain Bonenfant and the French State, represented by Charles Sarrazin.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

The principal address for CDC is 56, rue de Lille, 75007 Paris, France and for Bpifrance, Bpifrance S.A. and EPIC is 27-31 avenue du Général Leclerc, 94700 Maisons-Alfort, France.

(3) Consists of (i) 139,983 ordinary shares, (ii) 8,008 ordinary shares issuable upon conversion of convertible preferred shares and (iii) 209,962 ordinary shares issuable upon exercise of stock options vested within 60 days of October 1, 2021.

(4) Consists of (i) 485,889 ordinary shares, (ii) 5,668 ordinary shares issuable upon conversion of convertible preferred shares and (iii) 109,962 ordinary shares issuable upon exercise of stock options vested within 60 days of October 1, 2021.

(5) Consists of (i) 10,802 ordinary shares, (ii) 1,742 ordinary shares issuable upon conversion of convertible preferred shares and (iii) 10,997 ordinary shares issuable upon exercise of stock options vested within 60 days of October 1, 2021.

(6) Consists of (i) 264,246 ordinary shares, (ii) 6,250 ordinary shares issuable upon exercise of BSA vested within 60 days of October 1, 2021 and (iii) the securities held by Groupe Grimaud described in footnote (1) above. Mr. Grimaud is the chief executive officer of Groupe Grimaud.

(7) Consists of (i) 8,000 ordinary shares and (ii) 3,125 ordinary shares issuable upon exercise of BSA vested within 60 days of October 1, 2021.

(9) Consists of (i) 14,640,993 ordinary shares, (ii) 15,418 ordinary shares issuable upon conversion of convertible preferred shares, (iii) 9,375 ordinary shares issuable upon exercise of BSA vested within 60 days of October 1, 2021 and (iv) 330,921 ordinary shares issuable upon exercise of stock options vested within 60 days of October 1, 2021.

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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 June 30, 2021, our issued share capital consisted of a total of 99,888,424 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. Of these 99,888,424 issued ordinary shares, 99,760,077 shares are outstanding and 128,347 are treasury shares.

As of June 30, 2021, the outstanding equity warrants, stock options, Free Convertible Preferred Shares and free ordinary shares could potentially result in the following new ordinary shares:

- 40,625 ordinary shares issuable upon the exercise of outstanding equity warrants (*bons de souscription d'actions*, or BSA), including 6,250 ordinary shares issued upon exercise of equity awards subsequent to June 30, 2021;
- 4,054,937 ordinary shares issuable upon exercise of outstanding stock options;
- 1,842,404 ordinary shares issuable upon full vesting of outstanding free ordinary shares (*actions ordinaires gratuites*);
- 2,012,706 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 June 30, 2021, our share capital as set forth in our bylaws is €14,986,340.70, representing 99,888,424 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, based on the number of shares issued as of June 30, 2021, our issued 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 20,514 convertible preferred shares with a nominal value of €0.15 per share.

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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 and June 30, 2021:

	Ordinary Shares
Ordinary Shares issued 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 issued 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 issued at December 31, 2020	90,950,048
Number of ordinary shares issued in connection with the exercise of BSA equity warrants	3,125
Number of ordinary shares issued in connection with the exercise of stock options	790,075
Number of ordinary shares issued in connection with the Nasdaq Offering	8,145,176
Ordinary Shares issued at June 30, 2021	99,888,424

History of Securities Issuances

From January 1, 2018 through June 30, 2021, 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).
- On January 27, 2021, we issued 793,200 new ordinary shares to a former Supervisory Board member and to employees, in connection with, respectively (a) the exercise of 3,125 equity warrants on

January 22, 2021 carried out by a total cash contribution of €8,043.75 (including €468.75 as nominal value), and (b) the exercise of 790,075 stock options between January 18 and January 25, 2021 inclusive carried out by a total cash contribution of €2,200,886.75 (including €118,511.25 as nominal value).

- On May 10, 2021, we issued 8,145,176 new ordinary shares in connection with our Nasdaq Offering, comprised of a public offering of 2,850,088 ADSs in the United States at an offering price of $26.41 per ADS and a concurrent private placement of 2,445,000 ordinary shares in Europe (including France) and other countries outside of the United States at an offering price of €11.00 per ordinary share, resulting in aggregate gross proceeds of $107.6 million (€89.6 million).

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 favor its exploitation, realization or development.

Management Board

The Management Board is responsible for our management and is composed of a minimum of two members and a maximum of 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.

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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.

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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

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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.

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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.

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A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which we send to such shareholder either at the shareholder's request or at our initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting, for two meetings (an ordinary and an extraordinary meeting convened for the same day or within 15 days) or for successive meetings convened with the same agenda.

A shareholder may vote by correspondence by means of a voting form, which we send to such shareholder either at the shareholder's request or at our initiative, or which we include in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on our website at least 21 days before the date of the meeting. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

The above legislation provides that shareholders (and all the persons who may attend the general meeting of shareholders) may participate in the meeting by means of a teleconference or audio-visual conference call if this conference allows for the identification of the participants, transmits at least the voice of the participants and allows the continuous and simultaneous retransmission of the debates.

Our Bylaws and French Corporate Law Contain Provisions that May Delay or Discourage a Takeover Attempt

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

- under French law, the owner of 90% of the share capital or voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the European Economic Area, or EEA, Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, a non-resident of France as well as any French entity controlled by non-residents of France may have to file a declaration for statistical purposes with the Bank of France (*Banque de France*) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold. See ‘‘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.

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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.

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Differences in Corporate Law

We are a *société européenne à directoire et conseil de surveillance*, or S.E., incorporated under the laws of France. The laws applicable to French S.E. differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to us and the Delaware General Corporation Law, the law under which many public companies in the United States are incorporated. This summary is not intended to be a complete discussion of the respective rights.

	France	Delaware
Number of the members of the Management Board and of the Supervisory Board	Under French law, a *société européenne à directoire et conseil de surveillance* must have at least three and may have up to eighteen members of the Supervisory Board. The number of members of the Management Board cannot be greater than seven. In addition, the composition of the Management Board endeavors to seek a balanced representation of women and men. The number of members of the Management Board and of the Supervisory Board is fixed by or in the manner provided in the bylaws. The number of members of the Supervisory Board of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied will be null and void as well as the deliberations taken by the Supervisory Board member irregularly appointed. The members of the Supervisory Board are appointed at the shareholders' general meetings.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws, unless the certificate of incorporation fixes the number of directors.
Members of the Management Board and of the Supervisory Board Qualifications	Under French law, a corporation may prescribe qualifications for the members of the Management Board and of the Supervisory Board under its bylaws. In addition, under French law, members of a supervisory board of a corporation may be legal entities (with the exception of the chairman of the supervisory board), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the supervisory board.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.

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	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	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	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	France	Delaware
	acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. When the shareholders' meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice. The convening notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Commerce and Companies (*registre du commerce et des sociétés*), the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.	
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	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	France	Delaware
	ordinary and an extraordinary meeting convened for the same 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.	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	France	Delaware
	Preferential subscription rights are transferable during a period equivalent to the subscription period but starting two business days prior to the opening of the subscription period and ending two business days prior to the closing of the subscription period.	
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.
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,	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

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

France	Delaware
2014 provides for safe harbor exemptions when the acquisition is made for the following purposes: • to decrease its share capital, with the approval of the shareholders at the extraordinary general meeting; • to meet obligations arising from debt securities that are exchangeable into equity instruments; or • with a view to distributing the relevant shares to employees or managers under a profit-sharing, restricted free ordinary share or share option plan. All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L. 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules. Under the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form. No such repurchase of ordinary shares may result in the company holding, directly or through a	impair the capital of the corporation.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	France	Delaware
	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	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

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	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.

Confidential Treatment Requested by Valneva SE Pursuant to 17 C.F.R. Section 200.83

	France	Delaware
Shareholder Suits	French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the Management Board (but not from the Supervisory Board) of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action are borne by the relevant shareholder or the group of shareholders. The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the members of the Management Board only, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.	Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must: • state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or • state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.
Amendment of Certificate of Incorporation	Under French law, corporations are not required to file a certificate of incorporation with the French Registry of Commerce and Companies (*registre du commerce et des sociétés*) and only have bylaws (*statuts*) as organizational documents.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: • its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and • the amendment is adopted by the affirmative votes of a majority (or greater percentage as may be specified by the corporation) of the outstanding shares entitled to vote on the amendment and a majority

**Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83**

	France	Delaware
		(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

Our ADSs are listed on the Nasdaq Global Select Market under the symbol "VALN" and our ordinary shares are listed on Euronext Paris under the symbol "VLA."

Transfer Agent and Registrar

The depositary for our ADSs is 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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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."

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Citibank is the depositary for the ADSs representing our ordinary shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank Europe plc, located at 1 North Wall Quay, Dublin 1 Ireland.

We have appointed Citibank as depositary pursuant to a deposit agreement. The form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website (www.sec.gov). Please refer to registration number 333-255301 when retrieving such copy. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, two ordinary share**s** that are on deposit with the depositary and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-Share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as an owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of France, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary's services are made available to you.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs, you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC, which nominee will be the only "holder" of such ADSs for purposes of the deposit agreement and any applicable ADR. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Distributions

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of France.

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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.

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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.

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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 global 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 global offering, 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;

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- 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.

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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;

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- 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 global 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).

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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.

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- The depositary shall not be liable for acts or omissions of any successor depositary in connection with any matter arising wholly after the resignation or removal of the depositary.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation including regulations of any stock exchange, or by reason of present or future provision of any provision of our Articles of Incorporation, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Incorporation or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder or beneficial holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- We and the depositary disclaim liability arising out of losses, liabilities, taxes, charges or expenses resulting from the manner in which a holder or beneficial owner of ADSs holds ADSs, including resulting from holding ADSs through a brokerage account.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary and you as ADS holder.

Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

As the above limitations relate to our obligations and the depositary's obligations to you under the deposit agreement, we believe that, as a matter of construction of the clause, such limitations would likely to continue to apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred under the deposit agreement before the cancellation of the ADSs and the withdrawal of the ordinary shares, and such limitations would most likely not apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred after the cancellation of the ADSs and the withdrawal of the ordinary shares and not under the deposit agreement.

In any event, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder. In fact, you cannot waive our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

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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.*

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SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to our Nasdaq Offering in May 2021, while our ordinary shares have been listed on Euronext Paris since 2013, there was 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 June 30, 2021, 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 additional 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 Select 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 issued as of June 30, 2021; and
- the average weekly trading volume of the ADSs on the Nasdaq Global Select 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, 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 Bank Europe SE 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.

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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.

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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 impact of Special tax accounting rules under Section 451(b) of the Code, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding shares or ADSs in connection with a trade or business outside the United States;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between France and the United States, or the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

(1) an individual who is a citizen or resident of the United States;

(2) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ordinary shares or ADSs in their particular circumstances.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

Passive Foreign Investment Company rules

Under the Code, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the value of our assets (generally determined on the basis of a weighted quarterly average) consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. Cash and cash-equivalents are passive assets for these purposes. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation 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 do not believe that we were characterized as a PFIC for the year ended December 31, 2020. 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 Select Market, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq Global Select Market and are regularly traded, and you are a holder of ADSs, we

expect the mark-to-market election would be available to U.S. Holders if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs in any year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ordinary shares or ADSs cease to be marketable stock.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable stock." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report may result in substantial penalties and extend the statute of limitations with respect to the U.S. Holder's federal income tax return. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Taxation of distributions

Subject to the discussion above under "Passive Foreign Investment Company rules," distributions paid on ordinary shares or ADSs, other than certain *pro rata* distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder for our taxable year of the distribution or the preceding taxable year. The amount of a dividend will include any amounts withheld by us in respect of French income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in

respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain *pro rata* distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit purposes, our dividends will generally be treated as passive category income. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, any French income taxes withheld from dividends on ordinary shares or ADSs at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any French income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or other taxable disposition of ordinary shares and ADSs

Subject to the discussion above under "Passive Foreign Investment Company rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals and certain closely-held entities may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares

or ADSs held in accounts maintained by financial institutions, in which case the accounts themselves may have to be reported if maintained by non-U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

Material French Tax Considerations

The following describes the material French income tax consequences to U.S. holders of purchasing, owning and disposing of our ADSs.

This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of our ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

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.

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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), other than those mentioned in Article 238-0 A, 2 *bis*, 2° of the FTC, may be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds).

Under application of the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty and is entitled to Treaty benefits will not be subject to French tax on such capital gain unless the 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. Pursuant to Article 244 *bis* B of the FTC, such legal persons, whatever their form, may obtain a refund of the portion of such withholding tax which exceeds the corporate income tax which they would have been liable to pay if their registered seat had been located in France, provided that (i) they do not effectively either participate in our management or our control and (ii) their registered office is located in a State or territory that has concluded a tax treaty with France that contains an administrative assistance clause on the exchange of information and the fight against tax fraud and tax evasion and that is not a non-cooperative State or territory within the meaning of Article 238-0 A of the FTC.

Financial Transactions Tax and Registration Duties

Pursuant to Article 235 *ter* ZD of the FTC, purchases of 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 Select Market, on which ADSs are 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 Select Market is acknowledged by the French AMF.

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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 currently (i) 26.5% for payment benefiting legal persons which are not French tax residents, and (ii) 12.8% for payment benefiting individuals who are not French tax residents. Dividends paid by a French corporation in non-cooperative States or territories, as defined in Article 238-0 A of the FTC other than those mentioned in Article 238-0 A, 2 bis, 2° of the FTC, will generally be subject to French withholding tax at a rate of 75% unless the company which pays the dividend proves that the distribution of such proceeds in that State or territory has neither the object nor the effect of permitting their location in such State or territory for the purpose of tax evasion).

However, eligible U.S. holders entitled to Treaty benefits under the “Limitation on Benefits” provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to this 12.8% or 26.5%, 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 26.5%, 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 26.5% or 75% as applicable. In that case, the U.S. holders may claim a refund from the French tax authorities of the excess withholding tax.

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

Estate and Gift Taxes

In general, a transfer of securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the double tax treaty entered into between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978 (as amended), unless (i) the donor or the transferor has the French citizenship or is domiciled in France at the time of making the gift or at the time of his or her death, or (ii) the ADSs were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Wealth Tax

Since January 1, 2018, the French wealth tax *(impôt de solidarité sur la fortune)* has been repealed and replaced by the French real estate wealth tax *(impôt sur la fortune immobilière).* The scope of such new tax is narrowed to real estate assets (and certain assets deemed to be real estate assets) or rights, held directly or indirectly through one or more legal entities and whose net taxable assets amount at least to €1,300,000.

Broadly, subject to provisions of double tax treaties and to certain exceptions, individuals who are not residents of France for tax purposes within the meaning of Article 4 B of the FTC, are subject to real estate wealth tax *(impôt sur la fortune immobilière)* in France in respect of the portion of the value of their shares of our company representing real estate assets (Article 965, 2° of the FTC). Some exceptions are provided by the FTC. For instance, any participations representing less than 10% of the share capital of an operational company and shares representing real estate for the professional use of the company considered shall not fall within the scope of the French real estate wealth tax *(impôt sur la fortune immobilière).*

Under the Treaty (the provisions of which should be applicable to this new real estate wealth tax *(impôt sur la fortune immobilière)* in France), the French real estate wealth tax *(impôt sur la fortune immobilière*) will however

generally not apply to securities held by an eligible U.S. holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that such U.S. holder (i) does not own directly or indirectly more than 25% of the issuer's financial rights and (ii) that the ADSs do not form part of the business property of a permanent establishment or fixed base in France.

U.S. holders are advised to consult their own tax advisor regarding the specific tax consequences which may apply to their particular situation with respect to such French real estate wealth tax *(impôt sur la fortune immobilière*).

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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.

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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).

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 Bank Europe SE, Jefferies International Limited, Jefferies GmbH and Jefferies LLC are the representatives of the underwriters.

Underwriters	Number Of Ordinary Shares	Number Of ADSs
Goldman Sachs Bank Europe SE		
Jefferies LLC		
Jefferies International Limited		
Jefferies GmbH		
Guggenheim Securities, LLC		
Bryan Garnier & Co.		
Bryan Garnier Securities SAS		
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 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 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 ADSs are purchased pursuant to this option, the underwriters will severally purchase ADSs in approximately the same proportion as set forth in the column titled “Number of ADSs” in the table above.

The address of Goldman Sachs Bank Europe SE is Taunusanlage 9-10, 60329 Frankfurt am Main, Germany, 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 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, the exchange rate on , 2021, as reported by the European Central Bank.

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 may be made by affiliates of the underwriters.

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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.

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 ADSs are listed on the Nasdaq Global Select Market under the symbol “VALN” and our ordinary shares are listed on Euronext Paris under the symbol “VLA.”

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 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.

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We estimate that our share of the total expenses of the offering, excluding estimated underwriting commissions, will be approximately $ million. 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, as amended.

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MiFID II Product Governance

Solely for the purposes of each manufacturer's product approval process, the target market assessment in respect of ordinary shares has led to the conclusion that: (i) the target market for the ordinary shares is eligible counterparties, professional clients and retail clients, each as defined in Directive 2014/65/EU, as amended, or MiFID II; and (ii) all channels for distribution of the ordinary shares to eligible counterparties, professional clients and retail clients are appropriate. Any person subsequently offering, selling or recommending the ordinary shares, or a distributor, should take into consideration the manufacturers' target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the ordinary shares (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels. For the avoidance of doubt, even if the target market includes retail clients, it has been decided that the ordinary shares will only be offered to persons who meet the criteria of eligible counterparties and professional clients.

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*);

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- 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.

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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.

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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 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	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing expenses	*
Consulting fees and expenses	*
Miscellaneous fees and expenses	*
Total	$ *

* To be completed by amendment.

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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, New York, New York, and Gide Loyrette Nouel A.A.R.P.I, Paris, France.

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EXPERTS

The consolidated financial statements of Valneva SE as of and for the years ended December 31, 2020 and 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 an unqualified opinion on the consolidated financial statements and 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 at 19, 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.

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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 (File No. 333-255301) has been 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.

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers and are 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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Valneva SE Pursuant to 17 C.F.R. Section 200.83

TABLE OF CONTENTS

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

Report of Independent Registered Public Accounting Firms

To the Management Board and Shareholders of Valneva SE

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Valneva SE ("the Company") as of December 31, 2020 and 2019, and the related consolidated statements of income (loss) and comprehensive income (loss), consolidated statements of cash flows and consolidated statements of changes in equity for each of the two years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020 in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Change in Accounting Principle

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Associés

/s/ PricewaterhouseCoopers Audit

/s/ Cedric Mazille

Bordeaux and Neuilly-sur-Seine, France
March 24, 2021, except for the change in composition of reportable segments discussed in Note 5.4 to the consolidated financial statements, as to which the date is October 20, 2021

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

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

1.1 Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	Note	Year ended December 31, 2020	2019
Product sales	5.4/5.5	65,938	129,511
Revenues from collaboration, licensing and services	5.4/5.5	44,383	(3,315)
Revenues		**110,321**	**126,196**
Cost of goods and services	5.4	(54,302)	(52,781)
Research and development expenses	5.4	(84,454)	(38,022)
Marketing and distribution expenses	5.4	(18,264)	(24,145)
General and administrative expenses	5.4	(27,539)	(18,398)
Other income and expenses, net	5.8	19,117	6,338
OPERATING PROFIT/(LOSS)		**(55,120)**	**(811)**
Finance income	5.9	689	1,449
Finance expenses	5.9	(10,738)	(3,082)
Result from investments in associates	5.15	(133)	1,574
PROFIT/(LOSS) BEFORE INCOME TAX		**(65,302)**	**(870)**
Income tax income/(expense)	5.10	909	(874)
PROFIT/(LOSS) FOR THE PERIOD		**(64,393)**	**(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**		**(0.71)**	**(0.02)**
— **diluted**		**(0.71)**	**(0.02)**

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

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1.2 Comprehensive Income (Loss)

€ in thousand	Note	Year ended December 31, 2020	2019
Profit/(Loss) for the period		**(64,393)**	**(1,744)**
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences	5.21.1	2,438	656
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)	5.29.1	(78)	(13)
Other comprehensive income/(loss) for the year, net of tax		**2,360**	**644**
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(62,033)**	**(1,100)**

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

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2 CONSOLIDATED BALANCE SHEETS

€ in thousand	Note	At December 31, 2020	2019
ASSETS			
Non-current assets		**140,737**	**135,561**
Intangible assets	5.12	35,409	41,813
Right of use assets	5.13	43,374	49,334
Property, plant and equipment	5.14	34,779	20,003
Equity-accounted investees	5.15	2,130	2,263
Deferred tax assets	5.10.2	5,570	4,988
Other non-current assets	5.19	19,476	17,161
Current assets		**308,427**	**129,162**
Inventories	5.17	26,933	25,772
Trade receivables	5.18	19,232	24,030
Other current assets	5.19	57,828	14,921
Cash and cash equivalents	5.20	204,435	64,439
TOTAL ASSETS		**449,164**	**264,723**
EQUITY			
Capital and reserves attributable to the Company's equity holders		**77,422**	**135,153**
Share capital	5.21	13,646	13,642
Share premium	5.21	244,984	244,912
Other reserves	5.21	52,342	45,756
Retained earnings/(Accumulated deficit)	5.21	(169,156)	(167,412)
Profit/(loss) for the period		(64,393)	(1,744)
LIABILITIES			
Non-current liabilities		**195,872**	**88,269**
Borrowings	5.23	46,375	24,317
Lease liabilities	5.13/5.26	49,392	56,592
Contract liabilities	5.27	58	732
Refund liabilities	5.28	97,205	6,105
Provisions	5.27	2,358	426
Deferred tax liabilities	5.10.2	412	—
Other liabilities	5.30	72	97
Current liabilities		**175,870**	**41,300**
Borrowings	5.23	6,988	1,999
Trade payables and accruals	5.24	36,212	16,567
Income tax liability	5.10	—	2,458
Tax and Employee-related liabilities	5.25	13,165	10,624
Lease liabilities	5.13/5.26	2,696	2,308
Contract liabilities	5.27	89,578	694
Refund liabilities	5.28	14,222	448
Provisions	5.27	10,169	2,315
Other liabilities	5.30	2,841	3,886
TOTAL LIABILITIES		**371,742**	**129,569**
TOTAL EQUITY AND LIABILITIES		**449,164**	**264,723**

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

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3 CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Year ended December 31, 2020	2019
Cash flows from operating activities			
Profit/(Loss) for the year		(64,393)	(1,744)
Adjustments for non-cash transactions	5.31	37,941	12,704
Changes in non-current operating assets and liabilities	5.31	88,472	3,597
Changes in working capital	5.31	77,740	(6,682)
Cash generated from operations	5.31	**139,759**	**7,875**
Income tax paid		(2,021)	(2,346)
Net cash generated from operating activities		**137,738**	**5,529**
Cash flows from investing activities			
Purchases of property, plant and equipment	5.14	(18,936)	(10,502)
Purchases of intangible assets	5.12	(535)	(382)
Proceeds from sale of intangible assets		24	—
Interest received		107	199
Net cash used in investing activities		**(19,340)**	**(10,685)**
Cash flows from financing activities			
Proceeds from issuance of common stock, net of costs of equity transactions	5.22	75	(2,484)
Disposal/(Purchase) of treasury shares	5.22	215	21
Proceeds from borrowings, net of transaction costs	5.23/5.31.2	50,266	11,781
Repayment of borrowings	5.23/5.31.2	(21,995)	(11,684)
Payment of lease liabilities	5.13/5.26	(2,111)	(2,709)
Interest paid		(4,711)	(2,621)
Net cash generated from/(used in) financing activities		**21,740**	**(7,696)**
Net change in cash and cash equivalents		**140,138**	**(12,852)**
Cash and cash equivalents at beginning of the year		64,439	77,084
Exchange gains/(losses) on cash		(183)	207
Restricted cash	5.20	41	—
Cash and cash equivalents at end of the year		**204,435**	**64,439**

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

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4 CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand *(except number of shares)*	Note	*Number of shares issued*	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
Balance as at January 1, 2019 before IFRS 16 adoption		***90,917,837***	**13,638**	**244,900**	**52,060**	**(170,676)**	**3,264**	**143,186**
Changes in Accounting Policy — Initial Application of IFRS 16		—	—	—	(9,474)	—	—	(9,474)
Balance as at January 1, 2019		***90,917,837***	**13,638**	**244,900**	**42,587**	**(170,676)**	**3,264**	**133,712**
Total comprehensive loss		—	—	—	644	—	(1,744)	(1,100)
Income appropriation		—	—	—	—	3,264	(3,264)	—
Share-based compensation expense:	5.21							
— value of services		—	—	—	2,504	—	—	2,504
— exercises		*25,975*	4	12	—	—	—	16
Treasury shares	5.21	—	—	—	21	—	—	21
Balance as at December 31, 2019		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Balance as at January 1, 2020		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Total comprehensive loss		—	—	—	2,360	—	(64,393)	(62,033)
Income appropriation		—	—	—	—	(1,744)	1,744	—
Share-based compensation expense:	5.21							
— value of services		—	—	—	4,012	—	—	4,012
— exercises		*26,750*	4	71	—	—	—	75
Treasury shares	5.21	—	—	—	215	—	—	215
Balance as at December 31, 2020		***90,970,562***	**13,646**	**244,984**	**52,342**	**(169,156)**	**(64,393)**	**77,422**

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

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5 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

5.1 General information and significant events of the period

Valneva SE ("the Company") together with its subsidiaries ("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 several vaccines in development including a unique vaccine against Lyme disease, COVID-19 and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the United States with over 500 employees.

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	Interest held at December 31, 2020	Interest held at December 31, 2019
BliNK Biomedical SAS[1]	FR	Equity method	48.9%	48.9%
Vaccines Holdings Sweden AB	SE	Consolidation	100%	100%
Valneva Austria GmbH	AT	Consolidation	100%	100%
Valneva Canada Inc.	CA	Consolidation	100%	100%
Valneva France SAS	FR	Consolidation	100%	100%
Valneva Scotland Ltd.	UK	Consolidation	100%	100%
Valneva Sweden AB	SE	Consolidation	100%	100%
Valneva UK Ltd.	UK	Consolidation	100%	100%
Valneva USA, Inc.	US	Consolidation	100%	100%

The closing date for the consolidated financial statements is December 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 Austria GmbH commercializes IXIARO, DUKORAL and third party products such as Flucelvax, Fluad, Moskito Guard, Rabipur and Encepur.

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

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

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

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

1 see Note 5.15

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

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

SIGNIFICANT EVENTS OF THE PERIOD

COVID-19

The group has been and could continue to be materially adversely affected by the current COVID-19 pandemic, in regions where Valneva has significant manufacturing facilities, concentrations of clinical trial sites or other business operations. COVID-19 has adversely impacted sales of travel vaccines 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 the future 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 the 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 December 2020, Valneva reported cash and cash equivalents of €204.4 million. Valneva is prepared 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 December 31, 2020 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. For details on liquidity risk see Note 5.2.5.

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Impact from Covid-19 is described in following notes as of December 31, 2020 and for the year ended on December 31, 2020:

Impact from COVID-19	Note	
COVID-19 R&D program	5.1/5.27/5.28	Agreement with the UK Government to provide up to 190 million doses of its SARS-CoV-2 vaccine candidate—€19.0 million expenses for research and development included in 2020. €87.0 million included in contract liabilities and €20.9 million in refund liabilities, as of December 31, 2020.
Revenues from contracts with customers	5.5	Decline of revenues of Commercialized products for non-military market from Q2 2020 onward and therefore reduced Cash-inflows.
Impairment testing	5.12.2	Impairment test for IXIARO Cash Generating Unit “CGU” IXIARO and CGU DUKORAL CGU performed after triggering events – no impairment in 2020
Inventories	5.17	€7.4 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	5.18	Update of expected credit loss assessed—only minor impact in Group´s figures
Expenses		In H2 2020 a cost reduction of non-mission critical projects and expenses was introduced.

Brexit

The Group is of the opinion that Brexit will 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 2020.

Significant agreements signed in the periods

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 terminate the Strategic Alliance Agreement (“SAA”), originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively). Valneva paid €9.0 million to GSK immediately and 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). In 2019, the effect was €10.7 million negative revenues from collaboration and licensing reflecting both the current and future payment obligations (see Note 5.5).

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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 Notes 5.8, 5.22.5 and 5.30.

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 the Group's Lyme disease vaccine (Lyme VLA15) was signed with Pfizer Inc. (NYSE: PFE). This agreement was entered into with a customer as defined by IFRS 15 guidance on revenue contracts with customers, it included a $130 million (€116.9 million) upfront payment, which was received in June 2020. Valneva will refund 30% of all development costs through completion of the development program, which is planned for 2025. Therefore, as of December 31, 2020 €81.9 million has been recognized as discounted refund liabilities. The transaction price was determined taking into account the refund obligation of Valneva. The agreement includes R&D and service performance obligations for which revenue is recognized over time as well as a license performance obligation for which revenue is recognized at a point in time when Pfizer can benefit and use the license without further involvement of Valneva. The transaction has been allocated to the various performance obligations in proportion of their standalone selling price. In 2020, €31.6 million were recognized as Revenues from collaboration, licensing and services. €2.8 million costs to obtain a contract are included in other assets as of December 31, 2020. For more details see Notes 5.5 and 5.28.

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. This agreement had no material financial impact on the consolidated financial statement as of and for the year ended December 31, 2020. Revenues are recognized at a point in time when products are delivered to the customer.

In September 2020, DLA awarded Valneva 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 $53 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 COVID-19 vaccine candidate will be manufactured at Valneva's facilities in Livingston, Scotland. As part of broader COVID-19 response, Valneva plan to further invest in the manufacturing facilities in Livingston, Scotland and Solna, Sweden. The UK Government is obligated to provide Valneva advance payments to fund certain manufacturing-related expenses (related to the expansion of Valneva's Livingston, Scotland facility) over the life of the project, subject to Valneva's continued supply of product in accordance with the terms of the UK Supply Agreement. According to IFRS 15, this agreement includes two performance

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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. In 2020, none of these performance obligations were satisfied, therefore no revenue was recognized in this period. In December 2020 the option period to order 40 million doses was extended from December 31, 2020 to January 31, 2021. In January 2021 the UK Government has exercised its option to order 40 million doses. As of December 31, 2020, €87.0 million are included in contract liabilities, and €20.9 million are included in refund liabilities and represented the royalty obligation part of Valneva to the UK Government. Total expenses for research and development for the COVID-19 vaccine were €19.0 million in 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 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 for commercial use took place between Dynavax and Valneva in 2020. As of December 31, 2020 Valneva has included € 31.1 million in advance payments from this agreement (see Note 5.19). The Dynavax Agreement has a purchase order commitment amount of up to $136.8 million.

5.2 Summary of significant accounting policies

The principal accounting policies applied in preparing these consolidated financial statements are outlined below. These policies have been consistently applied to all years presented.

5.2.1 Basis of preparation

These 2020 Consolidated Financial Statements have been prepared in accordance with the International financial reporting standards, which comprise IFRS (International Financial Reporting Standards), IAS (International Accounting Standard) and their interpretations, SIC (Standards Interpretations Committee) and IFRIC (International Financial Reporting Interpretations Committee), as issued by the International Accounting Standards Board ("IASB").

The preparation of financial statements in conformity with IFRS as issued by the IASB requires the use of certain critical accounting estimates. It also requires the Group's management to exercise its judgement in applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 5.3.

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

These consolidated financial statements were approved by the Management Board on March 22, 2021 and were authorized for issuance by the Supervisory Board on March 23, 2021, except for the revised note 5.4 on segment information which retrospectively reflects the change in composition of reportable segments, which was approved by the Management Board on October 20, 2021.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

5.2.2 Impact of new, revised or amended Standards and Interpretations

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

Standard — Interpretation — Amendment		Effective Date	Effects
Amendments to IAS1 and IAS 8	Definition of Material	January 1, 2020	None
Amendments to IFRS 3	Definition of a Business	January 1, 2020	None
Amendments to IFRS 9, IAS 39 and IFRS 7	Interest Rate Benchmark Reform	January 1, 2020	None
Revised Conceptual Framework for Financial Reporting		January 1, 2020	None

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

(b) ***New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2020, 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, 2020:

- IFRS 17 — Insurance contracts;
- Amendments to IFRS 10 and IAS 28 — Sale or Contribution of Assets between an Investor and its Associate or Joint Venture;
- Amendments to IAS 1 — Classification of Liabilities as Current or Non-current;
- Amendments to IFRS 3 — Reference to the Conceptual Framework;
- Amendments to IFRS 4 — Insurance contracts;
- Amendments to IAS 16 — Property, Plant and Equipment — Proceeds before Intended Use;
- Amendments to IAS 37 — Onerous Contracts — Cost of Fulfilling a Contract;
- IBOR reform phase 2 — Amendments to IFRS 9 Financial instruments, IAS 39 Financial instruments: Recognition and Measurement, IFRS 7 Financial instruments: Disclosures, and IFRS 16 Leases
- Annual Improvements to IFRS Standards 2018-2020 Cycle — Amendments to IFRS 1 First-time Adoption of IFRS, IFRS 9 Financial Instruments, IFRS 16 Leases, and IAS 41 Agriculture

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

5.2.3 Consolidation

Subsidiaries

Subsidiaries are entities over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date that control ceases.

The Group uses the acquisition method of accounting to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair value of assets transferred, the liabilities incurred and the

equity interests issued by the Company. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Acquisition-related costs, other than those associated with the issue of debt or equity securities, are expensed as incurred. Identifiable assets acquired, liabilities, and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the consideration transferred over the fair value of the Company's share of the identifiable net assets acquired is recorded as goodwill. If the fair value of the net assets of the acquired subsidiary exceeds the consideration, the difference is recognized directly in the income statement as a bargain purchase gain. Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated.

Associates

Associates are entities over which the Company has significant influence.

5.2.4 Foreign currency translation

(a) ***Functional and presentation currency***

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Euros which is Valneva SE's functional and presentation currency.

(b) ***Transactions and balances***

Foreign currency transactions are converted into the functional currency using exchange rates applicable on the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in the income statement.

(c) ***Subsidiaries***

The results and financial position of all subsidiaries (none of which having the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are converted into the presentation currency as follows:

- assets and liabilities presented for each balance sheet are converted according to the exchange rate valid on the balance sheet date;
- 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.

5.2.5 Financial risks management

The Group's activities expose it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk, and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

Financial risk management is carried out under the CFO's responsibility and is closely supervised by the Management Board. The Group's risk management systems identify, evaluate and manage financial risks. The Management Board submits regular reports on its risk management systems, including the management of financial risks, to the Audit Committee of the Supervisory Board.

(a) ***Market risk***

Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risks arising from various currencies, primarily with respect to the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK) and the US Dollar ($). The foreign exchange risks from the exposure to other currencies, including the Danish Krone, the Swiss Franc and the Norwegian Krone, are relatively limited. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations.

The objective of the Group is to limit the potential negative impact of the foreign exchange rate changes, for example by currency conversion of cash and cash equivalents denominated in foreign currency and by using foreign currency options.

The Group has certain investments in foreign operations, the net assets of which are exposed to foreign currency translation risk.

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,	
	2020	2019
EUR/USD +10%	3,229	(3,134)
EUR/USD -10%	(3,947)	3,830
EUR/GBP +10%	(10,022)	(1,122)
EUR/GBP -10%	12,249	1,371
EUR/SEK +10%	(400)	114
EUR/SEK -10%	489	(140)
EUR/CAD +10%	(228)	(275)
EUR/CAD -10%	279	336

As of December 31, 2020, the changes in impact from an increase or a decrease in USD is mainly caused by a major increase in refund liabilities and borrowings denominated in USD in Valneva Austria GmbH.

As of December 31, 2020, the increase in the Foreign Currency Exchange Risk in GBP is caused by higher cash and cash equivalents and higher receivables within the group denominated in GBP. Both are related to the COVID-19 vaccine program (see Note 5.1). While the Group utilized a hedging strategy to lower its exposure to non-Euro currencies, there is business need to keep certain level of non-Euro funds available at its accounts at any time in order to cover payment obligations denominated in GBP or USD. In addition revaluation of certain non-Euro cash balances are offset by revaluation of non-Euro denominated refund liabilities on the Group's balance sheet (see Note 5.28).

Interest rate risks

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

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

Borrowings issued at variable rates expose the Group to cash flow interest rate risks, which are offset by cash and financial assets held at variable rates. During 2020, as well as 2019, the Group's investments at variable rates, 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, no material interest risk was identified. In case of increasing interest rates the positive effect from cash in banks will be higher than the negative effect from variable interest bearing liabilities, in case of decreasing interest rates there will be no material negative impact on interest from cash as long as banks do not charge negative interest for deposits. In 2019, the calculated impact on income before tax of a 0.25% shift in interest rate was an increase or decrease of €0.1 million.

(b) ***Credit risks***

The Group is exposed to credit risk. Valneva holds bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of its counterparts, the Group relies on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. The Group has policies that limit the amount of credit exposure to any single financial institution. The Group is also exposed to credit risks from its trade debtors, as its income from product sales, collaborations, licensing and services arises from a small number of transactions. The Group has policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits as set by the Management Board. Most of the trade receivables are receivables from governmental institutions with high credit rating (AAA-country or AA-country). The credit quality of financial assets is described in Note 5.16.3.

(c) ***Liquidity risks***

The Group is exposed to liquidity risk due to the maturity of its financial liabilities and the fluctuations of its operating cash-flow, and the potential implementation of early repayment clauses in loan or grant agreements. Furthermore, fluctuations in the Group's operating cash flow during accounting periods also generate liquidity risks. Prudent liquidity risk management therefore implies maintaining sufficient cash resources, cash equivalents and short-term deposits in order to satisfy ongoing operating requirements and the ability to close out market positions. Extraordinary conditions on the financial markets may, however, temporarily restrict the possibility to liquidate certain financial assets.

Although it is difficult to predict future liquidity requirements, the Group believes that the existing cash and cash equivalents as of December 31, 2020 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. For the existing loan agreement with covenants, amendments were agreed to reduce the minimum liquidity covenant and the minimum revenue covenant to prevent a breach of the covenants (see Note 5.23.2).

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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

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
Trade payables and accruals	16,567	—	—	—	—	—	16,567
Tax and employee-related liabilities[2]	6,570	—	—	—	—	—	6,570
Other liabilities	222	47	—	—	—	—	269
	30,882	**23,507**	**46,216**	**11,203**	**11,850**	**7,545**	**131,204**

At December 31, 2020 € in thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,004	25,569	37,900	5,148	—	—	75,621
Lease liabilities	3,442	28,078	3,677	9,446	9,963	3,850	58,456
Refund liabilities	20,025	82,670	48,566	—	—	—	151,260
Trade payables and accruals	36,212	—	—	—	—	—	36,212
Tax and employee-related liabilities[3]	8,300	—	—	—	—	—	8,300
Other liabilities	27	25	—	—	—	—	52
	75,010	**136,342**	**90,142**	**14,594**	**9,963**	**3,850**	**329,901**

The fair values as well as the book values of the Group's borrowings are disclosed in Note 5.22.5. To manage liquidity risk, the Group holds sufficient cash, cash equivalents and short-term deposit balances.

5.2.6 Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide benefits for shareholders and for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. The Group actively manages its funds to primarily ensure liquidity and principal preservation while seeking to maximize returns. The Group's cash and short-term deposits are located at several different banks. In order to maintain or adjust the capital structure, the Group may issue new shares or sell assets to reduce debt.

In order to pursue its business strategy to grow into a major, self-sustainable vaccine company through organic growth and opportunistic mergers & acquisitions, the Group may rely on additional equity and debt financing. Capital consists of "Equity" as shown in the consolidated balance sheet.

5.2.7 Fair value estimation

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

5.3 Critical accounting 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 recognized prospectively.

2 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.

3 Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required for financial instruments only.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

Estimates and judgements 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.

5.3.1 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 based on 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;
- Notes 5.8 and 5.30: Other income: The Group receives funding from the Coalition for Epidemic Preparedness Innovations (CEPI), which include performance obligations and refund obligations. Management's judgement is required to determine whether such components of an agreement are revenues from customers or fall within the standard of accounting for government grants. CEPI has global partnership between public, private, philanthropic, and civil society organizations. Because CEPI is an NGO and is acting in a way a government organization would, it was accounted for under IAS 20. In addition the valuation of the various components need Management's judgement;
- Note 5.13: Lease term: When determining lease terms, the Group make judgements whether it is reasonably certain to exercise renewal or early termination options.

5.3.2 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, 2020 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;
- Notes 5.8 and 5.30: Other income: estimates of income recognized and repayments from grants, measured according to cost incurred compared to the budget;
- Note 5.10: Recognition of deferred tax assets: availability of future taxable profit against which deductible temporary differences and tax losses carried forward can be utilized;
- Note 5.12: Intangibles: Amortization period of development expenditures and acquired technologies;
- Note 5.12 and 5.17: Impairment test of intangible, tangible assets, and inventories: key assumptions underlying recoverable amounts;
- Note 5.22: Share-based payments and related expected employer contribution costs: assumption for fair value determination as well as the determination of accelerated vesting in the event of a change of control (as considered remotely);

- Notes 5.29 and 5.32: Recognition and measurement of provisions and contingencies: key assumptions about the likelihood and magnitude of an outflow of resources.

5.3.3 Measurements of fair values

A number of the Group's accounting policies and disclosures require the measurement of fair values, for both financial and non-financial assets and liabilities.

When measuring the fair value of an asset or a liability, the Group uses observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

Further information about the assumptions made in measuring fair values is included in the following notes:

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

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," or CODM. The CODM reviews the consolidated operating results regularly to make decisions about resources and to assess overall performance.

The CODM primarily uses a measure of operating profit/(loss) to assess the performance of the operating segments. However, the CODM also receives information about the segments' product sales on a monthly basis.

The individual segments consist of the following:

- "**Commercialized products**" – marketed vaccines, currently the Group's vaccines IXIARO and DUKORAL, as well as third-party products
- "**COVID**" – development, manufacturing and distribution related to the Group's COVID-19 vaccine candidate, VLA2001.
- "**Vaccine candidates**" – proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding the Group's COVID-19 vaccine candidate, VLA2001, which is reported separately.
- "**Technologies and services**" – services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

As of January 1, 2021 – given the materiality of the Group's COVID-19 business, a separate segment was introduced covering all activities related to the development, manufacturing and distribution of the COVID-19 vaccine candidate, VLA2001. In addition, 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 four operational segments based on three criteria (each equally weighted): (1) revenues, (2) research and development spend and (3) full-time equivalent personnel. The allocation of local general and administrative costs is based on the above criteria measured on the local level, whereas the allocation of global functional general and administrative costs is based on the above criteria measured on a consolidated basis. The CODM also monitors the general and administrative expenses dedicated to corporate projects. Any project which (1) is material in spend, (2) is one-time in nature and (3) supports the entire business remains reported under Corporate Overhead.

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

5.4.1 Income statement by segment

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

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

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

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

[1] More information see Note 5.5.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

5.4.2 Geographical segments

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

Product sales per geographical segment

€ in thousand	Year ended at December 31,	
	2020	2019
United States	36,414	63,700
Canada	8,965	24,396
Germany	7,060	10,345
Austria	3,333	2,668
Nordics	2,866	11,027
United Kingdom	1,847	8,594
Other Europe	2,068	4,961
Rest of World	3,384	3,819
Product sales	**65,938**	**129,511**

Non-current operating assets per geographical segment

€ in thousand	At December 31,	
	2020	2019
United States	93	149
Canada	98	68
Austria	58,896	65,554
Nordics	27,540	29,334
United Kingdom	21,977	11,117
Other Europe	4,958	4,928
Non-current assets	**113,562**	**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 allocated on sites where production and research and development activities are performed. Sales activities by distribution sites do not require major non-current operating assets. Revenues are structured where the final customer is. In some countries there are customers, but no assets.

5.4.3 Information about major customers

Product sales to the largest customer amounted to €33.8 million (2019: €46.7 million). Collaboration and licensing revenue from the two largest customers amounted to €31.6 million and €7.5 million (2019: €4.1 million and €0.8 million). There are no further customers with a contribution exceeding 10% of the annual revenue.

5.5 Revenues from contracts with customers

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

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The core principle is that an entity will recognize 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. Recognize 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 retailers and with the U.S. government department of Defense (DoD) ("direct product sales") as well as with distributors ("indirect sales — sales through distributors"), generally include one performance obligation. Revenue is recognized at the point in time when the identified performance obligation is transferred to the customer, so when the customer obtains control over the goods.

Some of the Group's product sales agreements include retrospective rebates, charge-back clauses, discounts and under certain conditions return rights which give rise to variable consideration under IFRS 15. The expected rebates, discounts and considerations for product returns are recognized on an accrual basis and reported as refund liabilities in the consolidated balance sheet.

In most cases, Valneva sells the products through retailers. When more than one party is involved in providing/distributing goods or services, the standard requires an entity to determine whether itself and its retailers are principals or agents in these transactions by evaluating the nature of its promises to the customer. An entity is a principal if it controls a promised good or service before transferring that good or service to the customer. An entity is an agent if its role is to arrange for another entity to provide the goods or services. Retailers act as agent, if a) the price to be paid to Valneva is not fixed as long as the retailer has not completed his sale; b) the retailer has extensive rights to return, or c) the retailer does not have the power to establish the price for the sales to its customers. While revenues to principals are recognized when the control is transferred to the principals, revenue from product sales to agents are recognized when the control is transferred to the final customer, when the goods are delivered to the final customer. Payables to customers are deducted from revenue for principals, costs paid to agents are recognized as "Marketing and distribution expenses".

Valneva sells products acquired from third parties. Valneva considers that the company is acting as principal given the company controls products before transferring them to the final customer. More specifically, Valneva has an inventory risk before the goods have been transferred to customers and has discretion in establishing the prices. Revenue is recognized when the product is delivered to the customers. Products purchased from third parties are recognized as "inventory" in the balance sheets and when sold as "cost of goods" in the statements of income.

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 goods or 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, a license 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 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 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. The progress is measured on an input basis (costs incurred related to total costs expected). It is considered that this input method is an appropriate measure of the progress towards complete satisfaction of these performance obligations under IFRS 15.

Variable considerations are included in revenues only to the extent that it is highly probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the end of each reporting period the Group updates the estimated transaction price and its assessment of whether an estimate of variable consideration is constrained. Amounts allocated to a satisfied performance obligation are recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

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

Year ended December 31, 2019 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	129,674	(10,516)	5,768	124,926
Other revenues	—	—	1,270	1,270
Revenues	**129,674**	**(10,516)**	**7,038**	**126,196**

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

In 2020, commercialized products revenues were affected by the worldwide reduction in travelling due to the COVID-19 pandemic.

The revenue from the new collaboration agreement with Pfizer (€31.6 million) is recognized within the segment Vaccine candidates in 2020.

Valneva's total revenues for 2019 include a negative revenue of €10.7 million related to the June 2019 mutual agreement to terminate 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)**

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5.5.1 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 products	Vaccine candidates	Technologies and services	Total
IXIARO	94,307	—	—	94,307
DUKORAL	31,471	—	—	31,471
Third party products	3,896	—	—	3,896
Others	—	(10,516)	5,768	(4,748)
Revenues from contracts with customers	**129,674**	**(10,516)**	**5,768**	**124,926**

Year ended December 31, 2020 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
IXIARO	48,480	—	—	48,480
DUKORAL	13,300	—	—	13,300
Third party products	4,158	—	—	4,158
Lyme VLA15	—	31,604	—	31,604
Others	—	—	11,814	11,814
Revenues from contracts with customers	**65,939**	**31,604**	**11,814**	**109,357**

Geographical markets

Year ended December 31, 2019 € in thousand	Commercialized products	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**

Year ended December 31, 2020 € in thousand	Commercialized products	Vaccine candidates	Technologies and services	Total
United States	36,414	31,604	341	68,359
Austria	3,333	—	6,928	10,261
Canada	8,965	—	—	8,965
Germany	7,060	—	200	7,260
United Kingdom	1,848	—	1,038	2,886
Nordics	2,866	—	5	2,871
Switzerland	218	—	—	218
Other Europe	1,850	—	2,373	4,222
Other markets	3,384	—	930	4,314
Revenues from contracts with customers	**65,939**	**31,604**	**11,814**	**109,357**

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Sales channels

Commercialized products are sold via the following sales channels:

€ in thousand	At December 31 2020	2019
Direct product sales	54,160	110,386
Indirect product sales (Sales through distributors)	11,778	19,125
Total product sales	**65,939**	**129,511**

5.5.2 Assets and liabilities related to contracts with customers

See Note 5.18 for details on trade receivables, Note 5.19 for details on costs to obtain a contract, Note 5.27 for details of contract liabilities and Note 5.28 for details of refund liabilities.

5.6 Expenses by nature

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

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

Principal Accountant Fees and Services:

€ in thousand	Year ended December 31, PricewaterhouseCoopers 2020	%	2019	%	Deloitte & Associés 2020	%	2019	%
Audit fees	**607**	**78%**	**198**	**83%**	**589**	**77%**	**231**	**88%**
provided by the statutory auditor	*517*	—	*103*	—	*492*	—	*90*	—
provided by the statutory auditor's network	*90*	—	*95*	—	*97*	—	*114*	—
Audit-related fees	**170**	**22%**	**40**	**17%**	**173**	**23%**	**28**	**12%**
provided by the statutory auditor	*145*	—	*16*	—	*155*	—	*10*	—
provided by the statutory auditor's network	*25*	—	*24*	—	*18*	—	*18*	—
TOTAL	**777**	**100%**	**238**	**100%**	**762**	**100%**	**231**	**100%**

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Audit-related fees in 2020 comprised mainly the 2019 audit and limited review for the nine month ended September 30, 2020 and 2019 of the financial statements under PCAOB standards for statutory auditors as well as the annual audit to Austrian research and development tax credit.

5.7 Employee benefit expense

Employee benefit expenses include the following:

€ in thousand	Year ended December 31,	
	2020	2019
Salaries	38,515	34,128
Social security contributions	18,555	10,621
Share-based compensation expense	6,328	2,552
Training and education	351	672
Other employee benefits	842	798
Total Employee benefit expense	**64,592**	**48,771**

The social security contributions included a provision of €7.4 million (2019: nil) of employer contribution on IFRS 2 programs which is due at exercise of the programs.

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

5.8 Other income/(expenses), net

5.8.1 Grants

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and the Group will comply with all conditions.

Grant monies received as reimbursement of approved research and development expenses are recognized as other income when the respective expenses have been incurred and there is reasonable assurance that funds will be received. Advance payments received under such grants are deferred and recognized when these conditions have been met. Advanced payments received which need to be repaid are recognized as borrowings (see Note 5.23.2).

Government grant monies received to support the purchase of property, plant and equipment are included in non-current liabilities as deferred government grants and are credited to the income statement on a straight-line basis over the expected lives of the related assets.

In 2019 the Group signed a funding agreement with CEPI. Valneva will receive up to $23.4 million for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine (VLA1553) against chikungunya. In line with CEPI's commitment to equitable access, the funding will underwrite a partnership effort to accelerate regulatory approval of Valneva's single-dose chikungunya vaccine for use in regions where outbreaks occur and support WHO prequalification to facilitate broader access in lower and middle income countries. Valneva has to pay back part of the consideration, upon achievement of certain sales-milestones in the US and the EU. The consideration refundable is accounted for as loan and measured in accordance with IFRS 9 (see Note 5.23.2). The difference between the proceeds from CEPI and the carrying amount of the loan is treated under IAS 20 and presented as "Borrowings". In 2020, €5.8 million of grant income related to CEPI (2019: €1.8 million).

5.8.2 Research and development tax credits

Research and development tax credits granted by tax authorities are accounted for as grants under IAS 20. 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, 2020	2019
Research and development tax credit	9,937	6,314
Grant income	7,680	1,886
Profit/(loss) on disposal of fixed assets and intangible assets, net	(10)	(92)
Profit/(loss) from revaluation of lease agreements	1,584	—
Taxes, duties, fees, charges, other than income tax	(168)	(146)
Miscellaneous income/(expenses), net	95	(1,623)
Other income/(expenses), net	**19,117**	**6,338**

In 2019 miscellaneous income/(expenses) included €2.0 million relating to major litigations (detailed information see Note 5.29.2), and €0.6 million income mainly relating to a reimbursements of energy taxes and income from insurance claims.

More detailed information for Profit/(loss) from revaluation of lease agreements, see Note 5.13.1.

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

The net finance result amounted to minus €10.0 million for the year 2020 compared to minus €1.6 million in the year 2019. This increase in net finance expenses was mainly due to higher borrowings and the increase in non-current refund liabilities.

5.10 Income tax income/(expense)

The tax expense for the period comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively. The current

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Income tax income/(expense) is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Group's subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions, where appropriate, based on amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred income tax is provided on temporary differences arising on investments in subsidiaries and associates, except where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not be reversed within the foreseeable future.

5.10.1 Current income tax

Income tax income/(expense) is comprised of current and deferred tax.

€ in thousand	Year ended December 31, 2020	2019
Current tax		
Current income tax charge	(69)	(2,849)
Adjustments in respect of current income tax of previous year	109	(258)
Deferred tax		
Relating to origination and reversal of temporary differences	869	2,233
Income tax income/(expense)	**909**	**(874)**

The individual entities' reconciliations — prepared on the basis of the tax rates applicable in each country while taking consolidation procedures into account — have been summarized in the reconciliation below. The estimated tax charge is reconciled to the effective tax charge disclosed.

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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, 2020	2019
Profit/(Loss) before tax	(65,302)	(870)
Tax calculated at domestic tax rates applicable to profits in the respective countries	16,675	1,431
Income not subject to tax (mainly R&D tax credit)	2,612	1,727
Expenses not deductible for tax purposes	(1,789)	(169)
Deferred tax asset not recognized	(15,852)	(7,405)
Utilization of previously unrecognized tax losses	—	5,480
Income tax credit	109	105
Effect of change in applicable tax rate	(771)	(1,708)
Exchange differences	(105)	62
Income tax of prior years	170	(256)
Minimum income tax	(141)	(142)
Income tax income/(expense)	**909**	**(874)**
Effective income tax rate	—	—

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

5.10.2 Deferred tax

As of December 31, 2020 the deferred tax assets of €126.3 million (2019: €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, 2020, the Group has tax losses carried forward of €529.5 million (2019: €457.0 million), of which €192.0 million are related to Valneva SE (2019: €176.5 million), €321.1 million are related to Valneva Austria GmbH (2019: €278.7 million), €0.4 million are related to Valneva USA, Inc. (2019: €0.6 million), €3.1 million are related to Valneva Scotland, Ltd. (2019: €1.2 million) and €12.9 million are related to Valneva Sweden AB (2019: nil).

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

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

€ in thousand	2020	2019
Beginning of year	4,988	2,689
Exchange differences	(699)	66
Other adjustments due to tax changes		—
Income statement charge	869	2,233
End of year	**5,158**	**4,988**

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

€ in thousand	At December 31,	
	2020	2019
Deferred tax asset from		
Tax losses carried forward	131,633	114,148
Fixed assets	2,033	2,270
Inventory	4,108	3,399
Borrowings and accrued interest	1,161	1,332
Provision	1,564	1,570
Other items	2,019	1,903
Non-recognition of deferred tax assets	(126,283)	(110,215)
Total deferred tax assets	**16,235**	**14,408**
Deferred tax liability from		
Fixed assets	(1,187)	(246)
Intangible assets	(7,480)	(8,931)
Other items	(2,410)	(243)
Total deferred tax liability	**(11,077)**	**(9,421)**
Deferred tax, net	**5,158**	**4,988**

The corporate income tax rate in the United Kingdom is 19%.

The corporate income tax rate in France will be gradually reduced over the next years to 25%. 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 the United States is 25.2%.

The deferred tax assets and liabilities presented above as of December 31, 2020 have been adjusted for these changes in tax rates.

5.11 Earnings (Losses) per share

(a) Basic

Basic earnings (losses) per share are calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of outstanding shares during the year, excluding shares purchased by the Company and held as treasury shares (see Notes 5.21 and 5.22).

	Year ended December 31,	
	2020	2019
Net profit (loss) from continuing operations attributable to equity holders of the Company (€ in thousand)	(64,393)	(1,744)
Weighted average number of outstanding shares	90,757,173	91,744,268
Basic earnings (losses) from continuing operations per share (€ per share)	**(0.71)**	**(0.02)**

(b) Diluted

Diluted earnings per share are calculated by adjusting the weighted average number of ordinary outstanding shares to assume conversion of all dilutive potential ordinary shares. The Company has share options as dilutive potential ordinary shares. For the share options, a calculation is done to determine the number of shares that could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the

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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,	
	2020	2019
Profit used to determine diluted earnings per share (€ in thousand)	(64,393)	(1,744)
Weighted average number of outstanding shares for diluted earnings (losses) per share[5]	90,757,173	91,744,268
Diluted earnings/(losses) from continuing operations per share (€ per share)	**(0.71)**	**(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, at the end of each reporting period Valneva assesses whether there is any indication that an asset may be impaired. Indicators for the necessity of an impairment test are, among others, actual or expected declines in sales or margins and significant changes in the economic environment with an adverse effect on Valneva's business. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). The cash-generating units correspond with the specific vaccine products and vaccine candidates. Non-financial assets, other than goodwill, that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

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.

Acquired research and development technology and projects

Acquired research and development technology projects are capitalized. Amortization of the intangible asset over its useful life starts when the product has been fully developed and is ready for use. These costs are amortized on a straight-line basis over their useful lives. This useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods of 24 years, which is based on the patent life and technological replacement of a newer vaccine generation.

Development costs

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

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;

(5) Potentially dilutive securities (2020: 5,481,763 share options; 2019: 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.

- 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**
Year ended 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**

€ in thousand	Software	Acquired R&D technology and projects	Development costs	Intangible assets in the course of construction	Total
Year ended December 31, 2020					
Opening net book value	1,629	38,183	1,953	48	41,813
Exchange rate differences	3	(108)	(16)	3	(119)
Additions	48	401	—	86	535
Disposals	—	(3,329)	(5)	—	(3,333)
Amortization charge	(569)	(2,723)	(194)	—	(3,486)
Closing net book value	**1,112**	**32,423**	**1,737**	**137**	**35,409**
December 31, 2020					
Cost	5,589	80,183	9,851	137	95,759
Accumulated amortization and impairment	(4,477)	(47,759)	(8,113)	—	(60,350)
Net book value	**1,112**	**32,423**	**1,737**	**137**	**35,409**

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

5.12.1 Acquired research and development technology and projects

As of December 31, 2019 acquired research and development technology and projects assets with a definite useful life which are not yet amortized comprise solely the Lyme disease vaccine candidate (VLA15) amounting to €3.3 million. In December 2020 this intangible asset was de-recognized (see Note 5.12).

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 €33.2 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).

5.12.2 Impairment testing

By December 31, 2019 the Lyme disease candidate (VLA15) was the only active research and development program for which a book value was carried and reported on the balance sheet as intangible asset, which had not been amortized to date. An impairment test was performed as of December 31, 2019 resulting in no impairment charge. In 2019, the recoverable amount of this project was determined based on value-in-use calculations. The calculations used 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 different development phases (risk-adjustment) and a discount rate of 10.43% per annum. The discount rate of 10.43% was based on 0.34% risk-free rate, 8.96% market risk premium, minus 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 covered a period of 16 years as well as an estimate on the perpetual annual growth rate beyond this horizon and therefore accounted 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. In December 2020, this asset was de-recognized (see Note 5.12). No impairment test was consequently required per December 31, 2020.

In 2020, impairment tests have been performed on the IXIARO CGU and the Dukoral CGU.

Given the decrease in IXIARO annual product sales in 2020 due to the COVID-19 crisis and travel restrictions a triggering event was identified in Q1 2020 and in addition an updated impairment test has been performed for the IXIARO CGU per December 31st, 2020 (net book value of €46.7 million as of December 31, 2020).

	Year ended December 31,		
€ in thousand	2020	2019	% 2020 vs 2019
Product Sales			
IXIARO	48,480	94,144	-48.5%
DUKORAL	13,300	31,471	-57.7%

As a basis, the long range business model including product specific financial plans covering a period of 15 years was used, which is justified by the patent protection IXIARO enjoys beyond the 5 year horizon typically applied

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for impairment testing. Business plan assumptions have been revised to reflect reductions in expected sales and assuming a recovery of IXIARO sales to pre-COVID levels by 2025 to 2026. The calculation used post tax risk-adjusted cash flow projections and a discount rate of 7.55%. The discount rate of 7.55% was based on a negative risk-free rate of 0.14%, 7.00% market risk premium, minus 0.36% country risk premium, 0.82% currency risk, a levered beta of 1.19, and a peer group related equity-capital ratio.

During 2020, due to the impact of the COVID-19 pandemic situation affecting future profitability and cash generation of the DUKORAL CGU, the group tested the related product line for impairment. While there are no material intangible assets held for DUKORAL the carrying amount of fixed and right of use assets as well as working capital (net book value of €15.1 million as of December 31, 2020) was tested. As a basis the long-range business plan updated by Management was used and the recoverable amount of the DUKORAL CGU was determined based on value-in-use calculations. The Group's long range business model including assumptions on market size / market share, product sales and resulting profitability. For DUKORAL the value in use calculation is based on the plans for the next 5 years and a terminal value for the periods beyond 2025. For DUKORAL sales recovery to pre-COVID levels is not expected, driven by the expected entry of a competitor product in some European markets within the coming years. Different scenarios were prepared and value in use was assessed using a weighted average of five scenarios. The calculations used post tax risk-adjusted cash flow projections based on the Group's long-range business plan and a discount rate of 7.30% per annum. The discount rate of 7.30% per annum was based on negative risk-free rate of -0.14%, 6.73% market risk premium, negative country risk premium of -0.40%, 0.58% currency risk, a beta of 1.09 and a peer group related equity-capital ratio.

The impairment tests resulted in no impairment charges.

No triggering event was identified for the other projects.

Sensitivity to changes in assumptions

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

- discount rate
- reduction of expected revenues

The net present value calculation uses a discount rate of 7.30% for Dukoral and 7.55% for Ixiaro (2019: 10.18%). The recoverable amount of this CGU would equal its carrying amount if the key assumptions were to change as follows: increase in the discount rate to 10.58% would trigger an impairment loss for Dukoral (2019: increase of 1,071 basis points from 10.43% to 21.14%). Furthermore, an increase in the discount rate of one percentage point would result in no impairment loss.

Sensitivity analysis	2020		2019		
	Ixiaro	Dukoral	Lyme	Ixiaro	Dukoral
WACC	7.55%	7.30%	10.43%	10.18%	N/A
Break-even WACC	54.44%	10.58%	21.14%	68.76%	N/A
Impairment if WACC increases by 1%	NO	NO		NO	N/A
Impairment if sales reduce by 10%	NO	NO		NO	N/A

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% (which reflects the sensitivity to slower than currently expected recovery of the travel vaccine market assumption taken) would result in no additional impairment loss in 2020 and 2019.

5.13 Leases

The Group leases various premises, equipment and vehicles. Rental contracts are typically made for fixed periods of a 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. The rental contracts for the premises in Sweden include options to terminate the agreements earlier. The notice period is between 1 and 6 years. At the commencement date, it was not reasonably certain that these early termination options are exercised, so they were not included in the valuation of the lease liabilities and right of use assets.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

The lease 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. Valneva uses incremental borrowing rates between 0.013% and 3.186%, depending on the currency and the remaining term until maturity. For the rental contracts for the premises in Sweden an interest rate of 2.493% was determined.

The Group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset. This includes also the major contracts for the premises in Austria and Sweden, contain variable payments based on inflation rates or on published interest rates.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

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 recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less and without an option for the lessee to prolong the contract to more than 12 months or it is not reasonably certain to exercise such an option. Low-value assets comprise mainly IT equipment and small items of office furniture.

The Group does not have residual value guarantees in the rental contracts.

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5.13.1 Development of right-of-use assets and lease liabilities

€ in thousand	Right-of-use assets				
	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total	Lease liabilities
Balance as at January 1, 2019 before IFRS 16 adoption	**—**	**—**	**—**	**—**	**26,662**
Reclass (IAS 17)	26,414	—	—	26,414	—
IFRS 16 adoption	24,095	80	347	24,523	33,997
Balance as at 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**

€ in thousand	Right-of-use assets				
	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Furniture, fittings and other	Total	Lease liabilities
Balance as at January 1, 2020	**49,039**	**58**	**236**	**49,334**	**58,901**
Additions	177	—	151	267	267
Amortization	(2,309)	(22)	(141)	(2,471)	—
Revaluation	(4,507)	—	2	(4,505)	(6,096)
Termination of contracts	—	—	(33)	(33)	(26)
Lease payments	—	—	—	—	(2,910)
Interest expenses	—	—	—	—	800
Exchange rate differences	782	—	1	782	1,152
December 31, 2020	**43,121**	**37**	**216**	**43,374**	**52,088**

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

For more details on lease liabilities see Note 5.26.

5.13.2 Other amounts recognized in the consolidated income statement

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

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

5.13.3 Other lease commitments

In September 2020, the Group entered into a lease agreement for an additional building in Solna, Sweden. As the beginning of the lease period is in January 2021, no lease liability and right of use asset are included in the consolidated financial statements as of December 31, 2020. The non-cancellable period is 10 years. The discounted lease payments are €6.1 million over the term of the contract.

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.

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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**
Year ended December 31, 2019						
Opening net book value as at 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**

€ in thousand	Land, buildings and leasehold improvements	Manufacturing and laboratory equipment	Computer hardware	Furniture, fittings and other	Assets in the course of construction	Total
Year ended December 31, 2020						
Opening net book value	**9,248**	**5,944**	**707**	**313**	**3,791**	**20,003**
Exchange rate differences	(87)	16	(10)	(9)	(82)	(172)
Additions	2,578	8,553	241	30	7,535	18,936
Disposals	—	(2)	(1)	(3)	—	(6)
Depreciation charge	(1,087)	(2,471)	(211)	(73)	—	(3,842)
Impairment charge	—	—	—		(140)	(140)
Closing net book value	**10,651**	**12,041**	**726**	**257**	**11,105**	**34,779**
December 31, 2020						
Cost	24,062	28,743	2,573	1,453	11,105	67,935
Accumulated depreciation and impairment	(13,411)	(16,702)	(1,847)	(1,196)	—	(33,156)
Net book value	**10,651**	**12,041**	**726**	**257**	**11,105**	**34,779**

From the total of €9.9 million depreciation and amortization expenses (2019: €8.5 million), €5.0 million (2019: €5.0 million) were charged to cost of goods and services, €4.1 million were charged to research and development

expenses (2019: €2.5 million), €0.5 million were charged to marketing and distribution expenses (2019: €0.4 million) and €0.3 million were charged to general and administrative expenses (2019: €0.5 million). The increase in depreciation and amortization charged to research and development expenses is caused by investments in the sites in Scotland and Sweden in 2019 and 2020.

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 the impact on the estimated future cash flows from the net investment can be reliably estimated, the entire carrying amount of the investment is tested for impairment in accordance with IAS 36 as a single asset by comparing its recoverable amount (higher of value in use and fair value less costs of disposal) with its carrying amount. Any impairment loss recognized forms part of the carrying amount of the investment. Any reversal of that impairment loss is recognized in accordance with IAS 36 to the extent that the recoverable amount of the investment subsequently increases.

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

Name of associate	Place of business	Measurement method	% of ownership interest at December 31, 2020	% of ownership interest at December 31, 2019
BliNK Biomedical SAS	FR	Equity method	48.9%	48.9%

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

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

While the Company 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.

As of December 31, 2020, the Company recorded a loss of €0.3 million related to its share of equity in BliNK (2019: profit of €1.6 million). The total equity of BliNK amounts to €4.4 million as of December 31, 2020 (€4.6 million as of December 31, 2019).

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5.15.1 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, 2020	2019
BliNK Biomedical SAS		
Non-current assets	3	3
Current assets	4,759	6,370
Non-current liabilities	209	1,371
Current liabilities	38	217
Revenue	836	3,281
Profit/(loss) from continuing operations	(272)	1,629
Total comprehensive income	(272)	1,629

5.15.2 Reconciliation to the carrying amount

€ in thousand	At December 31, 2020	2019
Net assets of associate	4,355	4,627
Proportion of the Company's ownership interest in BliNK Biomedical SAS	48.9%	48.9%
Balance as at December 31,	**2,130**	**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.

5.16.1 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[6]	—	11,670	11,670
Cash and cash equivalents	—	64,439	64,439
Assets	**—**	**100,139**	**100,139**

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

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	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
Liabilities as per balance sheet			
Borrowings	—	26,316	26,316
Trade payables and accruals	—	16,567	16,567
Tax and employee-related liabilities[7]	—	6,570	6,570
Lease liabilities	—	58,901	58,901
Other liabilities[8]	—	220	220
Liabilities	—	**108,574**	**108,574**

December 31, 2020 € in thousand	Assets at fair value through profit and loss	Assets at amortized cost	Total
Assets as per balance sheet			
Trade receivables	—	19,232	19,232
Other assets[6]	—	11,918	11,917
Cash and cash equivalents	—	204,435	204,435
Assets	—	**235,584**	**235,584**

	Liabilities at fair value through profit and loss	Liabilities at amortized cost	Total
Liabilities as per balance sheet			
Borrowings	—	53,363	53,363
Trade payables and accruals	—	36,212	36,212
Tax and employee-related liabilities[9]	—	8,300	8,300
Lease liabilities	—	52,088	52,088
Refund liabilities	—	111,426	111,426
Other liabilities[10]	—	51	51
Liabilities	—	**261,439**	**261,439**

5.16.2 Fair value measurements

At December 31, 2020, the Company did not have assets and liabilities measured though profit and loss (2019: nil).

In 2020 and 2019, the Group entered into various foreign currency option and forward contracts to limit the risk of foreign currency losses on expected future cash flows. The underlying currency amount and the duration of the options depend on the amount and timing of the expected future cash flows.

At December 31, 2020, the Company did not have open foreign currency options nor foreign currency forwards (2019: nil).

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

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5.16.3 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, 2020	2019
Trade receivables		
Receivables from governmental institutions (AAA-country)	36	37
Receivables from governmental institutions (AA-country)	15,595	8,825
AA	188	—
A	787	5,519
Counterparties without external credit rating	2,631	9,650
Trade receivables	**19,237**	**24,030**
Other assets		
A	11,644	11,430
Counterparties without external credit rating or rating below A	336	310
Other assets	**11,979**	**11,740**
Cash and cash equivalents		
AA	3,984	2,755
A	149,477	56,703
Counterparties without external credit rating or rating below A	50,973	4,981
Cash and cash equivalents	**204,435**	**64,439**

The rating information refers to long-term credit ratings as published by Standard & Poor's or another rating organization (equivalent to the Standard & Poor's rating).

The maximum exposure to credit risk at the reporting date is the fair value of the financial assets.

5.16.4 Impairment of financial assets

Trade receivables

According to IFRS 9.5.5.15 the simplified approach (measure the loss allowance at an amount equal to lifetime expected credit losses) has to be used for trade receivables, which do not contain a significant financing component. This is the case for the Group, as all trade receivables are short term with a maturity lasting less than 12 months.

Loss allowances have to be established for each trade receivables based on the expected credit losses. Accordingly, at the end of each reporting period, trade receivables were adjusted through a loss allowance in accordance with the revised expected outcome.

According to IFRS 9.5.5.17 default probabilities are to be determined on the basis of historical data, but must be adjusted on the balance sheet date on the basis of up-to-date information and forward looking information. The analysis of the historical data showed on December 31, 2020 and 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 5.2.5. Therefore, loss allowance has been considered immaterial as of December 31, 2020 and as of December 31, 2019

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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 and at December 31, 2020, the expected credit loss was calculated using the cumulative expected default rate based on the counterparties' ratings, and was immaterial.

5.17 Inventories

Inventories are stated at the lower of cost and net realizable value. 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,	
	2020	2019
Raw materials	4,790	4,191
Work in progress	14,814	14,395
Finished goods	13,625	8,737
Purchased goods (third party products)	1,303	309
Gross amount of Inventory before write-down	**34,631**	**27,632**
Less: write-down	(7,698)	(1,860)
Inventory	**26,933**	**25,772**

The cost of inventories is recognized as an expense and is included in the position "Cost of goods and services" amounted to €27.0 million (2019: €34.6 million), of which €9.6 million (2019: €2.8 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 as of December 31, 2020. Commercial inventories not carrying a minimum residual shelf-life at the expected time of sale on the basis of the most current sales expectations have been written down. The write-down of €7.7 million relates €4.4 million to finished goods, €2.7 million to work in progress (thereof €0.3 million to faulty products), €0.5 million to raw materials and €0.1 million to purchased goods.

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.

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Trade receivables include the following:

€ in thousand	At December 31, 2020	2019
Trade receivables	19,237	24,030
Less: loss allowance of receivables	(6)	—
Trade receivables, net	**19,232**	**24,030**

During the years 2020 and 2019, no material impairment losses have been recognized. The amount of trade receivables past due in 2020 amounted to €0.4 million (2019: €2.0 million). Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

Trade receivables include €18.7 million (2019: €24.0 million) receivables from contracts with customers.

5.19 Other assets

Other assets include the following:

€ in thousand	At December 31, 2020	2019
Advances	33,671	2,245
R&D tax credit receivables	19,637	11,323
Tax receivables	5,468	4,372
Contract costs	2,846	—
Prepaid expenses	2,544	1,798
Consumables and supplies on stock	1,061	601
Miscellaneous current assets	158	51
Other non-financial assets	65,385	20,392
Deposits	11,358	11,323
Miscellaneous financial assets	560	367
Other financial assets	11,918	11,690
Other assets	**77,303**	**32,081**
Less non-current portion	(19,476)	(17,161)
Current portion	**57,828**	**14,921**

Due to the short-term nature of the financial instruments included in other assets, their carrying amount is considered to be the same as their fair value.

As of December 31, 2020, the Deposits related to a deposit in connection with a lease agreement, whereas advances are mainly related to advance payments in connection to advance payments for production components.

As of December 31, 2020, the advances mainly related to the received advance payments from the collaboration agreement with Dynavax amounting to € 31.1 million (see Note 5.1)

Contract costs relate to the collaboration with Pfizer (see Note 5.1) and refer to costs to obtain a contract. It will be amortized in line with the pattern of revenue recognition. In 2020, €0.1 million (2019: nil) amortization was recognized as costs.

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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.

€ in thousand	At December 31,	
	2020	2019
Cash in hand	2	10
Cash at bank	173,107	39,429
Short-term bank deposits (maximum maturity of 3 months)	31,285	25,000
Restricted cash	41	—
Cash and cash equivalents	**204,435**	**64,439**

As at December 31, 2020, the restricted cash was a Certificate of Deposit with restricted limited access to secure the credit limit for the Company's commercial card (December 31, 2019: nil). At December 31, 2020 the minimum liquidity requirement for the Group according to the debt financing agreement with US Healthcare Funds Deerfield and OrbiMed (see Note 5.23.2) is €75.0 million and was amended in January 2021 to be €50.0 million in 2021 and 2022 and €35.0 million from 2023 on. Cash and cash equivalents net of the US Healthcare Funds Deerfield and OrbiMed financial liability amounts to €158.2 million as of December 31, 2020.

5.21 Equity

Ordinary shares and the convertible preferred shares are classified as equity.

Number of shares	At December 31,	
	2020	2019
Ordinary shares issued (€0.15 par value per share)	90,950,048	90,923,298
Convertible preferred shares registered	20,514	20,514
Total shares issued	**90,970,562**	**90,943,812**
Less Treasury shares	(146,322)	(191,322)
Outstanding shares	**90,824,240**	**90,752,490**

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, 2020, the Company had 9,123,251 shares of conditional capital in connection with (see Note 5.22):

+ the possible exercise of existing stock options;

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

+ 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. 10 of the Extraordinary General Meeting held on December 22, 2020, the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future, under resolutions 2 to 9 of said Meeting, may not exceed €5.37 million, it being specified that to this maximum aggregate amount will be added the additional nominal amount of shares or securities to be issued in accordance with applicable legal or regulatory provisions and, if applicable, with contractual provisions providing for other forms of adjustment, in order to preserve the rights of the holders of securities or other rights giving immediate and/or future access to the capital of the Company.

5.21.1 Other reserves

€ in thousand	Other regulated reserves	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance as at January 1, 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 at 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**

€ in thousand	Other regulated reserves	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance as at January 1, 2020	**52,820**	**(4,836)**	**(1,112)**	**8,357**	**(9,474)**	**45,756**
Currency translation differences	—	2,438	—	—	—	2,438
Defined benefit plan actuarial losses	—	(78)	—	—	—	(78)
Share-based compensation expense:						
- value of services	—	—	—	4,012	—	4,012
Purchase/sale of treasury shares	—	—	215	—	—	215
Balance at December 31, 2020	**52,820**	**(2,474)**	**(898)**	**12,368**	**(9,474)**	**52,342**

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

The Company has not obtained a dividend from its subsidiaries or associates nor paid a dividend to its shareholders in the years ended December 31, 2020 and December 31, 2019.

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5.22 Share-based compensation

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

€ in thousand	Year ended December 31,	
	2020	2019
Stock option plans	1,182	1,177
Free convertible preferred share plans	1,266	1,198
Free ordinary shares program	1,563	130
Equity warrants	—	—
Phantom shares	2,317	74
Share based compensation expense	**6,328**	**2,578**

5.22.1 Stock option plans

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

The proceeds received net of any directly attributable transaction costs are credited to nominal capital (nominal value) and share premium (amount exceeding nominal value) when the options are exercised.

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

Since 2015, the employee stock option plans have primarily been for the benefit of non-executive employees, while members of the Management Board and the Management Committee (or formerly “Executive Committee”), as well as the Manufacturing site Heads (since 2017), would have the opportunity to participate in 4-year free share programs (convertible preferred shares or ordinary).

Stock options granted from 2013 to 2017 are exercisable in two equal portions after being held for two and for four years (the vesting periods), while stock options granted from 2019 onwards are exercisable in three equal portions after being held for one year, two years and three years.

All options expire no later than ten years after being granted. Stock options are not transferable or negotiable and unvested options lapse without compensation upon termination of employment with the Group (forfeiture). Stock options granted from 2013 onwards vest with the effectiveness of the takeover of more than 50% of the outstanding voting rights of the Group. As this change of control event was considered remote, it has not been considered in the determination of the vesting period.

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Changes in the number of stock options outstanding and their related weighted average exercise prices are as follows:

	2020			2019		
	Number of options	Number of shares available	Average exercise price in € per share	Number of options	Number of shares available	Average exercise price in € per share
Outstanding at January 1	5,247,110	5,313,098	3.06	2,859,850	2,927,662	3.14
Granted	—	—	—	2,569,510	2,569,510	3.05
Forfeited	(335,700)	(337,267)	3.06	(182,250)	(184,074)	3.03
Exercised	—	—	—	—	—	—
Outstanding at year end	**4,911,410**	**4,975,831**	**3.06**	**5,247,110**	**5,313,098**	**3.06**
Exercisable at year end	2,855,570	2,919,991		1,941,475	2,007,463	

No stock options have been exercised in 2019 and in 2020.

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, 2020	Number of options at December 31, 2019
2020	4.72	—	7,000
2023	2.919	645,900	654,600
2025	3.92	533,000	543,750
2026	2.71	399,250	418,750
2027	2.85	998,000	1,053,500
2029	3.05	2,335,260	2,569,510
Outstanding at year end		**4,911,410**	**5,247,110**

In 2020, no stock options were granted (2019: 2,569,510). 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.

5.22.2 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 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
Free ordinary shares granted	**2,191,947**

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

	Number of free shares	
	2020	2019
Outstanding at January 1	2,191,947	—
Granted	—	2,191,947
Forfeited	349,543	—
Definitively granted	—	—
Outstanding at year end	**1,842,404**	**2,191,947**

Subject to vesting conditions (including performance and presence conditions), the free share granted to a participant will vest in and be delivered to that participant ("*seront définitivement attribuées*") in three tranches. Each tranche will amount to one third of the total individual allocation. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche.

The first tranche 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 shares, no compulsory holding period will apply to the vested shares.

The plan further provides for accelerated vesting of the free shares in the event of a Change of Control (as defined in the applicable terms & conditions) occurring no earlier than December 19, 2023. As this was considered remote at the grant date (judgement by 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 share plan state that if a Change of Control takes place before December 19, 2021, and section III of Article L. 225-197-1 of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the participants for the loss of unvested free shares, subject again to meeting the performance conditions and, for the Management Board members, to getting all required shareholder approvals. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable terms and conditions of the plan will apply to this calculation, *mutatis mutandis*.

In accordance with section II (4th paragraph) of Article L. 225-197-1 of the French Commercial Code, the Supervisory Board decided on November 21, 2019 that the Management Board members should keep no less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.

5.22.3 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.

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

The granted payable convertible preferred shares ("SPS") were as follows:

	Number of payable convertible preferred shares subscribed for by the beneficiaries	Subscription amount (in euros)
Management Board	744	119,784
Other Executive Committee members	330	53,130
Payable convertible preferred shares granted	**1,074**	**172,914**

Following the subscription of SPS the Management Board conditionally granted the Program beneficiaries a number of free convertible preferred shares ("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
Free convertible preferred shares granted	**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.

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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.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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

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

Changes in the SPS and FCPS are as follows (information for both FCPS plan 2015 and FCPS plan 2017):

	Number of SPS		Number of FCPS	
	2020	2019	2020	2019
Outstanding at January 1	—	789	34,017	53,742
Granted	—	—	—	—
Expired	—	(789)	(1,554)	(18,617)
Outstanding at year end	**—**	**—**	**32,463**	**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.

5.22.4 Phantom shares

In 2017 and 2019, phantom share plans were issued for employees who are US citizens, with the same conditions as the stock options program (see above) but which will not be settled in equity, but in cash. Therefore it is considered as a cash settled plan. The liability for the phantom shares is measured (initially and at the end of each reporting period until settled) at the fair value of the share options rights, by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

The carrying amount of the liability relating to the phantom shares at December 31, 2020 was €2.3 million (December 31, 2019: €0.1 million).

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,	
		2020	2019
2023	2.919	10,450	10,098
2025	3.92	14,000	14,000
2026	2.71	9,000	9,000
2027	2.85	32,000	143,000
2029	3.05	176,750	179,750
2030	—	690,000	—
Outstanding at year end		**932,200**	**355,848**

In 2020, 690,000 new phantom shares were granted (2019: 176,750). The fair values of the granted options were determined on the balance sheet date December 31, 2020 and December 31, 2019 using the Black Scholes valuation model.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

The significant inputs into the models were:

	2020	2019
Expected volatility (%)	43.81	34.67
Expected vesting period (term in years)	0.25 – 5.40	0.25 –6.42
Risk-free interest rate (%)	(0.82) – (0.71)	(0.67) – (0.41)

5.22.5 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	
	2020	2019
Outstanding at January 1	103,875	164,000
Granted	—	—
Exercised	(26,750)	(6,250)
Forfeited	(33,375)	(53,875)
Outstanding at year end	**43,750**	**103,875**

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 year-end include the following:

€ in thousand	At December 31,	
	2020	2019
Non-current		
Bank borrowings	—	19,759
Other loans	46,375	4,558
Non-current borrowings	**46,375**	**24,317**
Current		
Other loans	6,988	1,999
Current borrowings	**6,988**	**1,999**
Total borrowings	**53,363**	**26,316**

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

The maturity of non-current borrowings is as follows:

€ in thousand	At December 31,	
	2020	2019
Between 1 and 2 years	5,925	2,055
Between 2 and 3 years	14,270	11,552
Between 3 and 4 years	12,559	317
Between 4 and 5 years	10,524	10,000
Over 5 years	3,097	393
Non-current borrowings	**46,375**	**24,317**
Current borrowings	6,988	1,999
Total borrowings	**53,363**	**26,316**

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

€ in thousand	At December 31,	
	2020	2019
EUR	4,855	25,923
USD	47,508	393
Total borrowings	**53,363**	**26,316**

5.23.1 Bank borrowings

In July 2016, the Company entered into a loan agreement with the European Investment Bank by which the Company was granted a €25.0 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 was repayable at the end of a five-year period starting from the drawing date. The loan was 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 €3.0 million at all times. In the year ended December 31, 2017, two €5.0 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 €10.0 million tranche was drawn following the same conditions as the last two tranches of this loan. In March 2020, the full loan was early repaid.

At December 31, 2020, the loan is included in the balance sheet item "Borrowings" as follows:

€ in thousand	2020	2019
Balance at January 1	**19,759**	**9,797**
Proceeds of issue	—	10,000
Transaction costs	—	(40)
Accrued interests	241	1,323
Payment of interest and loan	(20,000)	(1,322)
Balance at December 31	**—**	**19,759**
Less: non-current portion	—	19,759
Current portion	**—**	**—**

5.23.2 Other loans

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

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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 December 31, 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 Valneva's assets, including the intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. Furthermore, the loan agreement contains covenants, including a minimum liquidity in the amount of €35.0 million and minimum consolidated net revenue in the amount of €115.0 million on a consecutive twelve month basis. To avoid a breach of covenants due to the decline in revenues caused by the COVID-19 pandemic, the initial agreement was amended in July 2020, to postpone the application of the minimum revenue covenant until December 31, 2020 (included) in exchange for a minimum liquidity covenant of €75.0 million (instead of €35.0 million) during that period. On January 15, 2021, a new amendment was executed to (i) bring the minimum liquidity covenant to the amount of €50.0 million from 2021 onward and to €35.0 million from 2023 onward and (ii) modify the minimum revenue covenant to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.8 million in 2022 and €115.0 million thereafter. If the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, Valneva would not be able to comply with the financial covenants in the financing agreement with Deerfield and OrbiMed, which could result in additional costs (up to additional 10 %-points of interest over the duration of the default) and an early repayment obligation (payment of the principal increased by 8% and of an indemnity representing the interests expected until March 2023). The Group does not expect these limitations to affect its ability to meet its cash obligations.

The loan was included in the balance sheet item "Borrowings".

€ in thousand	2020	2019
Balance at January 1	**—**	**—**
Proceeds of issue	52,935	—
Transaction costs	(4,162)	—
Accrued interests	1,840	—
Exchange rate difference	(4,423)	—
Balance at December 31	**46,190**	**—**
Less: non-current portion	(41,261)	—
Current portion	**4,929**	**—**

Other loans also include borrowings related to financing of Research and Development expenses and CIR (R&D tax credit in France) of €5.9 million (December 31, 2019: €6.2 million).

Other loans also include the CEPI loan in amount of €1.3 million (December 31, 2019: €0.4 million), which relates to advanced payments received which are expected to be paid back in the future. For detailed information see Note 5.8.1.

5.23.3 Borrowings and other loans secured

As at December 31, 2020, €52.0 million (December 31, 2019: €26.3 million) of the outstanding borrowings and other loans are guaranteed, secured or pledged. These borrowings and other loans are related to financing of research and development expenses, fixed assets and CIR (R&D tax credit in France) and have various conditions (interest rates) and terms (maturities).

5.23.4 Fair value of borrowings and other loans

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

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As at December 31, 2020, material differences are identified only for guaranteed other loans. Based on an estimated arms' length interest rate of 9.41%, the fair value is €5.2 million (carrying amounts is €5.9 million).

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,	
	2020	2019
Trade payables	24,898	8,868
Accrued expenses	11,314	7,699
Balance as at December 31	**36,212**	**16,567**
Less non-current portion	—	—
Current portion	**36,212**	**16,567**

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

5.25 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,	
	2020	2019
Employee-related liabilities	8,300	6,570
Social security and other taxes	4,866	4,054
Balance as at December 31	**13,165**	**10,624**
Less non-current portion	—	—
Current portion	**13,165**	**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 Note 5.13.

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

€ in thousand	At December 31,	
	2020	2019
Between 1 and 2 years	2,296	2,372
Between 2 and 3 years	24,434	2,341
Between 3 and 4 years	1,280	24,618
Between 4 and 5 years	1,331	1,510
Between 5 and 10 years	7,384	8,258
Between 10 and 15 years	8,907	10,248
Over 15 years	3,759	7,245
Non-current lease liabilities	**49,392**	**56,592**
Current lease liabilities	2,696	2,308
Total Lease liabilities	**52,088**	**58,901**

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

€ in thousand	At December 31,	
	2020	2019
EUR	25,633	26,617
SEK	26,166	31,943
Other	289	340
Total lease liabilities	**52,088**	**58,901**

5.27 Contract liabilities

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	2020	2019
Balance as at January 1	1,426	4,735
Revenue recognition	(594)	(462)
Other releases	—	(4,274)
Exchange rate differences	101	—
Addition	88,703	1,426
Balance as at December 31	**89,636**	**1,426**
Less non-current portion	(58)	(732)
Current portion	**89,578**	**694**

As of December 31, 2020, €87.0 million are related to the agreement with UK Government to supply up to 190 million doses SARS-CoV-2 vaccine (see Note 5.1), €1.6 million are related to CTM services provided to different customers and €1.0 million are related to the agreement for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine, VLA1553, in Low and Middle Income Countries (LMICs) with Instituto Butantan.

As of December 31, 2019, €1.4 million are related to CTM services provided to Hookipa.

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5.28 Refund liabilities

A refund liability has to be recognized when the customer already provided a consideration which is expected to be refunded partially or totally. It is measured at the amount of consideration received for which the Group does not expect to be entitled.

Development of refund liabilities:

€ in thousand	2020	2019
Balance as at January 1	6,553	—
Additions	109,296	6,553
Payments	(477)	—
Interest expense capitalized	3,640	—
Exchange rate difference	(7,586)	—
Balance as at December 31	**111,426**	**6,553**
Less non-current portion	(97,205)	(6,105)
Current portion	**14,222**	**448**

As of December 31, 2020, €81.9 million (thereof €70.0 million non-current) are related to the collaboration with Pfizer Inc. (see Note 5.1), €20.9 million (all non-current) are related to the agreement with UK government to develop and commercialize a SARS-CoV-2 vaccine (see Note 5.1), €6.3 million (all non-current) are related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 (see Note 5.1) and €2.3 million are related to refund liabilities to customers related to rebate programs and right to return products.

As of December 31, 2019, €6.1 million are related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 (see Note 5.1) and €0.5 million are related to refund liabilities to customers related to rebate programs and right to return products.

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

5.29 Provisions

5.29.1 Provisions for employee commitments

€ in thousand	At December 31, 2020	2019
Employer contribution costs on share-based compensation plans	7,351	—
Phantom shares	2,390	74
Retirement termination benefits	550	404
Leaving indemnities	112	—
Balance at December 31	**10,403**	**477**
Less non-current portion	2,358	426
Current portion	**8,045**	**52**

(a) Share-based provisions

Employer contribution costs on share-based compensation plans and Phantom shares are calculated at the balance sheet date using the share price of Valneva as of December 31, 2020: €7.75 (Dec 31, 2019: €2.57).

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(b) Retirement termination benefits

Some Group companies provide retirement termination benefits to their retirees.

For defined benefit plans, retirement costs are determined once a year using the projected unit credit method. This method sees each period of service as giving rise to an additional unit of benefit entitlement and measures each unit separately to determine the final obligation. The final obligation is then discounted. These calculations mainly use the following assumptions:

- a discount rate;
- a salary increase rate;
- an employee turnover rate.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise.

For basic schemes and defined contribution plans, the Group recognizes the contributions as expenses when payable, as it has no obligations over and above the amount of contributions paid.

Assumptions used

	At December 31,	
	2020	2019
Discount rate	0.50%	0.70%
Salary increase rate	2.00%	2.00%
Turnover rate	0%-21.35%	0%-33.24%
Social security rate	43.00%-47.00%	43.00%-47.00%
Average remaining lifespan of employees (in years)	22	22

Changes in defined benefit obligation

Present value of obligation development:

€ in thousand	2020	2019
Balance at January 1	**404**	**333**
Current service cost	68	59
Actuarial losses/(gains)	78	13
Balance at December 31	**550**	**404**

5.29.2 Other provisions

€ in thousand	At December 31,	
	2020	2019
Non-current	—	—
Current	2,124	2,264
Provisions	**2,124**	**2,264**

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As of December 31, 2020, the position comprised of €1.8 million (December 31, 2019: €2.0 million) from a provision for expected legal and settlement costs under a court proceeding is related to the Intercell AG/Vivalis SA merger. Furthermore, a provision for call-off goods in raw material amounted to €0.3 million in 2020 for the site in United Kingdom is included.

5.30 Other liabilities

€ in thousand	At December 31, 2020	2019
Deferred income	2,861	3,715
Other financial liabilities	51	220
Miscellaneous liabilities	2	49
Other liabilities	**2,913**	**3,983**
Less non-current portion	(72)	(97)
Current portion	**2,841**	**3,886**

Deferred income mainly includes conditional advances from government grants and a grant from CEPI (see Note 5.8).

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5.31 Cash flow information

5.31.1 Cash generated from operations

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

€ in thousand	Note	Year ended at December 31, 2020	2019
Profit/(Loss) for the year		(64,393)	(1,744)
Adjustments for			
• Depreciation and amortization	5.12/5.13/5.14	9,799	8,532
• Write-off / impairment fixed assets/intangibles	5.12/5.13/5.14	140	75
• Share-based compensation expense	5.22	6,328	2,552
• Income tax expense/(income)	5.10	(909)	874
• Dividends received from associated companies	5.15	—	433
• (Profit)/loss from disposal of property, plant, equipment and intangible assets	5.8	10	92
• Share of (profit)/loss from associates	5.15	133	(1,574)
• Fair value (gains)/losses on derivative financial instruments		—	178
• Provision for employer contribution costs on share-based compensation plans	5.29.1	7,351	—
• Other non-cash (income)/expense		4,470	(892)
• Interest income	5.9	(119)	(199)
• Interest expense	5.9	10,738	2,633
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):			
• Other non-current assets		(2,303)	79
• Long term contract liabilities	5.27	(674)	(2,321)
• Long term refund liabilities	5.28	90,653	6,016
• Other non-current liabilities and provisions		795	(178)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):			
• Inventory		(4,196)	(2,415)
• Trade and other receivables		(24,023)	(17,278)
• Contract liabilities	5.27	88,801	(989)
• Refund liabilities	5.28	10,614	448
• Trade and other payables and provisions		6,544	13,552
Cash generated from operations		**139,759**	**7,875**

In 2020, other non-cash (income)/expense includes €3.3 million (2019: nil) from disposal of Lyme VLA15 (see Notes 5.1 and 5.12) and €1.6 million (2019: nil) from a revaluation of lease liabilities and right of use assets.

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

€ in thousand	At December 31, 2020	2019
Net book value	34	92
Profit/(loss) on disposal of fixed assets	(10)	(92)
Proceeds from disposal of property, plant, equipment and intangible assets	**24**	**—**

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5.31.2 Reconciliation of liabilities arising from financing activities

The table below details changes in the Group's liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were (or future cash flows will be) classified in the Group's consolidated statement of cash flows as cash flows from financing activities. For development of lease liabilities see Note 5.13.

€ in thousand	Bank borrowings	Other loans	Total
Balance at January 1, 2019	**9,918**	**21,019**	**30,937**
Repayments	—	(11,684)	(11,684)
Additions, net of transaction costs	9,960	1,821	11,781
Foreign exchange movements	—	(1)	(1)
Other changes[11]	(119)	(4,598)	(4,717)
Balance at December 31, 2019	**19,759**	**6,557**	**26,316**
Balance at January 1, 2020	**19,759**	**6,557**	**26,316**
Repayments	(20,000)	(1,995)	(21,995)
Additions, net of transaction costs	—	50,266	50,266
Foreign exchange movements	—	(4,556)	(4,556)
Other changes[11]	241	3,090	3,331
Balance at December 31, 2020	**—**	**53,363**	**53,363**

5.32 Commitments and contingencies

5.32.1 Capital commitments

As of December 31, 2020, there are €48.0 million capital expenditure contracted, mainly related to manufacturing sites for the new COVID-19 vaccine candidate (December 31, 2019: nil).

5.32.2 Lease commitments

For lease commitments see Note 5.13.3.

5.32.3 Other commitments, pledges and guarantees

The other commitments relate to minimum payments consist of:

€ in thousand	At December 31, 2020	2019
Loans and grants	1,454	1,209
Royalties	9,393	11,331
Other commitments	**10,846**	**12,540**

[11] Other changes include interest accruals and payments.

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The pledges consist of:

€ in thousand	At December 31, 2020	2019
Pledges on consolidated investments	19,474	—
Pledges on bank accounts	150,642	—
Pledges on receivable	160,511	—
Guarantees and pledges	**330,626**	**—**

5.32.4 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 has been discussing potential settlement agreements. The Company therefore holds a provision of €1.9 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 December 31, 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 in the second half 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.

5.33 Related-party transactions

5.33.1 Rendering of services

Services provided by Valneva to Groupe Grimaud La Corbière SAS are considered related party transactions as being shareholders of Valneva 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, 2020	2019
Provision of services:		
Operating activities	187	236
Provision of services	**187**	**236**

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5.33.2 Key management compensation

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

€ in thousand	Year ended December 31,	
	2020	2019
Salaries and other short-term employee benefits[12]	2,950	2,449
Other long-term benefits	18	15
Share-based payments (expense of the year)	1,786	1,174
Key management compensation	**4,755**	**3,638**

5.33.3 Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounts to €0.2 million (2019: €0.3 million). In the years 2015 and 2017 the Company granted equity warrants to members of the Supervisory Board. For more information, see Note 5.22.

5.34 Events after the reporting period

In January 2021, Valneva and US-based healthcare investment firms Deerfield Management Company and OrbiMed agreed to modify the covenant for the existing debt facility. The minimum liquidity covenant is brought to the amount of €50.0 million from 2021 onward and to €35.0 million from 2023 onward and the minimum revenue covenant is modified to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.8 million in 2022 and €115.0 million thereafter (see Note 5.23.2).

In January 2021, Valneva and Instituto Butantan, producer of immunobiologic products, announced the signing of definitive agreements for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine, VLA1553, in Low and Middle Income Countries (LMICs). This finalization follows the signing of a binding term sheet in May 2020. The collaboration falls within the framework of the $23.4 million funding agreement Valneva signed with CEPI in July 2019 (see Note 5.1). Under the collaboration, Valneva will transfer its chikungunya vaccine technology to Instituto Butantan, who will develop, manufacture and commercialize the vaccine in LMICs. In addition, Instituto Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. The agreement includes small upfront and technology transfer milestones.

In January 2021, the UK Government exercised its option to order 40 million doses of its inactivated, adjuvanted COVID-19 vaccine candidate for supply in 2022 (see Note 5.1). This brings the total volume of the Valneva vaccine ordered by UK Government to 100 million doses and the UK Government retains options over a further 90 million doses for supply between 2023 and 2025.

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

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UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2021 AND FOR THE SIX MONTHS ENDED JUNE 30, 2021

UNAUDITED INTERIM CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

Unaudited Interim Condensed Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	**Note**	**Six months ended June 30,**	
		2021	**2020**
Product sales	4	31,762	40,942
Revenues from collaboration, licensing and services	4	15,740	6,965
Revenues		**47,502**	**47,907**
Cost of goods and services	5	(34,778)	(22,546)
Research and development expenses	5	(78,737)	(33,081)
Marketing and distribution expenses	5	(9,643)	(10,046)
General and administrative expenses	5	(20,904)	(10,615)
Other income and expenses, net	6	10,389	6,453
OPERATING PROFIT/(LOSS)		**(86,172)**	**(21,928)**
Finance income	7	8,962	549
Finance expenses	7	(8,431)	(6,109)
Result from investments in associates		(90)	90
PROFIT/(LOSS) BEFORE INCOME TAX		**(85,730)**	**(27,398)**
Income tax		(668)	1,759
PROFIT/(LOSS) FOR THE PERIOD		**(86,399)**	**(25,639)**
Earnings/(Losses) per share			
for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share			
— **basic**		**(0.91)**	**(0.28)**
— **diluted**		**(0.91)**	**(0.28)**

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

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Unaudited Interim Condensed Consolidated Statements of Comprehensive Income (Loss)

€ in thousand	Note	Six months ended June 30,	
		2021	2020
Profit/(Loss) for the period		**(86,399)**	**(25,639)**
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences	17.2	(424)	(673)
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)		—	—
Other comprehensive income/(loss) for the period, net of tax		**(424)**	**(673)**
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(86,823)**	**(26,312)**

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

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UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

€ in thousand	Note	June 30, 2021	December 31, 2020
ASSETS			
Non-current assets		**183,145**	**140,737**
Intangible assets	8	34,424	35,409
Right of use assets	9/11	48,239	43,374
Property, plant and equipment	10/11	74,789	34,779
Equity-accounted investees		2,039	2,130
Deferred tax assets		5,591	5,570
Other non-current assets	15	18,063	19,476
Current assets		**561,962**	**308,427**
Inventories	13	125,664	26,933
Trade receivables	14	18,007	19,232
Other current assets	15	88,526	57,828
Cash and cash equivalents	16	329,766	204,435
TOTAL ASSETS		**745,107**	**449,164**
EQUITY			
Capital and reserves attributable to the Company's equity holders		**77,070**	**77,422**
Share capital	17.1	14,986	13,646
Share premium	17.1	328,688	244,984
Other reserves	17.2	53,344	52,342
Retained earnings/(Accumulated deficit)		(233,549)	(169,156)
Profit/(loss) for the period		(86,399)	(64,393)
LIABILITIES			
Non-current liabilities		**211,119**	**195,872**
Borrowings	18	47,402	46,375
Lease liabilities	9	53,916	49,392
Contract liabilities	19	—	58
Refund liabilities	20	104,493	97,205
Provisions	21	4,648	2,358
Deferred tax liabilities		590	412
Other liabilities	22	70	72
Current liabilities		**456,917**	**175,870**
Borrowings	18	7,079	6,988
Trade payables and accruals		71,502	36,212
Tax and employee-related liabilities		12,265	13,165
Lease liabilities	9	3,089	2,696
Contract liabilities	19	338,474	89,578
Refund liabilities	20	6,875	14,222
Provisions	21	14,973	10,169
Other liabilities	22	2,660	2,841
TOTAL LIABILITIES		**668,037**	**371,742**
TOTAL EQUITY AND LIABILITIES		**745,107**	**449,164**

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

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UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Six months ended June 30, 2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES			
Profit/(Loss) for the period		(86,399)	(25,639)
Adjustments for non-cash transactions	24	17,003	11,256
Changes in non-current operating assets and liabilities	24	8,341	63,467
Changes in working capital	24	146,614	64,382
Cash generated from operations	24	**85,560**	**113,466**
Income tax paid		(1,313)	(247)
Net cash generated from operating activities		**84,247**	**113,219**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	10/11	(39,173)	(1,816)
Purchases of intangible assets		(761)	(82)
Interest received		33	67
Net cash used in investing activities		**(39,902)**	**(1,831)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions	17	85,177	8
Disposal/(Purchase) of treasury shares		209	99
Proceeds from borrowings, net of transaction costs		—	48,773
Repayment of borrowings		(1,764)	(21,521)
Payment of lease liabilities		(1,161)	(1,082)
Interest paid		(3,718)	(1,791)
Net cash generated from financing activities		**78,743**	**24,468**
Net change in cash and cash equivalents		**123,088**	**135,874**
Cash and cash equivalents at beginning of the period, excluding restricted cash		204,394	64,439
Exchange gains/(losses) on cash		2,242	(267)
Restricted cash	16	42	—
Cash and cash equivalents at end of the period	16	**329,766**	**200,046**

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

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UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand *(except number of shares)*	Note	*Number of Shares issued*	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
Balance as at January 1, 2020		***90,943,812***	**13,642**	**244,912**	**45,756**	**(167,412)**	**(1,744)**	**135,153**
Total comprehensive loss		—	—	—	(673)	—	(25,639)	(26,312)
Income appropriation		—	—	—	—	(1,744)	1,744	—
Share-based compensation expense:	17							
— value of services		—	—	—	2,112	—	—	2,112
— exercises		*3,125*	—	8	—	—	—	8
Treasury shares	17	—	—	—	98	—	—	98
Balance as at June 30, 2020		***90,946,937***	**13,642**	**244,920**	**47,293**	**(169,156)**	**(25,639)**	**111,059**
Balance as at January 1, 2021		***90,970,562***	**13,646**	**244,984**	**52,342**	**(169,156)**	**(64,393)**	**77,422**
Total comprehensive loss		—	—	—	(424)	—	(86,399)	(86,823)
Income appropriation		—	—	—	—	(64,393)	64,393	—
Share-based compensation expense:	17							
— value of services		—	—	—	1,217	—	—	1,217
— exercises		*793,200*	119	2,090	—	—	—	2,209
Treasury shares	17	—	—	—	209	—	—	209
Issuance of ordinary shares, May 2021	17	*8,145,176*	1,222	88,375	—	—	—	89,597
Cost of equity transactions, net of tax	17	—	—	(6,761)	—	—	—	(6,761)
Balance as at June 30, 2021		***99,908,938***	**14,986**	**328,688**	**53,344**	**(233,549)**	**(86,399)**	**77,070**

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

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SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT

1. Basis of preparation

The unaudited interim condensed consolidated financial statements of Valneva SE ("the Company") together with its subsidiaries (the "Group" or "Valneva") as of June 30, 2021 and for the six months ended June 30, 2021 and June 30, 2020, have been prepared in accordance with IAS 34 Interim Financial Reporting as issued by the IASB. In consequence, these consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2020.

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 October 20, 2021.
The accounting policies adopted in the preparation of the unaudited interim 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, 2020.

Standards, amendments to existing standards and interpretations issued by the IASB whose application has been mandatory since January 1, 2021

A number of amended standards became applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these amended standards.

Standards, amendments to existing standards and interpretations issued by the IASB whose application is not yet mandatory

No standards, amendments to existing standards, or interpretations published that were not yet applicable as of June 30, 2021, are expected to significantly impact the Company's financial statements.

No standards or interpretations were adopted early if they are not mandatory to apply in 2021. 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.

Interest rate benchmark reform

The Group does not expect a material impact from the interest rate benchmark reform on the financial statements.

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 primarily 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 to remain impacted by the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its July 2021 report, the United Nations World Tourism Organization, or UNWTO, noted that international travel, as measured by international arrivals, is slowly picking up, though the recovery remains fragile and uneven. Rising concerns over the Delta variant of the virus have led several countries to re-impose restrictive measures. In addition, the volatility and lack of clear information on entry requirements could continue to affect the resumption of

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international travel during the Northern Hemisphere's summer season. However, vaccination programs worldwide, together with softer restrictions for vaccinated travelers and the use of digital tools such as the EU Digital COVID Certificate, contribute to the gradual normalization of travel. The recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels between mid-2023 to end of 2024. If international travel does not resume as quickly or as much as expected, the 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. Valneva continues to closely monitor how the pandemic and related response measures are affecting the Company's business. Valneva reported cash and cash equivalents of €329.8 million as of June 30, 2021. Valneva is prepared 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 June 30, 2021 will be sufficient to fund its operations for at least the next 12 months from the authorization of publication of these consolidated financial statements. For details on liquidity risk see Note 23.

Impact from COVID-19 is described in following notes as of June 30, 2021:

Impact from COVID-19	Note	
COVID-19 R&D program	1	Agreement with the UK Government to provide up to 190 million doses of the Group's SARS-CoV-2 vaccine candidate — €60.1 million expenses (of which €46.1 million were for research and development) included in first six months of 2021, €94.9 million included in inventories (of which €82.8 million were for raw material), €46.9 million prepayments included in other current assets, €349.7 million included in contract and refund liabilities, as of June 30, 2021.
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	11	Impairment test on Property, plant and Equipment, Intangible assets, and Right of Use assets performed after triggering events — no impairment required as of June 30, 2021.

Significant agreements signed in the period

In January 2021, Valneva and Instituto Butantan ("Butantan"), producer of immunobiologic products, announced the signing of definitive agreements for the development, manufacturing, and marketing of Valneva's single-shot chikungunya vaccine candidate, VLA1553, in Low and Middle-Income Countries (LMICs). This finalization follows the signing of a binding term sheet in May 2020. The collaboration falls within the framework of the $23.4 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations ("CEPI") in July 2019 (see Note 6). Under the collaboration, Valneva will transfer its chikungunya vaccine technology to Butantan, who will develop, manufacture and commercialize the vaccine in LMICs. In addition, Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. The agreement includes small upfront and technology transfer milestones. In the first half of 2021, €1.8 million were recognized as Revenues from collaboration, licensing, and services. As of June 30, 2021, €1.0 million are included in contract liabilities (December 31, 2020: €1.0 million).

Valneva's share price development and capital increase the six months ended June 30, 2021

The Company's share price increased by almost 50% during the six months ended June 30, 2021, with high fluctuations throughout the period.

On May 11, 2021, Valneva announced the closing, which occurred on May 10, 2021, of its previously announced global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares. The full

exercise of the overallotment option granted to the underwriters (the "Option") consisted of a public offering of 2,850,088 American Depositary Shares, each representing two ordinary shares, in the United States at an offering price of $26.41 per ADS (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, after full exercise of the Option, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately $107.6 million (€89.6 million), see Note 17.

2. Group structure

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	June 30, 2021	December 31, 2020
BliNK Biomedical SAS	FR	Equity method	48.9%	48.9%
Vaccines Holdings Sweden AB	SE	Consolidation	100%	100%
Valneva Austria GmbH	AT	Consolidation	100%	100%
Valneva Canada Inc.	CA	Consolidation	100%	100%
Valneva France SAS	FR	Consolidation	100%	100%
Valneva Scotland Ltd.	UK	Consolidation	100%	100%
Valneva Sweden AB	SE	Consolidation	100%	100%
Valneva UK Ltd.	UK	Consolidation	100%	100%
Valneva USA, Inc.	US	Consolidation	100%	100%

3. Segment reporting

The Company's Management Board, as its chief decision maker, considers the business from a product rather than geographic perspective and has identified four reportable segments.

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

- Given the expected materiality of the Group's COVID-19 business, a separate segment was introduced covering all activities related to the development, manufacturing, and distribution of the SARS-CoV-2 vaccine candidates.
- With the transfer of the license of Valneva's VLA15 Lyme vaccine candidate to Pfizer in December 2020, all related revenues and costs previously included in the "Vaccine candidates" segment are now included in the "Technologies and services" segment.

The individual segments consist of the following:

- "Commercialized products" (marketed vaccines, currently the Group's vaccines IXIARO and DUKORAL as well as third-party products)
- "COVID" (development, manufacturing, and distribution related to Valneva's SARS-CoV-2 vaccine candidates)
- "Vaccine candidates" (proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding COVID vaccine candidates, which is presented separately)
- "Technologies and services" (services and inventions at the commercialization stage, i.e. revenue generating through collaborations, service, and licensing agreements)

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

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

Income statement by segment for the six months ended June 30, 2020:

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	40,942	—	—	—	—	40,942
Revenues from collaboration, licensing and services	—	—	1,333	5,632	—	6,965
Revenues	40,942	—	1,333	5,632	—	47,907
Cost of goods and services	(18,148)	—	—	(4,397)	—	(22,546)
Research and development expenses	(1,514)	(1,548)	(29,568)	(451)	—	(33,081)
Marketing and distribution expenses	(9,817)	—	(179)	(50)	—	(10,046)
General and administrative expenses	(5,482)	—	(4,151)	(930)	(52)	(10,615)
Other income and expenses, net	71	307	5,835	107	133	6,453
Operating profit/(loss)	**6,051**	**(1,241)**	**(26,730)**	**(89)**	**81**	**(21,928)**

Income statement by segment for the six months ended June 30, 2021:

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	31,762	—	—	—	—	31,762
Revenues from collaboration, licensing and services	10	—	1,849	13,880	—	15,740
Revenues	31,772	—	1,849	13,880	—	47,502
Cost of goods and services	(19,326)	(4,156)	—	(11,295)	—	(34,778)
Research and development expenses	(878)	(46,105)	(29,513)	(2,241)	—	(78,737)
Marketing and distribution expenses	(7,086)	(444)	(2,037)	(75)	—	(9,643)
General and administrative expenses	(2,519)	(9,438)	(3,256)	(2,194)	(3,498)	(20,904)
Other income and expenses, net	2,126	4,690	2,952	900	(279)	10,389
Operating profit/(loss)	**4,089**	**(55,454)**	**(30,005)**	**(1,025)**	**(3,776)**	**(86,172)**

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Product sales per geographical segment

€ in thousand	Six months ended June 30,	
	2021	2020
United States	23,589	19,068
Canada	2,006	8,126
Austria	3,006	324
United Kingdom	1,067	1,653
Nordics	897	2,691
Germany	—	4,441
Other Europe	1,181	1,539
Other markets	15	3,099
Product sales	**31,762**	**40,942**

4. Revenues from contracts with customers

4.1 Overview

Revenues, as presented in the unaudited Consolidated Interim Income Statement and in the Segment Reporting (See Note 3), include both revenues from contracts with customers and other revenues, which are out of scope of IFRS 15:

Six months ended June 30, 2020 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	40,942	—	1,333	5,121	47,396
Other revenues	—	—	—	511	511
Revenues	**40,942**	**—**	**1,333**	**5,632**	**47,907**

Six months ended June 30, 2021 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	31,772	—	1,849	13,429	47,050
Other revenues	—	—	—	451	451
Revenues	**31,772**	**—**	**1,849**	**13,880**	**47,502**

In the second quarter 2020 and in the first half of 2021, commercialized products revenues were affected by the worldwide reduction in traveling due to the COVID-19 pandemic.

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Disaggregated revenue information

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

Type of goods or service

Six months ended June 30, 2020 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO product	28,406	—	—	—	28,406
DUKORAL product	12,140	—	—	—	12,140
Third party products	396	—	—	—	396
Lyme VLA15	—	—	1,333	—	1,333
Chikungunya VLA1553	—	—	—	—	—
Services related to clinical trial material	—	—	—	3,420	3,420
Others	—	—	—	1,701	1,701
Revenues from contracts with customers	**40,942**	**—**	**1,333**	**5,121**	**47,396**

Six months ended June 30, 2021 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO product	25,394	—	—	—	25,394
DUKORAL product	428	—	—	—	428
Third party products	5,950	—	—	—	5,950
Lyme VLA15	—	—	—	5,616	5,616
Chikungunya VLA1553	—	—	1,849	—	1,849
Services related to clinical trial material	—	—	—	5,727	5,727
Others	—	—	—	2,085	2,085
Revenues from contracts with customers	**31,772**	**—**	**1,849**	**13,429**	**47,050**

4.2 Information on specific contracts

In April 2020, a new collaboration to co-develop and commercialize the Group's Lyme disease vaccine (Lyme VLA15) was signed with Pfizer Inc. (NYSE: PFE). This agreement was entered into with a customer as defined by IFRS 15 guidance on revenue contracts with customers. It included a $130 million (€116.9 million) upfront payment, which was received in June 2020. Valneva will refund 30% of all development costs through completion of the development program, which is planned for 2025. Therefore, as of June 30, 2021, €90.0 million has been recognized as discounted refund liabilities. The transaction price was determined while taking into account the refund obligation of Valneva. The agreement includes R&D and service performance obligations for which revenue is recognized over time as well as a license performance obligation for which revenue was recognized in the year 2020, when Pfizer benefited and started to use the license without further involvement of Valneva. The transaction has been allocated to various performance obligations in proportion to their standalone selling price. In the first half of 2021, €5.6 million were recognized as Revenues from collaboration, licensing and services. €3.0 million of costs to obtain a contract are included in other assets (see Note 15) and €0.9 million are included in contract liabilities (see Note 19) as of June 30, 2021.

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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 is acting as principal according to IFRS and will commercialize Bavarian Nordic's marketed vaccines leveraging its commercial infrastructure in Canada, the 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. Revenues are recognized at a point in time when products are delivered to the customer. In the first half of 2021, Valneva recognized €4.7 million of revenue with Bavarian Nordic's vaccines. This partnership also caused an increase in purchased goods (third party products) (see Note 13).

In September 2020, the US Defense Logistics Agency ("DLA") awarded Valneva 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 Valneva's 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 beginning 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 manufacturing scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the collaboration. The COVID-19 vaccine candidate will be manufactured at Valneva's facilities in Livingston, Scotland and fill-finishing activities will take place at Valneva's facilities in Solna, Sweden. As part of its broader COVID-19 response, Valneva plan to further invest in the manufacturing facilities in Livingston, Scotland and Solna, Sweden. The UK Government is obligated to provide Valneva advance payments to fund certain manufacturing-related expenses (related to the expansion of Valneva's Livingston, Scotland facility) over the life of the project, subject to Valneva's 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. In June 2021, none of these performance obligations were satisfied, therefore no revenue was recognized in this period. In December 2020, the option period to order 40 million doses was extended from December 31, 2020, to January 31, 2021. In January 2021, the UK Government has exercised its option to order 40 million doses. As of June 30, 2021, €335.6 million are included in contract liabilities (see Note 19), and €14.1 million are included in refund liabilities (see Note 20) and relate to a payment obligation of Valneva to the UK Government for sales that are expected to occur outside UK. Total expenses for research and development for the COVID-19 vaccine were €46.1 million in the first half of 2021. As of June 30, 2021, €94.9 million of inventories (see Note 13) relate to the COVID-19 vaccine.

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Geographical markets

In presenting information on the basis of geographical segments, segment revenue is based on the final location where our distribution partner sells the product or where the customer/partner is located.

Six months ended June 30, 2020 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	19,068	—	1,333	—	20,401
Canada	8,126	—	—	—	8,126
Germany	4,441	—	—	50	4,491
Austria	324	—	—	3,420	3,744
United Kingdom	1,653	—	—	707	2,360
Nordics	2,691	—	—	—	2,691
Other Europe	1,539	—	—	679	2,219
Other markets	3,099	—	—	264	3,363
Revenues from contracts with customers	**40,942**	**—**	**1,333**	**5,121**	**47,396**

Six months ended June 30, 2021 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
United States	23,589	—	—	5,781	29,370
Canada	2,006	—	—	—	2,006
Austria	3,006	—	—	4,126	7,131
United Kingdom	1,074	—	—	40	1,114
Nordics	901	—	—	—	901
Germany	—	—	—	15	15
Other Europe	1,181	—	—	3,001	4,182
Other markets	15	—	1,849	466	2,330
Revenues from contracts with customers	**31,772**	**—**	**1,849**	**13,429**	**47,050**

Sales channels for product sales

Commercialized products are sold via the following sales channels:

	Six months ended June 30,	
€ in thousand	2021	2020
Direct product sales	30,663	31,025
Sales through distributors	1,110	9.917
Total product sales	**31,772**	**40,942**

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.

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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	Six months ended June 30,	
	2021	2020
Consulting and other purchased services	(76,213)	(27,860)
Employee benefit expense other than share-based compensation[1]	(35,955)	(26,376)
Share-based compensation expense	(3,653)	(2,631)
Depreciation and amortization and impairment	(6,101)	(4,687)
Raw materials and consumables used	(5,371)	(5,494)
Building and energy costs	(5,286)	(3,732)
Supply, office and IT-costs	(3,308)	(1,527)
Cost of services and change in inventory	(2,940)	2,257
License fees and royalties	(2,490)	(2,379)
Advertising costs	(1,318)	(1,810)
Warehousing and distribution costs	(745)	(1,219)
Travel and transportation costs	(126)	(419)
Other expenses	(554)	(410)
Operating expenses	**(144,062)**	**(76,288)**

Consulting and other purchased services include €33.4 million (June 30, 2020: €0) expenses related to the COVID program.

6. Other income and expenses, net

Other income and expenses, net include the following:

€ in thousand	Six months ended June 30,	
	2021	2020
Research and development tax credit	9,635	3,889
Grant income	1,145	2,995
Profit/(loss) on disposal of fixed assets, net	(21)	(7)
Taxes, duties, fees, charges, other than income tax	(133)	(116)
Miscellaneous income/(expenses), net	(237)	(308)
Other income/(expenses), net	**10,389**	**6,453**

Of the Research and development tax credit, €9.1 million (June 30, 2020: €3.3 million) related to R&D programs executed in Austria, mainly for COVID-19 and chikungunya vaccine candidates, whereas €0.6 million (June 30, 2020: €0.6 million) related to France.

In July 2019, the Group signed a funding agreement with the Coalition for Epidemic Preparedness Innovations (“CEPI”). Under this funding agreement, Valneva is eligible to receive up to $23.4 million for vaccine

1 As of June 30, 2021 the position “employee benefit other than share-bases compensations” includes additions to a provision in the amount of €4.6 million of employer contribution fees, which are payable at the exercise of the IFRS 2 programs (as of June 30, 2020: €1.3 million).

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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 an agreement with Instituto Butantan ("Butantan") in January 2021, where Valneva transferred the chikungunya vaccine technology. Butantan will develop manufacture and commercialize the vaccine in LMICs. In addition, Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. CEPI work packages where Butantan is the beneficiary are be recognized as revenue related to Butantan, while work packages where Valneva is the beneficiary are still recognized as grant income (IAS 20) and presented as other income within the operating income. Valneva is obligated to repay up to $7.0 million to CEPI when certain sales milestones are reached or if and when a Priority Review Voucher ("PRV") is granted. Since the inception of the CEPI agreement, Valneva has recognized €6.7 million of grant income. In the period ended June 30, 2021, a negative grant income of €1.1 million was recognized due to the increase of the probability of reaching the PRV milestone. This negative amount was offset by €2.2 million of grants from government authorities related to the current COVID-19 pandemic situation to cover fixed costs of the commercial activities.

7. Finance income/(expenses), net

€ in thousand	Six months ended June 30,	
	2021	2020
Finance income		
Interest income from other parties	228	74
Fair value gains on derivative financial instruments	—	475
Foreign exchange gains, net	8,735	—
Total finance income	**8,962**	**549**
Finance expense		
Interest expense on loans	(3,820)	(2,961)
Interest expense on refund liabilities	(4,104)	(486)
Interest expense on lease liabilities	(419)	(447)
Other interest expense	(88)	(16)
Foreign exchange losses, net	—	(2,200)
Total finance expenses	**(8,431)**	**(6,109)**
Finance income/(expense), net	**532**	**(5,560)**

For more details regarding interest expense on loans see Note 18. For more details regarding interest on refund liabilities see Note 20.

8. Intangible assets

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 €32.0 million (December 31, 2020: €33.2 million). Other intangible assets with a definite useful life are comprised primarily of the IC31 technology amounting to €0.4 million (December 31, 2020: €0.5 million) and the EB66 technology amounting to €0.1 million (December 31, 2020: €0.1 million).

9. Right of use assets

In the first six months of 2021, right of use assets increased from €43.4 million as of December 31, 2020 to €48.2 million as of June 30, 2021, mainly due to a new lease contract for land and building in Sweden (addition

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€6.1 million), partly offset by amortization expenses (€1.3 million). Major lease agreements are for the premises in Austria (book value as of June 30, 2021: €24.4 million, December 31, 2020: €24.8 million) and Sweden (book value as of June 30, 2021: €22.9 million, December 31, 2020: €17.6 million).

10. Property, plant and equipment

In the first six months of 2021, property, plant and equipment increased from €34.8 million as of December 31, 2020 to €74.8 million as of June 30, 2021. This increase mainly relates to investments in land and building and equipment for the manufacturing of the COVID-19 vaccine on sites in the United Kingdom and Sweden. The increase was partly offset by depreciation expenses (€3.0 million).

11. Impairment testing

11.1 Impairment testing

Due to a reduction in product sales realized during the first half of 2021 caused by the COVID-19 pandemic and travel restrictions, a triggering event has been identified for DUKORAL. Consequently, an impairment test has been performed as of June 30, 2021. While there are no material intangible assets held for DUKORAL the carrying value of Property, plant and equipment and Right of use assets as well as working capital (net book value of €15.4 million as of June 30, 2021) was tested.

The Company’s long range business model, including assumptions on market size/market share, product sales and resulting profitability over a 5.5 year period as well as a Terminal Value for the period beyond 5.5 years, has been used as a basis to calculate the value in use. For DUKORAL, sales recovery to pre-COVID levels is expected to progress more slowly over the next 2 years. This is additionally driven by the expected entry of a competitor product in some European markets within the coming years. The uncertainty of whether sales can return to pre-COVID levels has been taken into account in the impairment test.

The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 6.93%. The discount rate of 6.93% is based on 0.31% risk-free rate, 6.87% market risk premium, minus 0.37% country risk premium, 0.61% currency risk, a levered beta of 1.02 and a peer group related equity-capital ratio.

The impairment test for DUKORAL has resulted in no impairment losses.

11.2 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 DUKORAL, the net present value calculation for DUKORAL uses a discount rate of 6.93%. An increase in the discount rate of 418 basis points from 6.93% to 11.11 % would trigger an impairment loss.

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% over the planning period of 5.5 years would result in no impairment loss in 2021.

12. Financial Instruments

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

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are of a short-term nature. As of June 30, 2021, material differences are identified only for guaranteed other loans. Based on an estimated interest rate of 9.73%, the fair value is €3.6 million (carrying amount is €4.0 million).

The fair values of all other financial instruments equal their book values as of June 30, 2021.

13. Inventories

Inventories include the following:

€ in thousand	June 30, 2021	December 31, 2020
Raw materials	90,192	4,790
Work in progress	23,025	14,914
Finished goods	15,357	13,625
Purchased goods (third party products)	6,301	1,303
Gross amount of Inventory before write-down	**134,875**	**34,631**
Less: write-down	(9,211)	(7,698)
Inventory	**125,664**	**26,933**

As of June 30, 2021, Raw materials include €82.8 million COVID-19 related inventories in total, whereas Work in progress includes €12.1 million (December 31, 2020: €0) for the COVID-19 product. The net realizable value of the COVID-19 related inventories is expected to exceed the net book value as a result of the contractual terms of the COVID-19 agreement with UK government (see Note 4.2). In addition payments to cover those costs have been received already and are non-refundable.

The increase in Purchased goods (third party products) is mainly caused by the partnership with Bavarian Nordic (see Note 4.2).

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 as of June 30, 2020, December 31, 2020, and June 30, 2021. 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. The write-down of €9.2 million relates €5.5 million to finished goods, €3.0 million to work in progress (of which nil to faulty products), €0.7 million to raw materials and nil to purchased goods.

The cost of inventories is recognized as an expense and is included in the position "Cost of goods and services" amounted to 12.1 million (June 30, 2020: €12.8 million), of which €4.4 million (June 30, 2020: €2.2 million) related to defective products, which were written down.

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 HEPLISAVB 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 SARSCoV-2 vaccine candidate, VLA2001. As of June 30, 2021, Valneva has included €73.5 million of CpG 1018 in Raw material inventories and €46.9 million in advance payments in other current assets.

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14. Trade receivables

Trade receivables include the following:

€ in thousand	June 30, 2021	December 31, 2020
Trade receivables	18,022	19,237
Less: loss allowance of receivables	(15)	(6)
Trade receivables, net	**18,007**	**19,232**

During the six months ended June 30, 2021 and during the six months ended June 30, 2020, no material impairment losses have been recognized. Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

Trade receivables include €18.0 million (December 31, 2020: €18.7 million) receivables from contracts with customers.

15. Other Assets

Other assets include the following:

€ in thousand	June 30, 2021	December 31, 2020
Advances	52,256	33,671
R&D tax credit receivables	24,017	19,637
Tax receivables	8,016	5,468
Prepaid expenses	6,479	2,544
Contract costs	3,034	2,846
Consumables and supplies on stock	1,238	1,061
Miscellaneous current assets	29	158
Other non-financial assets	95,070	65,385
Deposits	11,335	11,358
Miscellaneous financial assets	184	560
Other financial assets	11,519	11,918
Other assets	**106,589**	**77,303**
Less non-current portion	(18,063)	(19,476)
Current portion	**88,526**	**57,828**

As of June 30, 2021, Advances mainly included advances relating to the collaboration agreement with Dynavax, amounting to € 46.9 million (December 31, 2020: €31.1 million) (see Note 1).

As of June 30, 2021, Deposits related to a deposit in connection with a lease agreement, whereas Advances mainly related to advance payments in connection to advance payments for production components.

Contract costs were related to the collaboration with Pfizer (see Note 4.2) and refer to costs to obtain a contract. They will be amortized in line with the pattern of revenue recognition. In the six months ended June 30, 2021, €21 thousand (June 30, 2020: nil) in amortization was recognized as costs.

Due to the short-term nature of the financial instruments included in other assets, their carrying amount is considered to be the same as their fair value.

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16. Cash and cash equivalents

Cash, cash equivalents and short-term deposits include the following

€ in thousand	June 30, 2021	December 21, 2020
Cash on hand	2	2
Cash at bank	329,721	173,107
Short-term bank deposits (maximum maturity of 3 months)	—	31,285
Restricted cash	42	41
Cash and cash equivalents	**329,766**	**204,435**

As of June 30, 2021, and as of December 31, 2020, Restricted cash pertained to a certificate of deposit with limited access that secures the credit limit for the Company's commercial card.

On June 30, 2021, the minimum liquidity requirement for the Group according to the debt financing agreement with US Healthcare Funds Deerfield and OrbiMed (see Note 18) was €50.0 million (December 31, 2020: €75.0 million). This requirement continues to be valid through 2022 and will be amended to €35.0 million from 2023 on (see Note 18).

Cash and cash equivalents net of the US Healthcare Funds Deerfield and OrbiMed financial liability amounted to €281.6 million (December 31, 2020: €158.2 million).

17. Equity

17.1 Share capital and Share premium

Ordinary shares and the convertible preferred shares are classified as equity.

Number of shares	June 30, 2021	December 31, 2020
Ordinary shares issued (€0.15 par value per share)	99,888,424	90,950,048
Convertible preferred shares registered	20,514	20,514
Total shares issued	**99,908,938**	**90,970,562**
Less Treasury shares	(128,347)	(146,322)
Outstanding shares	**99,780,591**	**90,824,240**

On May 10, 2021, the Company announced that the underwriters of its global offering of an aggregate of 7,082,762 new ordinary shares, consisting of a public offering of 2,318,881 American Depositary Shares ("ADSs"), each representing two ordinary shares (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"), had exercised in full their option to purchase up to 1,062,414 additional new ordinary shares in the form of 531,207 ADSs. The additional ADSs were delivered concurrently with the closing of the Global Offering.

As a result, the total number of Valneva's ordinary shares (including in the form of ADSs) issued in the Global Offering amounted to 8,145,176 ordinary shares, including 5,700,176 ordinary shares represented by 2,850,088 ADSs, each representing two ordinary shares, bringing the gross proceeds of the Global Offering to approximately $107.6 million (€89.6 million). The Cost of equity transactions in the amount of €6.8 million, which were directly attributable to the issue of new shares, are shown in equity as a deduction, net of tax, if any, from the proceeds.

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

17.2 Other reserves

€ in thousand	Other regulated reserves[2]	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance at January 1, 2020	**52,820**	**(4,836)**	**(1,112)**	**8,357**	**(9,474)**	**45,756**
Currency translation differences	—	(673)	—	—	—	(673)
Share-based compensation expense:						
- value of services	—	—	—	2,112	—	2,112
Purchase/sale of treasury shares	—	—	98	—	—	98
Balance at June 30, 2020	**52,820**	**(5,507)**	**(1,015)**	**10,468**	**(9,474)**	**47,293**
Balance at January 1, 2021	**52,820**	**(2,474)**	**(898)**	**12,368**	**(9,474)**	**52,342**
Currency translation differences	—	(424)	—		—	(424)
Share-based compensation expense:						
- value of services	—	—	—	1,217		1,217
Purchase/sale of treasury shares	—	—	209	—	—	209
Balance at June 30, 2021	**52,820**	**(2,898)**	**(689)**	**13,585**	**(9,474)**	**53,344**

18. Borrowings

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 primary Lyme and chikungunya development programs in the short term. As of June 30, 2021, $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 by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries. Furthermore, the loan agreement contains covenants, including a minimum liquidity in the amount of €35.0 million and minimum consolidated net revenue in the amount of €115.0 million on a consecutive twelve month basis. To avoid a breach of covenants due to the decline in revenues caused by the COVID-19 pandemic, the initial agreement was amended in July 2020 to postpone the application of the minimum revenue covenant until December 31,2020 (inclusive) 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 from 2021 onward and to €35.0 million from 2023 onward and (ii) modify the minimum revenue covenant to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.8 million in 2022 and €115.0 million thereafter. If the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, Valneva would not be able to comply with the financial covenants in the financing agreement with Deerfield and OrbiMed, which could result in additional costs (up to an additional 10% 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.

As of June 30, 2021, the liability relating to this financing agreement was €48.2 million, of which €5.1 million is reported as current (December 31, 2020: €46.2 million, of which €4.9 million is reported as current).

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

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As of June 30, 2021, other loans included in borrowings related to financing of Research and Development expenses and CIR (R&D tax credit in France) of €4.0 million (December 31, 2020: €5.9 million) which are guaranteed by governmental parties and the CEPI loan in the amount of €2.3 million (December 31, 2020: €1.3 million), which relates to advanced payments received which are expected to be paid back in the future. For detailed information see Note 6.

19. Contract liabilities

Development of contract liabilities:

€ in thousand	June 30, 2021	December 31, 2020
Balance as at January 1	89,636	1,426
Revenue recognition	(2,228)	(594)
Exchange rate differences	(12)	101
Addition	251,078	88,703
Closing balance	338,474	89,636
Less non-current portion	—	(58)
Current portion	**338,474**	**89,578**

As of June 30, 2021, €335.7 million (as of December 31, 2020: €87.0 million) related to the agreement with the UK Government to supply up to 190 million doses of SARS-CoV-2 vaccine (see Note 4.2), €1.0 million (as of December 31, 2020: €1.0 million) related to the agreement with Butantan (see Notes 1 and 6), €0.9 million (as of December 31, 2020: €0) related to the collaboration with Pfizer Inc. (see Note 4.2) and €0.9 million (as of December 31, 2020: €1.6 million) related to other technologies and services provided to different customers.

20. Refund liabilities

Development of refund liabilities:

€ in thousand	June 30, 2021	December 31, 2020
Balance as at January 1	111,426	6,553
Additions	5,691	109,296
Payments	(3,699)	(477)
Other releases	(8,545)	—
Interest expense capitalized	4,104	3,640
Exchange rate difference	2,390	(7,586)
Closing balance	**111,368**	**111,426**
Less non-current portion	(104,493)	(97,205)
Current portion	**6,875**	**14,222**

As of June 30, 2021, €90.0 million (thereof €84.1 million non-current; as of December 31, 2020: €81.9 million, thereof €70.0 million non-current) related to the collaboration with Pfizer Inc. (see Note 4.2), €14.1 million (non-current; as of December 31, 2020: €20.9 million, non-current) related to the agreement with UK Government to develop and commercialize a SARS-CoV-2 vaccine (see Note 4.2), €6.5 million (thereof €6.3 million non-current; as of December 31, 2020: €6.3 million, non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 and €0.8 million (as of December 31, 2020: €2.3 million) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products.

Other releases mainly refer to changes in the refund liability related to changes in assumptions and estimates.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

Expected cash outflows for refund liabilities are disclosed in Note 23.

21. Provisions

21.1 Provisions for employee commitments

€ in thousand	June 30, 2021	December 31, 2020
Employer contribution costs on share-based compensation plans	11,998	7,351
Phantom shares	4,657	2,390
Retirement termination benefits	581	550
Leaving indemnities	—	112
Balance at June 30	**17,237**	**10,403**
Less non-current portion	4,648	2,358
Current portion	**12,589**	**8,045**

Employer contribution costs on share-based compensation plans and Phantom shares are calculated at the balance sheet date using the share price of Valneva as of June 30, 2021: €11.14 (December 31, 2020: €7.75).

21.2 Other provisions

€ in thousand	June 30, 2021	December 31, 2020
Non-current	—	—
Current	2,384	2,124
Provisions	**2,384**	**2,124**

As of June 31, 2021, Other provisions included €2.1 million (December 31, 2020: €1.8 million) from a provision for expected legal and settlement costs under a court proceeding is related to the Intercell AG/Vivalis SA merger.

22. Other liabilities

€ in thousand	June 30, 2021	December 31, 2020
Deferred income	2,685	2,861
Other financial liabilities	44	51
Miscellaneous liabilities	1	2
Other liabilities	**2,730**	**2,913**
Less non-current portion	(70)	(72)
Current portion	**2,660**	**2,841**

Deferred income mainly includes conditional advances from government grants and a grant from CEPI (see Note 6.)

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23. Contractual obligations

The following tables disclose aggregate information about the Group'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 December 31, 2020 € in thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,004	25,569	37,900	5,148	—	—	75,621
Lease liabilities	3,442	28,078	3,677	9,446	9,963	3,850	58,456
Refund liabilities	20,025	82,670	48,566	—	—	—	151,260
Trade payables and accruals	36,212	—	—	—	—	—	36,212
Tax and employee-related liabilities	8,300	—	—	—	—	—	8,300
Other liabilities	27	25	—	—	—	—	52
	75,010	**136,342**	**90,142**	**14,594**	**9,963**	**3,850**	**329,901**

At June 30, 2021 € in thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,107	32,171	33,267	2,250	—	—	74,795
Lease liabilities	4,013	29,052	5,219	12,853	9,945	2,954	64,035
Refund liabilities	12,163	84,035	30,018	—	—	—	126,216
Trade payables and accruals	71,502	—	—	—	—	—	71,502
Tax and employee-related liabilities[3]	8,516	—	—	—	—	—	8,516
Other liabilities	19	25	—	—	—	—	45
	103,320	**145,283**	**68,504**	**15,103**	**9,945**	**2,954**	**345,110**

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.

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24. Cash Flow information

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

€ in thousand	Six months ended June 30, 2021	2020
Profit/(Loss) for the year	(86,399)	(25,639)
Adjustments for		
• Depreciation and amortization	6,101	4,687
• Share-based compensation expense	3,484	2,631
• Income tax expense/(income)	668	(1,759)
• (Profit)/loss from disposal of property, plant, equipment and intangible assets	23	7
• Share of (profit)/loss from associates	90	(90)
• Provision for employer contribution costs on share-based compensation plans	4,596	600
• Other non-cash income/expense	(6,163)	1,345
• Interest income	(228)	(74)
• Interest expense	8,431	3,909
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):		
• Other non-current assets	1,413	1,158
• Long term contract liabilities	(58)	(331)
• Long term refund liabilities	6,988	62,663
• Other non-current liabilities and provisions	(2)	(23)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
• Inventory	(97,006)	(6,274)
• Trade and other receivables	(13,271)	15,812
• Contract liabilities	248,910	47,790
• Refund liabilities	(11,157)	6,555
• Trade, other payables and provisions	19,139	500
Cash generated from operations	**85,560**	**113,466**

Cash generated from operations included payments of €241.6 million from the UK Government for the delivery of the COVID-19 vaccine. The payments are reported in short term contract liabilities (see Notes 4 and 19).

25. 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 has been 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 (December 31, 2020: €1.9 million). €0.3 million of additional expenses related to this litigation is included in “other expenses” in the period ended June 30, 2021.

In July 2016, a claim for additional payment was raised and litigation was filed in December 2016, in connection with the 2009 acquisition of Humalys SAS, from which the Company had acquired a technology, which was later combined with other antibody discovery technologies and spun off to BliNK Biomedical SAS in early 2015. Former shareholders of Humalys claimed additional consideration as a result of the spin-off transaction. A first instance decision in the Humalys case is now expected in the first half of 2022. After consultation with its external advisors the Company believes that this claim is unsubstantiated and the filed litigation is not likely to succeed in court.

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Valneva SE Pursuant to 17 C.F.R. Section 200.83

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.

26. Related party transaction

Key management compensation

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

€ in thousand	Six months ended June 30,	
	2021	2020
Salaries and other short-term employee benefits	677	742
Other long-term benefits	15	8
Share-based payments (expense of the period)	448	924
Key management compensation	**1,140**	**1,673**

Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounted to €140 thousand (six months ended June 30, 2020: €70 thousand).

27. Events after the reporting period

In September 2020, the Company 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 the Company was to develop, manufacture and supply a COVID-19 vaccine to the UK Authority in the United Kingdom of Great Britain and Northern Ireland, or the UK. As part of the UK Supply Agreement, it was agreed that a significant amount of the government advance funding to be provided by the UK Authority would be used to upgrade the Company's manufacturing facilities in Scotland. Funding for UK-based clinical trials was agreed to in a separate, linked Clinical Trial Agreement. This Clinical Trial Agreement has not been terminated and the Company reported positive topline Phase 3 clinical trial results on October 18, 2021.

Following the close of business on September 10, 2021, the Company received notice of the UK Authority's decision to terminate the UK Supply Agreement. The Company never received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for the Company.

First, the UK Authority purported to terminate the UK Supply Agreement on the common law (non-contractual) ground that the Company would allegedly, at some time in the future, in the future breach its obligations regarding the delivery schedule under the UK Supply Agreement. The Company strongly disputes the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and does not consider that termination to be valid. However, in the event of termination of the UK Supply Agreement on this basis, the UK Authority could be entitled to recover damages and funding provided to the Company under the UK Supply Agreement. In a worst case scenario, it could be argued that the Company's liability under the UK Supply Agreement could range up to as high as all sums paid to the Company. As of June 30, 2021, the UK Authority had placed orders and provided advance and funding payments related to the development and manufacture of VLA2001 of £310 million (€350 million), reported as refund/contract liability specified below. However, the Company considers that, even in the unlikely event that the UK Authority is able to successfully demonstrate that it suffered loss as a result of an alleged anticipatory breach by the Company, it would be highly

unlikely that the Company would be held liable for any damages, let alone damages of that magnitude. In any event, the UK Authority has not notified the Company of any specific claim for damages in connection with the purported termination nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. The Company has acknowledged the UK Authority's termination of the UK Supply Agreement on the basis of this discretionary right, and the termination became effective on October 10, 2021. The UK Supply Agreement provides that, in the case of termination for convenience by the UK Authority, the Company shall not be obliged to refund or repay any paid amount by the UK Authority paid. A royalty on sales and other obligations, as described below, may survive termination in certain circumstances.

The Company was still, and still is, completing the construction of its new manufacturing facility, Almeida, at its site in Livingston, Scotland; this project was largely funded through certain advance payments made by the UK Authority pursuant to the UK Supply Agreement.

The Company considers that the event of termination is a non-adjusting subsequent event under IAS10, as it arose after the end of the reporting period and is not indicative of conditions existing as of June 30, 2021. As of June 30, 2021, the Company was not in breach of its delivery obligations, nor had it received any notification from the UK Authority indicating concern that such a breach had occurred or would occur. Therefore, no impact was recorded on the Company's financial position and results as of and for the period ended June 30, 2021.

As of June 30, 2021, the significant assets and liabilities relating to the COVID-19 vaccine program that could be impacted by the termination of the UK Supply Agreement are the following:

- Property, Plant and Equipment of €43.9 million.
- Advance payments paid to suppliers for raw materials of €46.9 million.
- Inventories of €94.9 million.
- Refund liabilities of €14.1 million related to potential royalty payments.
- Contract liabilities of €335.6 million.

The final terms of the termination, which the Company is discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and our future results of operations. The impact is uncertain as of the date of issuance of the Company's unaudited interim condensed consolidated financial statements as of June 30, 2021:

- Inventories and advance payments for inventories may be revalued to net realizable value. As changes in the Company's business plan resulting from the termination of the UK Supply Agreement may have an impact on the Company's manufacturing plan, a write-down of raw materials, work in progress and advance payments of raw materials of up to €141.8 million may be necessary. This depends on concomitant changes to the supply plan, marketing authorization, commercial traction and ability to extend the current shelf life (expiry dates) of the Company's existing inventory.
- The Company considers that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay it certain monies in respect of commitments that it had made prior to termination. Nevertheless, a provision regarding related onerous supplier and lease agreements may be needed depending on the outcome of the negotiations with the UK Authority and the Company's suppliers.
- The Company is currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If the Company was to cease to use its COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, acquired with funds advanced by the UK Authority, it may have certain obligations to the UK Authority, such as a partial reimbursement of funding received, in respect of those assets if they are sold, disposed or repurposed.

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- Depending on the final outcome of discussions with the UK Authority, some or all of the Company's contract liabilities may be recorded as revenue or other income for an amount that is unknown at this time.
- The termination of the UK Supply Agreement is considered to be an impairment indicator and therefore an impairment test of the Property, Plant and Equipment dedicated to the COVID-19 vaccine program and other assets used for the COVID-19 vaccine program and other products will be performed as part of the December 2021 accounting closing process.
- Under the terms of the UK Supply Agreement, the Company is required to pay the UK Authority a royalty in respect of sales of its UK-manufactured vaccine to non-UK customers. This requirement may survive termination of the UK Supply Agreement, and the aggregate maximum royalty payable to the UK Authority is €100 million, of which €14.1 million is recognized as refund liability as of June 30, 2021.

In October 2021, the Company announced positive Phase 3 topline results in which it observed that VLA2001 demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of GMT for neutralization antibodies, as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. The Company observed that VLA2001 induced broad T-cell responses with antigen- specific IFN-gamma-producing T-cells against the S, M and N proteins. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222.

Table of Contents

Confidential Treatment Requested by
Valneva SE Pursuant to 17 C.F.R. Section 200.83

Ordinary Shares

Including Ordinary Shares
Represented by
American Depositary Shares

PROSPECTUS

, 2021

Goldman Sachs

Jefferies

Guggenheim Securities

Bryan, Garnier & Co.

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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 have entered 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 June 30, 2021, 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).

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- 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).
- On January 27, 2021, we issued 793,200 new ordinary shares to a former Supervisory Board member and to employees, in connection with, respectively (a) the exercise of 3,125 equity warrants on January 22, 2021 carried out by a total cash contribution of €8,043.75 (including €468.75 as nominal value), and (b) the exercise of 790,075 stock options between January 18 and January 25, 2021 inclusive carried out by a total cash contribution of €2,200,886.75 (including €118,511.25 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

Exhibit Number	Description of Document	Incorporated by Reference			
		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	F-1/A	333-255155	4.1	April 29, 2021
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-255155	4.2	April 29, 2021
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.	F-1	333-255155	10.1	April 9, 2021

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Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibits	Filing Date
10.2†	SARS-CoV-2 Vaccine Supply Agreement, dated September 13, 2020, by and among the Secretary of State for Business, Energy and Industrial Strategy, Valneva SE and Valneva Austria GmbH, as amended on December 17, 2020 and January 30, 2021.	F-1	333-255155	10.2	April 9, 2021
10.3†	Supply Agreement, dated September 12, 2020, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.	F-1	333-255155	10.3	April 9, 2021
10.4†	Funding Agreement, dated April 1, 2019, by and between Coalition for Epidemic Preparedness Innovations and Valneva SE.	F-1	333-255155	10.4	April 9, 2021
10.5†	Distribution Agreement, dated December 9, 2015, by and between GlaxoSmithKline GmbH & Co. KG and Valneva Austria GmbH.	F-1	333-255155	10.5	April 9, 2021
10.6†	Sublicense Agreement, dated April 14, 2003, by and between VaccGen International LLC and Intercell AG, as assigned to the Registrant and as amended.	F-1	333-255155	10.6	April 9, 2021
10.7†	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.	F-1	333-255155	10.7	April 9, 2021
10.8†	Contract dated September 9, 2020, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.	F-1	333-255155	10.8	April 9, 2021
10.9†	Amendment, dated August 23, 2021, to Contract dated September 9, 2020 by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.				
10.10#	Credit Agreement, dated February 3, 2020, by and among Valneva Austria GmbH, Valneva SE, Wilmington Trust, National Association and the Lenders, as amended to date.	F-1	333-255155	10.9	April 9, 2021
10.11†	Distribution Agreement (IXIARO), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Austria GmbH.	F-1	333-255155	10.10	April 9, 2021
10.12†	Distribution Agreement (DUKORAL), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Sweden AB, as amended to date.	F-1	333-255155	10.11	April 9, 2021

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Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibits	Filing Date
10.13+	Employee Stock Option Plan 2013	F-1	333-255155	10.12	April 9, 2021
10.14+	Employee Stock Option Plan 2015	F-1	333-255155	10.13	April 9, 2021
10.15+	Employee Stock Option Plan 2016	F-1	333-255155	10.14	April 9, 2021
10.16+	Employee Stock Option Plan 2017	F-1	333-255155	10.15	April 9, 2021
10.17+	Employee Stock Option Plan 2019	F-1	333-255155	10.16	April 9, 2021
10.18+	Free Convertible Preferred Share Plan 2017-2021	F-1	333-255155	10.17	April 9, 2021
10.19+	Free Share Plan 2019-2023	F-1	333-255155	10.18	April 9, 2021
10.20+	Phantom Stock Option Plan 2017 and Form of Exercise Notice	F-1	333-255155	10.19	April 9, 2021
10.21+	Phantom Stock Option Plan 2019	F-1	333-255155	10.20	April 9, 2021
10.22+	Phantom Stock Plan 2020	F-1	333-255155	10.21	April 9, 2021
10.23+	Terms and Conditions Applicable to BSA 27 Equity Warrants and Form of Exercise Notice	F-1	333-255155	10.22	April 9, 2021
21.1	List of subsidiaries	F-1	333-255155	21.1	April 9, 2021
23.1*	Consent of Deloitte & Associés				
23.2*	Consent of PricewaterhouseCoopers Audit				
23.3*	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.
\+ Indicates management contract or compensatory plan.
† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
\# Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

(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

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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.

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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

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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 Frédéric Jacotot, 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
David Lawrence	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
Sharon Tetlow	Member of the Supervisory Board	, 2021
Johanna Willemina Pattenier	Member of the Supervisory Board	, 2021

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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: Thomas Lingelbach
Title: Director

[***] = 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.

VALNEVA USA, INC.
910 Clopper Road, Suite 160S
Gaithersburg, MD 20878, *USA*
August 23, 2021

[***]
[***]

Defense Logistics Agency – Troop Support
Business Opportunities Office
Bldg. 36, 2nd Floor, Room 2035
700 Robbins Avenue
Philadelphia, PA 19111-5092

BY EMAIL

Re: Option Year 1 Under DLA Contract No. SPE2DP-20-D-0005 For Japanese Encephalitis Virus, Purified, Inactivated Vaccine

Dear [***],

As discussed, Valneva USA, Inc. ("Valneva") has set forth below the revisions to DLA Contract No. SPE2DP-20-D-0005 (the "Contract") that will be implemented with the exercise of the first Option Year for the period of August 24, 2021 through August 23, 2022 under the Contract as agreed to between DLA and Valneva. Specifically:

1. Valneva will provide [***] replacement doses at no cost to DLA should any of the doses purchased during the base year of the Contract expire. DLA will be required to return the expired doses, [***], to Valneva within [***] of the expiry date. Valneva will ship replacement doses, [***], to DLA upon receipt of notice from DLA, provided that DLA notifies Valneva at least [***] prior to the expected delivery date for the replacement doses.
2. Valneva will provide [***] expiry dating on all Option Year 1 delivered quantities to DDSP [***].
3. The minimum quantity for Option Year 1 will be revised from [***] to [***] doses. The maximum quantity for Option Year 1 will be revised from [***] to [***]. Doses are packaged in quantities of [***] so quantities must be divisible by [***].
4. The following delivery schedule will apply:

Month/Year	Doses
08/21	[***]
09/21	[***]
10/21	[***]
11/21	[***]
12/21	[***]
01/22	[***]
02/22	[***]

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www.valneva.com

03/22	[***]
04/22	[***]
05/22	[***]
06/22	[***]
07/22	[***]
08/22	[***]

As noted above, no doses to be shipped from January to June 2022. For orders above the minimum guaranteed quantities, Valneva will agree to deliveries at DLA's discretion provided that DLA (a) provides Valneva with [***] lead time for each order and (b) each order is equal to or in excess of the minimum order quantity set forth in FAR Clause 52.216-19, Order Limitations. The dates above are proximate. Valneva will work with DLA to accommodate minor revisions as reasonably necessary.

5. DLA will provide monthly utilization reports to Valneva of doses distributed at the lowest level permissible but in no event no lower than the national level.

6. All other terms and conditions remain the same.

Per past practices, Valneva would appreciate if DLA would incorporate this letter by reference into the Option Year 1 modification for clarity.

Thank you for your assistance in this matter.

Best regards,

/S/ [***]

[***]
[***]
VALNEVA USA, INC.
(A VALNEVA SE AFFILIATE)
910 Clopper Rd. Suite 160S
Gaithersburg, MD 20878
U.S.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.