valneva

Building
ON OUR STRENGTHS

2020 Universal Registration Document Amendment 1

October 26, 2021

Summary

Amendment 1 to the 2020 Universal Registration Document

A European Company (*Societas Europaea*) with a Management Board and Supervisory Board
Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain (France)
422 497 560 R.C.S. Nantes

AUTORITÉ DES MARCHÉS FINANCIERS
AMF

This amendment to the Universal Registration Document was filed on October 26, 2021 with the French Financial market authority (Autorité des Marchés Financiers or AMF), as the competent authority under Regulation (EU) 2017/1129, without prior approval in accordance with Article 9 of the said Regulation.

The Universal Registration Document may be used for the purpose of a public offer of securities or the admission of securities to trading on a regulated market, if it is supplemented by a Note d'Opération and, as the case may be, by a summary and all the amendments to the Universal Registration Document. These documents are then together approved by the AMF in accordance with Regulation (EU) 2017/1129.

This Amendment (***Amendment 1***) updates and should be read in conjunction with the 2020 Universal Registration Document filed with the AMF on April 9, 2021 under number D.21-0286 (the ***2020 URD***).

A table of concordance of this Amendment 1 with the 2020 URD is provided on pages 90 *et seq*.

Copies of the 2020 URD and this Amendment 1 are available free of charge at Valneva's registered office at 6 rue Alain Bombard, 44800 Saint-Herblain (France). The 2020 URD, together with this Amendment 1, may also be viewed on Valneva's website (www.valneva.com) and on the website of the AMF (www.amf-france.org).

Incorporation by reference :

In accordance with the provisions of Article 19 of Regulation (EU) 2017/1129 dated June 14, 2017, the following are included by reference in this Amendment 1 : the condensed consolidated interim financial statements for the six months ended June 30, 2021, as well as the related Statutory Auditors' report (Sections 2 and 3 of the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website (www.valneva.com[i])

The information in the aforementioned Half-Year Financial Report not incorporated in this Amendment 1 is either covered elsewhere in this Amendment 1 or is not relevant for investors.

In this Amendment 1, unless otherwise indicated, ***the Company*** refers to Valneva SE, while ***the Group***, ***the Valneva Group*** or ***Valneva*** refers to Valneva SE and all its subsidiaries.

This is a free translation of the French original document. In the event of any discrepancy between the French version and the English translation, the French version shall prevail in all cases.

[i] https://valneva.com/investors/financial-reports/

General introductory comments

This Amendment 1 updates the 2020 Universal Registration Document filed with the *Autorité des Marchés Financiers* on April 9, 2021 under number D.21-0286.

It has been prepared in the context of the launch by the Company of a capital increase, with cancellation of the shareholders' preferential subscription rights, reserved for certain categories of persons (within the meaning of Article L. 225-138 of the French Commercial Code), meeting the characteristics determined by the Combined General Meeting of shareholders of June 23, 2021 in its 17th resolution.

This transaction, as announced via press release dated October 26, 2021[ii], includes:

- a public offering of ordinary shares issued in the form of *American Depositary Shares* (***ADS***) in the United States; and
- a concurrent private placement of ordinary shares in Europe (including France) and in other countries outside the United States.

Disclaimer: This Amendment 1 contains forward-looking statements about the Group's objectives, prospects and development strategy[iii]. These statements are based on data, assumptions and estimates considered reasonable by the Company. They are subject to change or adjustment owing to uncertainties arising from unpredictable outcomes inherent to all research and development activities, as well as in the economic, financial, competitive, regulatory and climatic environment. In addition, the Group's business activities and its ability to meet its targets and forecasts may be affected by the occurrence of risk factors described in this Amendment 1[iv].

The Company makes no commitment, nor gives any guarantee, that the objectives and forecasts contained in this Amendment 1 will be achieved. Investors are advised to carefully consider each of the risk factors contained in this Amendment 1 before making an investment decision. The occurrence of some or all of these risks could have an adverse effect on the Group's business, condition, financial results or its objectives and forecasts. In addition, other risks, not yet identified or considered insignificant by the Group, could have the same negative effect and investors could lose all or part of their investment.

The forward-looking statements targets and forecasts shown in this Amendment 1 may be affected by risks, either known or unknown, uncertainties, and other factors that may cause the Group's future results, performance and achievements to be significantly different from the stated or implied targets and forecasts. These factors may include changes in economic and business environment or in regulations, as well as risk factors set out in the 2020 URD[v] and this Amendment 1.

[ii] https://valneva.com/media/press-releases/?y=2021
[iii] Including in Section 1.4.4.
[iv] See Section 1.5.
[v] See Section 1.5.

Indicative financial reporting timetable

The indicative financial reporting timetable appearing in the 2020 URD is modified as follows:

The Company had planned to communicate its third quarter 2021 results on November 18, 2021. Given the difficulty of assessing the impact of a number of post-closing events at this time, the Company will communicate, on November 18, 2021, only its cash position for the quarter ended September 30, 2021 and its revenues for the nine months ended September 30, 2021.

The year-end closing on December 31, 2021 will allow for the integration of all necessary elements.

Company stock market and shareholding information

The introductory text to the Section of the 2020 URD titled “Company stock market and shareholding information” is replaced in its entirety by the following:

The Valneva SE ordinary shares (ISIN: FR0004056851) are traded on Compartment B of Euronext Paris (ticker: VLA.PA)[(1)]. The ordinary shares are eligible for the Deferred Settlement Service.

Some of the Company's ordinary shares are also dual-listed on Nasdaq in the form of *American Depositary Shares*. Valneva SE has been listed on the Nasdaq Global Select Market since May 6, 2021, under the symbol “VALN”[(2)].

Since March 22, 2021, the Company has been a member of the SBF 120 and the CAC Mid 60[(3)].

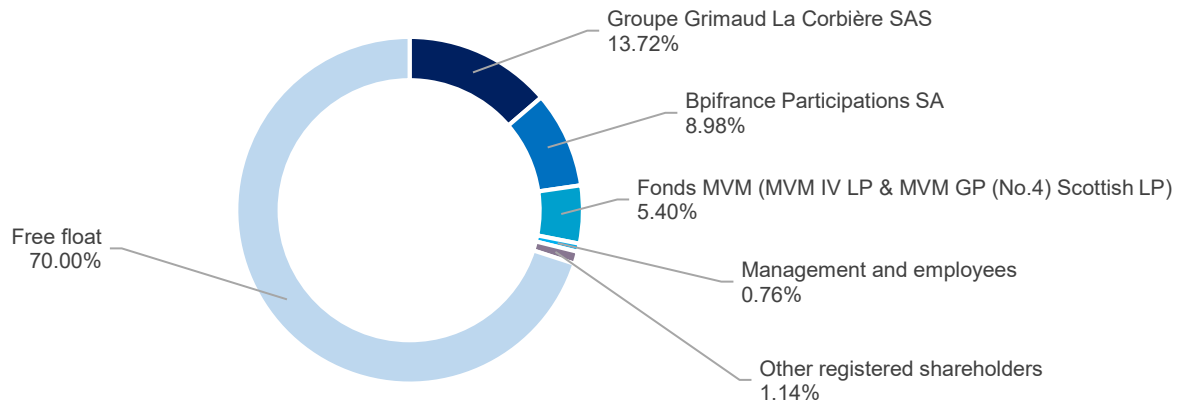
[(1)] Valneva SE ordinary shares were also previously traded on the Vienna Stock Exchange until December 20, 2019 (see the Company's press releases dated September 19 and December 20, 2019: https://valneva.com/media/press-releases/?y=2019).
Upon decision of the Vienna Stock Exchange, Valneva SE shares listed on Euronext Paris continue to be traded electronically on the “global market” segment of the Vienna Stock Exchange's Multilateral Trading Facility (MTF).

[(2)] See the Company's press releases dated December 22, 2020 (https://valneva.com/media/press-releases/?y=2020), April 10 and 29, 2021, and May 5, 6, 10 and 11, 2021 (https://valneva.com/media/press-releases/?y=2021).
See also Section 1.1.2(r) of this Amendment 1.

[(3)] See the Company's press release dated March 22, 2021: https://valneva.com/media/press-releases/?y=2021

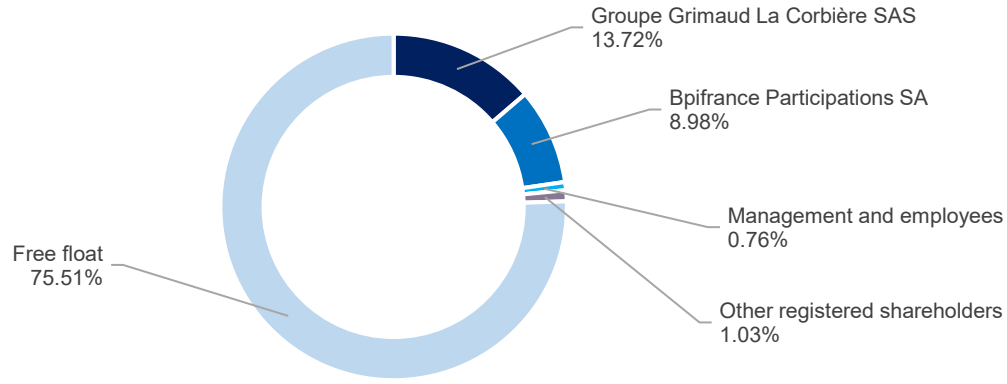
The Sub-section "Shareholding structure at December 31, 2020", appearing in Section "Company stock market and shareholding information" of the 2020 URD, is completed by the following information relative to the shareholding structure at June 30 and September 30, 2021:

Shareholding structure of the Company at June 30, 2021



***Share ownership calculated in reference to a total share capital of 99,908,938 ordinary shares of Valneva SE**, comprised of (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.*

Shareholding structure of the Company at September 30, 2021



***Share ownership calculated in reference to a total share capital of 99,915,188 ordinary shares of Valneva SE**, comprised of (a) 99,894,674 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.*

There have been no significant changes in the shareholding structure since September 30, 2021.

1. Presentation of the Group and its business

1.1. Selected financial information

1.1.1. Financial data and key figures

Section 1.1.1 of the 2020 URD is supplemented with the following information, which is included in the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website and incorporated by reference in this Amendment 1[vi]:

- Unaudited Interim Condensed Consolidated Statement of Income (Loss) and Comprehensive Income (Loss);
- Unaudited Interim Condensed Consolidated Balance Sheets;
- Unaudited Interim Condensed Consolidated Statement of Cash Flows;
- Unaudited Interim Condensed Consolidated Statements of changes in equity.

[vi] See Section 3 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/

1.1.2. Recent events

Events occurring after the filing date of the 2020 URD with the AMF are described below. Section 1.1.3 of the 2020 URD is thus supplemented by the following information:

Since April 9, 2021, Valneva has made the following announcements:

Research & Development:

(a) Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

On September 28, 2021, Valneva announced further positive Phase 2 results, including booster response, for its Lyme disease vaccine candidate VLA15.

The Phase 2 study, VLA15-202, is evaluating the immunogenicity and safety of VLA15 in a Month 0-2-6 vaccination schedule. The study enrolled 246 healthy adults 18 to 65 years of age in the United States. As announced in October 2020, the study met its primary endpoint of demonstrating that VLA15 was immunogenic across all dose groups tested and elicited high antibody responses across all serotypes (ST1 – ST6) at one month after completion of the primary vaccination series. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all groups, remaining above baseline but confirming the need for a booster strategy.

VLA15 was safe and well-tolerated across all doses and age groups tested. No related Serious Adverse Events (SAEs) were observed in any treatment group.

Participants who received a complete primary vaccination series with 180 µg doses of VLA15 were invited to continue the study in a booster extension phase and were randomized to receive an additional 180 µg dose of VLA15 (N=39) or placebo (N=19) at Month 18.

VLA15's acceptable safety profile was confirmed through one-month post-booster. Administration of a booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (Geometric Mean Fold Rise) in anti-OspA IgG antibody titers compared with titers observed after primary immunization. All participants seroconverted to anti-OspA IgG after the booster dose, meaning Seroconversion Rates (SCRs) were 100% for all OspA serotypes. SCR was defined as the rate of subjects that changed from seronegative at baseline to seropositive. Additionally, subjects who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by Serum Bactericidal activity Assays, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The study is continuing to monitor persistence of antibody responses

(b) Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate

On July 19, 2021, Valneva and Pfizer Inc. announced that they completed recruitment for the Phase 2 trial, VLA15-221, of Valneva's Lyme disease vaccine candidate, VLA15. The trial builds on previous positive Phase 2 trials and includes both adult and pediatric participants with the aim to support acceleration of the vaccine candidate's pediatric program.

A total of 625 participants, 5 to 65 years of age, were randomized in the Phase 2 trial to receive VLA15 at Month 0-2-6 or Month 0-6 (200 volunteers each) or placebo at Month 0-2-6 (200 volunteers). The main safety and immunogenicity readout will be performed approximately one month after completion of the primary vaccination schedule (i.e., at Month 7). 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.

(c) Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate

On August 5, 2021, Valneva announced positive topline results from the Phase 3 pivotal trial of its single-shot chikungunya vaccine candidate, VLA1553.

The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the United States, 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 U.S. Food and Drug Administration ("FDA"). The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission of VLA1553 under the accelerated approval pathway. The vaccine candidate was highly immunogenic with a GMT of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 trial.

Additionally, VLA1553 was also 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 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The 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 study 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.

(d) Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate

On July 7, 2021, Valneva announced that it had been awarded Breakthrough Therapy Designation for its single-shot chikungunya vaccine candidate, VLA1553, by the FDA. Breakthrough Therapy Designation intends to facilitate and expedite development and review of new drugs for serious or life-threatening conditions where preliminary clinical data demonstrates that the drug may have substantial improvement for at least one endpoint over available therapies.

This U.S. milestone came in addition to the FDA Fast Track designation and PRIME designation by the European Medicines Agency ("EMA") that the Company received in December 2018 and in October 2020, respectively.

(e) Valneva Completes Recruitment for Phase 3 Lot-to-Lot Consistency Trial of its Chikungunya Vaccine Candidate

On June 10, 2021, Valneva announced that it had completed recruitment for the clinical lot-to-lot consistency Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials at this time.

410 participants aged 18 to 45 years were randomized in the Phase 3 trial VLA1553-302 and are 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.

(f) Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial

On April 12, 2021, Valneva announced that it has completed recruitment for the pivotal Phase 3 trial, VLA1553-301, of its single-shot chikungunya vaccine candidate, VLA1553. A total of 4,131 adults aged 18 or above were recruited across 44 sites in the US for the VLA1553-301 trial, which was launched in September 2020. If the trial results are positive, the trial is expected to support VLA1553's licensure.

(g) Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

On October 18, 2021, Valneva announced positive topline results from the pivotal Phase 3 "Cov-Compare" trial of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

The Cov-Compare trial recruited a total of 4,012 participants aged 18 years and older across 26 trial sites in the United Kingdom. The trial met its co-primary endpoints: VLA2001 demonstrated superiority against AZD1222 (ChAdOx1-S), in terms of geometric mean titer for neutralization antibodies (GMT ratio=1.39, p<0.0001), (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59)), (AZD1222(ChAdOx1-S) GMT 576.6 (95% CI 543.6, 611.7)), as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older.

T-cell responses analyzed in a sub-set of participants showed that VLA2001 induced broad antigen-specific IFN-gamma producing T-cells reactive against the S- (74.3%), N- (45.9%) and M- (20.3%) protein.

VLA2001 was generally well tolerated. The tolerability profile of VLA2001 was significantly more favorable compared to the active comparator vaccine. Participants 30 years and older reported significantly fewer solicited adverse events up to seven days after vaccination, both with regards to injection site reactions (73.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001) and systemic reactions (70.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001). No unsolicited treatment-related serious adverse events (SAE) have been reported. Less than 1% reported an adverse event of special interest in both treatment groups. Participants in the younger age group vaccinated with VLA2001 showed an overall safety profile comparable to the older age group.

The occurrence of COVID-19 cases (exploratory endpoint) was similar between treatment groups. The complete absence of any severe COVID-19 cases may suggest that both vaccines used in the study prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta).

(h) Valneva Continues Expansion of Clinical Trials of its Inactivated COVID-19 Vaccine Candidate VLA2001

On September 23, 2021, Valneva announced that it had commenced recruitment of adolescents in its pivotal Phase 3 clinical trial (VLA2001-301, "Cov-Compare") for its inactivated COVID-19 vaccine candidate VLA2001 in the United Kingdom. Topline results from the pivotal Cov-Compare trial are intended to form the basis for potential regulatory approval in adults. The Company has also started to provide boosters to volunteers in its Phase 1/2 VLA2001-201 trial. This planned expansion of VLA2001 clinical trials will support future approval in further age groups, in addition to adults.

Recruitment of adolescents, aged 12 to 17 years, commenced in the United Kingdom as part of Valneva's pivotal Cov-Compare Phase 3 trial (VLA2001-301). An initial cohort of adolescents was enrolled in an open label, non-randomized format. Subject to safety review, remaining participants were randomized to receive two doses of either VLA2001 or a placebo 28 days apart, followed by a booster dose seven months after enrolling into the study. Approximately 660 participants are to 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. A further expansion of the study to include volunteers younger than 12 years old is also envisaged, subject to data from the adolescent group.

Valneva has also commenced booster vaccinations as a continuation of the Phase 1/2 VLA2001-201 trial for which the Company reported positive topline data in April 2021. The booster shot will be provided to each volunteer six months after initial vaccination.

Valneva is conducting several clinical trials of VLA2001. In addition to Cov-Compare and VLA2001-201, VLA2001 is being evaluated in elderly volunteers in study VLA2001-304 in New Zealand as well as in a small, policy-led trial sponsored by University Hospital Southampton NHS Foundation Trust, which is not part of Valneva's regulatory package.

Valneva continues discussions with the European Commission regarding a potential VLA2001 supply contract. The Company is also actively pursuing opportunities to make VLA2001 available to other customers, subject to positive Cov-Compare data and regulatory approval.

(i) Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine

On September 14, 2021, Valneva announced that it had completed recruitment of the initial cohort of elderly participants in Valneva's Phase 3 trial, VLA2001-304, of its inactivated COVID-19 vaccine candidate, VLA2001.

300 volunteers aged 56 years and older were recruited in New Zealand into the VLA2001-304 trial with the objective to generate further safety and immunogenicity data for this age group. The cohort size was increased to 300, from 150, in consultation with the EMA. Topline data from this cohort will read out in early 2022, and it is expected that the data will support additional regulatory submissions.

(j) Valneva Receives Notice of Termination of COVID-19 Vaccine Supply Agreement by UK Government

On September 13, 2021, Valneva announced that it had received a termination notice from the UK Government (HMG) in relation to the Supply Agreement for its COVID-19 vaccine candidate, VLA2001. The contract provides HMG with the right to terminate. HMG has alleged that the Company is in breach of its obligations under the Supply Agreement, but the Company strenuously denies this.

Valneva is continuing its VLA2001 development plan. The results of the Company's pivotal Phase 3 trial, Cov-Compare, will form part of its rolling submission for conditional approval of VLA2001 with the UK's Medicines and Healthcare products Regulatory Agency (MHRA). Subject to these data and MHRA approval, Valneva believes that initial approval for VLA2001 could be granted in late 2021.

Valneva has worked tirelessly, and to its best efforts, on the collaboration with HMG including investing significant resources and effort to respond to HMG's requests for variant-derived vaccines. Valneva continues to be committed to the development of VLA2001 and will increase its efforts with other potential customers to ensure that its inactivated vaccine can be used in the fight against the pandemic.

(k) Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine

On August 23, 2021, Valneva announced that it had commenced rolling submission, for initial approval of its COVID-19 vaccine candidate, VLA2001, with the MHRA in the United Kingdom.

VLA2001 is currently being studied in the UK in a pivotal Phase 3 trial, "Cov-Compare" (VLA2001-301). Subject to positive Cov-Compare data and MHRA review, Valneva believes that initial approval for VLA2001 could be granted before the end of 2021.

(l) Valneva Initiates Further Phase 3 Clinical Trial for its COVID-19 Vaccine Candidate

On August 11, 2021, Valneva announced the initiation of a further Phase 3 trial (VLA2001-304) for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

VLA2001-304 aims to generate data in the elderly and is also designed to potentially enable variant-bridging through immune-comparability. Data from this study are expected to complement ongoing clinical trials and support additional regulatory submissions.

(m) Valneva Completes Phase 3 Trial Recruitment for its Inactivated COVID-19 Vaccine Candidate

On June 3, 2021, Valneva announced that it had completed recruitment for the pivotal Phase 3 trial of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

Over 4,000 volunteers in the United Kingdom were randomized in the Phase 3 "Cov-Compare" trial (VLA2001-301), which compares Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria. Cov-Compare's primary endpoint is to determine the immune response (Geometric Mean Titer [GMT] of SARS-CoV-2-specific neutralizing antibodies) two weeks after completion of a two-dose immunization schedule administered in a four-week interval.

(n) Valneva to Participate in the World's First COVID-19 Vaccine Booster Trial in the UK

On May 19, 2021, Valneva announced that VLA2001 would be evaluated in a small, policy-led trial called Cov-Boost sponsored by University Hospital Southampton NHS Foundation Trust. This trial is not part of Valneva's regulatory package for the VLA2001 vaccine candidate.

(o) Valneva Initiates Phase 3 Clinical Trial for its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

On April 21, 2021, Valneva announced it had initiated the pivotal Phase 3 clinical trial for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

The Phase 3 trial, "Cov-Compare" (VLA2001-301), compares Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria, in a comparative immunogenicity trial.

Approximately 4,000 participants received two doses of either vaccine. The primary endpoint of Cov-Compare is to determine the immune response (Geometric Mean Titer ("GMT")) of SARS-CoV-2-specific neutralizing antibodies) two weeks after completion of a two-dose immunization schedule administered in a four-week interval. The trial is powered to demonstrate superiority of VLA2001 in terms of GMT ratio (VLA2001/Vaxzevria). The trial is being conducted in the UK and is supported by the National Institute for Health Research.

(p) Valneva Switches Focus to Bilateral Discussions to Supply its Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

On April 20, 2021, Valneva announced that it would focus on bilateral discussions, on a country by country basis, to supply its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001, and was consequently deprioritizing the ongoing centralized discussions with the European Commission.

Following a media article published on June 30, Valneva indicated on July 1, 2021 that it continues ongoing discussions with the European Commission regarding VLA2001, Valneva's inactivated COVID-19 vaccine candidate.

Commercial Activities

(q) Valneva: U.S. DoD Exercises First Year Option on IXIARO® Supply Contract

On September 3, 2021, Valneva announced that the U.S. Department of Defense (DoD) has exercised the first option of the contract signed in September 2020 to purchase further supply of its Japanese encephalitis vaccine IXIARO®.

Due to the ongoing impact of the COVID-19 pandemic on DoD operations, the option terms have been 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 contract to approximately $118 million, assuming the exercise of the second year option that remains unchanged, compared to a minimum value of $135 million in the initial contract.

In order to support its customer through this pandemic period, Valneva will also provide additional inventory to DoD after September 2023 to mitigate the potential impact of unused stock that may expire. This replacement inventory will be provided free of charge and will be recognized as deferred revenue of up to $9 million beginning in fiscal year 2021.

Financing:

(r) Valneva Announces Closing of $107.6 Million Global Offering

On May 11, 2021, Valneva announced the closing of its previously announced global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares, after full exercise of the overallotment option granted to the underwriters (the "Option"), consisting of a public offering of 2,850,088 American Depositary Shares ("ADSs"), each representing two ordinary shares, in the United States at an offering price of $26.41 per ADS (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering").

Aggregate gross proceeds of the Global Offering, after full exercise of the Option, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately $107.6 million (€89.6 million).

Valneva's ordinary shares are listed on Euronext Paris under the symbol "VLA" and its ADSs are listed on the Nasdaq Global Select Market under the symbol "VALN". The ADSs began trading on the Nasdaq Global Select Market on May 6, 2021.

Appointments:

(s) Valneva Appoints Peter Buhler as Chief Financial Officer

On July 29, 2021, Valneva announced the appointment of Peter Buhler as Chief Financial Officer and Management Board member, with an expected arrival at Valneva within the next six months.

To ensure business continuity and transition, David Lawrence, Acting CFO of Valneva, has agreed to continue supporting Valneva until late 2021.

(t) Valneva Strengthens Management Team; Appoints Vincent Dequenne as SVP Operations and Joshua Drumm as VP Investor Relations

On July 6, 2021, Valneva announced it had appointed Vincent Dequenne as Senior Vice President Operations and Joshua Drumm as Vice President Investor Relations.

Vincent has taken responsibility for Valneva's industrial operations and works closely with Valneva's Chief Operating Officer Perry Celentano.

Joshua is notably focused on developing the Company's Investor Relations in the US following the Company's recent Initial Public Offering on Nasdaq. He works closely with Laetitia Bachelot-Fontaine who continues to lead European Investor Relations and Global Communications.

Others:

(u) Valneva Announces the Cancellation of Ordinary Shares Held by the Company following Termination of its Liquidity Agreement

On October 4, 2021, Valneva announced that the Management Board had decided to cancel all ordinary shares held by the Company following the termination of its liquidity agreement with Oddo BHF on June 11, 2021 (i.e., 4,025 ordinary shares in total, representing 0.004% of the share capital).

The Company's share capital is now set at 14,986,674.45 Euros, divided into 99,890,649 ordinary shares and 20,514 preferred shares convertible into ordinary shares, with a par value of 0.15 Euro each (i.e., 99,911,163 Shares in total).

(v) Valneva Announces Termination of Liquidity Contract with Oddo BHF and Natixis

On June 11, 2021, Valneva announced that it terminated the liquidity agreement relating to its ordinary shares concluded with Oddo BHF and Natixis on June 25, 2018, as the liquidity of the Company's securities had improved. The termination became effective as of June 11, 2021.

1.2. Overview and development of the Group

1.2.1. Business overview

(a) About Valneva

Section 1.2.1 (a) of the 2020 URD is replaced in its entirety by the following:

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need.

The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases.

Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

(b) Significant events in the development of the Group's activities

Section 1.2.1 (b) of the 2020 URD is updated with the information included in Sections 1.1.2, 1.3 and 1.4.4 of this Amendment 1.

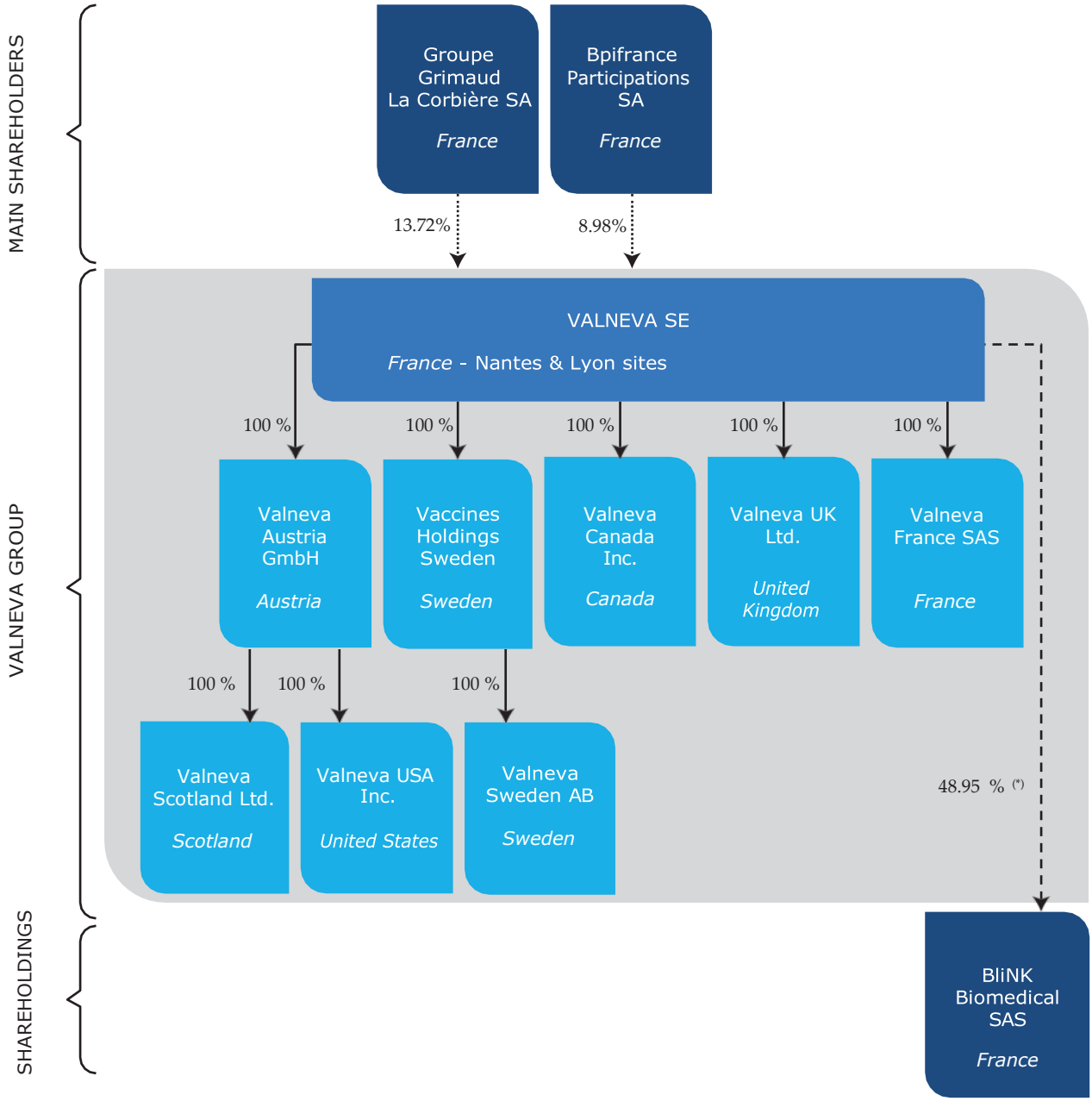
(c) Valneva's regulatory environment

The paragraph "Risks relating to the Group's regulatory environment - Litigation" included in Section 1.2.1 (c) of the 2020 URD is updated with the information included in Sections 1.5.1, 1.5.2 and 1.5.3 of this Amendment 1.

1.2.2. Organization of the Group

Section 1.2.2 (a) of the 2020 URD is supplemented with the following information relating to the presentation of the Group's organizational chart as at September 30, 2021:

Organization at September 30, 2021



The percentages indicated correspond to the percentages of total capital (all classes combined) held in each company.

(*) Valneva SE's shareholding in BliNK Biomedical SAS consists of approximately 5.5% of class A2 preferred shares (with voting rights) and approximately 10% of class A1 preferred shares (without voting rights). The Company thus holds 43.29% of the total voting rights of BliNK Biomedical SAS.

1.2.3. **Property, plant and equipment**

The paragraph relating to the Group's offices in Fleet, UK, in Section 1.2.3 of the 2020 URD, is amended as follows:

- 27m² offices located at Fleet (UK) used primarily for sales and marketing activities;

In addition, the paragraph relating to facilities leased in Scotland is amended to include the following information, as a result of the leasing of an additional facility:

- five offices and warehouses in Livingston, Scotland (UK), including a 724 m² warehouse with offices, a 600 m² warehouse with offices, a 240 m^2 office, a 1,000 m^2 office and warehouse, and an additional warehouse (also including offices) with a total surface area of approximately 2,573 m².

1.3. Description of the Group's activities

1.3.1. Products and technologies of the Group

(a) IXIARO® / JESPECT®

The paragraph "Commercialization" in Section 1.3.1 (a) of the 2020 URD is completed with information relating to the sales of IXIARO® / JESPECT® in the first half of 2021. This information is included in the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website and is incorporated by reference in this Amendment 1[vii].

In addition, the paragraph "Intellectual Property" in Section 1.3.1 (a) of the 2020 URD is updated with the information included in Section 1.3.3 (b) of this Amendment 1.

(b) DUKORAL®

The paragraph "Commercialization" in Section 1.3.1 (b) of the 2020 URD is completed with information relating to the sales of DUKORAL® in the first half of 2021. This information is included in the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website and is incorporated by reference in this Amendment 1[viii].

In addition, the paragraph "Intellectual Property" in Section 1.3.1 (b) of the 2020 URD is updated with the information included in Section 1.3.3 (b) of this Amendment 1.

[vii] See Section 1.2.2 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/
[viii] See Section 1.2.2 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/

1.3.2. Vaccines market analysis

(a) Lyme disease vaccines

The sub-section "Lyme disease vaccines" appearing under "Vaccines market analysis" in Section 1.3.2 (a) of the 2020 URD is replaced in its entirety by the following:

Currently, there is no vaccine available to protect humans against Lyme disease, the most common tick-transmitted infection in the Northern hemisphere.

Valneva has the only Lyme disease vaccine program in clinical development today. Valneva is also aware of potential non-vaccine treatments to prevent Lyme disease that are in early clinical development.

According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans are diagnosed and treated for Lyme disease each year with at least a further 200,000 cases in Europe. Studies indicate that Lyme disease costs up to approximately $1.3 billion each year in direct medical costs in the United States alone.

The market for potential Lyme disease vaccine is estimated to reach a value of $1 billion globally by 2030[(1)].

[(1)] Lyme Disease, L.E.K interviews, research and analysis for traveler vaccine market.

(b) Chikungunya vaccine market

The sub-section “Chikungunya vaccines” appearing under “Vaccines market analysis” in Section 1.3.2 (a) of the 2020 URD is replaced in its entirety by the following:

Chikungunya is considered a major public health threat with no preventive vaccines or effective treatments available.

As of 2017, there had been more than one million reported cases in the Americas[(2)] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million[(3)]). The medical burden is expected to grow as the distribution of the chikungunya virus through primary mosquito vectors continues to spread further geographically.

Three other companies are conducting clinical trials to develop a vaccine against chikungunya, but Valneva is the only one to have announced positive topline Phase 3 data.

Valneva plans to take this vaccine to market with the prospect of leveraging major manufacturing and commercial synergies. While the Group will focus its efforts on the traveler vaccine market, it has also partnered with the Instituto Butantan in Brazil, in collaboration with CEPI, to meet the needs of Low and Middle-Income Countries.

The global market potential for chikungunya vaccines is estimated to reach up to $500 million annually by 2032[(4)].

[(2)] PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 51 (December 22, 2017).
[(3)] Cardona-Ospina et al, Trans R Soc Trip Med Hyg 2015.
[(4)] VacZine Analytics Chikungunya virus vaccines Global demand analysis, February 2020.

1.3.3. Research and development, patents, licenses

(a) Research and development

Section 1.3.3 (a) of the 2020 URD is replaced in its entirety by the following:

Valneva's vaccine candidates

Valneva's 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. Its lead program, VLA15, is a Phase 2 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease, under development in collaboration with Pfizer, and it is the only active vaccine candidate against Lyme disease currently in clinical development.

Valneva's clinical portfolio also includes VLA1553, the first vaccine candidate in Phase 3 clinical trials 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. The Company believes that VLA1553 is differentiated from other clinical stage chikungunya vaccine candidates since it is the only live-attenuated vaccine, which makes it particularly well-suited to target long-term protection with a single administration.

Valneva is 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 the only inactivated vaccine candidate for COVID-19 currently in clinical trials in Europe. After announcing positive initial results from its Phase 1/2 clinical trial in April 2021, Valneva launched a pivotal Phase 3 clinical trial of VLA2001 in April 2021 and announced positive initial results of this trial in October 2021.

Valneva's advanced clinical portfolio is supported by its significant development, manufacturing and commercial capabilities. The Company believes that its deep understanding of the regulatory requirements in various countries and strong connections to key stakeholders in select geographies such as the United States, Europe and Canada strengthen its expertise in product development and set it up for success. The Company also has a robust manufacturing and laboratory platform in place with facilities across Europe to meet its clinical and commercial needs, including three BioSafety Level 3 research and development facilities. Additionally, sales of its proprietary products, IXIARO® and DUKORAL®, as well as products that it commercializes on behalf of third parties have given Valneva the ability to reinvest in its research and development programs and to build the necessary infrastructure to support manufacturing of its product candidates.

Portfolio of products in clinical development

Valneva has 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 its portfolio are differentiated products that either target diseases currently lacking a preventative and effective therapeutic treatment option or that the Company believes may have meaningful therapeutic advantages relative to other existing vaccine and treatment options. The Company develops its vaccine candidates with the mechanism of action it believes will be most effective against the targeted disease. As a result of this strategy and the Company's ability to mobilize expertise to achieve rapid product candidate selection and development, Valneva believes that two of its vaccine candidates, VLA15 and VLA1553, are the leading candidates against their target diseases.

Lyme disease vaccine candidate, VLA15

Valneva has developed 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, Canada and Europe. More specifically, VLA15 generates antibodies targeting the OspA protein on the surface of Borrelia, killing the bacteria before it can be transmitted from an infected tick. VLA15 is the only vaccine Valneva announced a collaboration with Pfizer for late phase development and, if approved, commercialization of VLA15.

Valneva has reported positive initial results for 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 serotypes of Borrelia as detailed further below.

As part of the collaboration with Pfizer, Valneva announced in December 2020 that it had accelerated the pediatric development of VLA15 with an additional Phase 2 clinical trial, which began in March 2021. This study, which will

include approximately 600 subjects, will be the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old, and the Company expects to report initial data from the pediatric population in the second quarter of 2022. The trial will also include a reduced immunization schedule, at months zero and six compared to zero, two, and six, and will investigate a booster dose of VLA15 administered one year following the six-month dose. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of $10 million.

Together with Pfizer, Valneva expects that its pivotal, placebo-controlled field efficacy Phase 3 clinical trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the 2023 tick season. 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 180 µg (with alum) or placebo at the primary immunization schedule as determined by the 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.

Clinical readout of the initial results of the Phase 3 clinical trial, based on one tick season, is projected for the end of 2023. If the results from these clinical trials are positive, Valneva expects Pfizer to submit a biologics license application, or BLA, and marketing authorization application in the second half of 2024. The dosing of the first subject of the Phase 3 trial will trigger a $25 million milestone payment from Pfizer. VLA15 has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

Results of the VLA15 Clinical Trials

Phase 1 Clinical Trials and results

Valneva 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%) 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. Additional data about a booster dose follow in the Phase 2 discussion below.

Phase 2 Clinical Trials and results

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

VLA15-201 Clinical Trial and results

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

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

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

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

The 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

The second Phase 2 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, Valneva 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% (serotype 1) to 98.8% (serotype 2, serotype 4).

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 the Company's observations in VLA15-201. Furthermore, results did not indicate that prior exposure to Lyme (sero-positivity) has an impact on immunogenicity or safety, also consistent with the Company's observations in VLA15-201.

Unlike the Company's previous trials of VLA15, VLA15-202 also included a Serum Bactericidal Assay (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 the trial, the SBAs demonstrated functionality of antibodies against all OspA serotypes.

VLA15 was generally well tolerated across all doses and age groups tested in VLA15-202. The tolerability profile including fever rates was comparable to what has been observed in trials of other lipidated recombinant vaccines or lipid containing formulations. Overall, 232 of 246 participants (94.3%) reported any adverse event, solicited or unsolicited, up to Day 208. Rates of participants who experienced adverse events were similar in the VLA15 treatment groups: 96.9% (135 µg group) and 99% (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% in the placebo group. One participant in the 135 µg group experienced a severe unsolicited adverse event of ventricular extrasystoles 13 days after the second vaccination, which was assessed as possibly related to the study vaccine by the investigator. The participant had a history of benign premature ventricular contractions, was treated with propranolol and recovered after 39 days. Six unrelated serious adverse events were reported: 3.1% in the 135 µg group (invasive ductal breast carcinoma, prostate cancer, and vertigo) and 2% 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, the Company announced further positive results from VLA15-202. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all dose groups, remaining above baseline and confirming the need for a booster strategy. Participants who received a complete primary vaccination series with the 180 µg dose of VLA15 were invited to continue the trial in a booster extension phase and were randomized 2:1 to receive an additional 180 µg dose of VLA15 or placebo at Month 18. VLA15's acceptable safety profile was confirmed through one-month post-booster. No related serious adverse events were observed in any treatment group. Administration of the booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (GMT) in anti-OspA IgG antibody titers compared with titers observed after primary immunization. All participants seroconverted to anti-OspA IgG after the booster dose, meaning SCRs were 100% for all OspA serotypes. SCR was defined as the rate of subjects that changed from seronegative at baseline to seropositive. Additionally, subjects who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by SBA, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The trial is continuing to monitor persistence of antibody responses.

VLA15-221 Clinical Trial

On December 2, 2020, Valneva 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. Valneva announced completion of recruitment for VLA15-221 in July 2021, and the Company expects 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 burgdorferi* 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 Clinical Trials

Valneva is working closely with Pfizer on a large-scale efficacy trial which will be conducted in the United States, Canada and countries in the European Union. The pivotal field efficacy trial will evaluate the ability of a VLA15 vaccine regimen to prevent Lyme disease compared to a placebo regimen. Valneva anticipates that this trial will start in the third quarter of 2022, subject to feedback from regulatory authorities. Valneva expects to report initial data, based on the first tick season of the trial, by the end of 2023. The Company is targeting a BLA/MAA submission in the second half of 2024.

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 the 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.

About Lyme Disease

Lyme disease is a systemic infection caused by Borrelia bacteria transmitted to humans by infected Ixodes ticks[(1)]. It is considered the most common vector borne illness in the Northern Hemisphere. According to the US Centers for Disease Control and Prevention, approximately 476,000 Americans are diagnosed and treated for Lyme disease each year [(2)] with at least a further 200,000 cases in Europe[(3)].

Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called Erythema migrans or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[(4)].

Currently no Lyme disease vaccine is available to protect humans from this devastating illness.

(1) Stanek et al. 2012, The Lancet 379: 461-473.
(2) As estimated by the CDC, https://www.cdc.gov/lyme/stats/humancases.html
(3) Estimate based on available national data. Largely underestimated if WHO report on Lyme disease in Europe is taken into account, due to the fact that case reporting is very irregular in Europe and many Lyme infections are not diagnosed; ECDC tick-borne-diseases-meeting-report.
(4) New Scientist, Lyme disease is set to explode and we still don't have a vaccine; 29 March 2017.

Chikungunya vaccine candidate, VLA1553

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 VLA1553 is the only chikungunya vaccine candidate that has reported positive topline Phase 3 data. Chikungunya is considered to be a major public health threat, and the global market for a chikungunya vaccine is estimated to exceed $500 million annually by 2032.

VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease. VLA1553 has been designed by deleting a part of the chikungunya virus genome. As a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection which differentiates it when compared to other chikungunya assets that are being evaluated in clinical trials.

In the Phase 1 clinical trial, Valneva 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 Valneva was able to advance directly into Phase 3 clinical development and is 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. The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher. Valneva has also received confirmation for its proposal to seek licensure of VLA1553 under the accelerated approval pathway from the FDA. Under this pathway, Valneva plans to seek licensure of VLA 1553 based on a surrogate of protection agreed with the FDA and the EMA. The surrogate of protection is an immune response that predicts protection against clinical endpoints and is reasonably likely to predict protection from chikungunya infection. This eliminates the need to execute a time-intensive and costly field trial where a group of patients receiving a placebo is compared to groups of patients receiving VLA1553. The rates of infection are observed and compared at various points in time across each of the various trial groups.

Valneva reported positive topline results for its Phase 3 clinical trial of VLA1553 in August 2021. These data indicated a seroprotection rate of 98.5% compared to the 70% threshold surrogate of protection (for non-acceptance) agreed with the FDA and the EMA. Valneva expects to report final trial results in early 2022. If approved, the Company intends to market VLA1553 as a traveler vaccine in North America and Europe.

In May 2020, Valneva partnered with the Instituto Butantan in Brazil to develop, manufacture and market VLA1553 in low and middle income countries. As part of this collaboration, Valneva plans 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, and will be sponsored by Instituto Butantan. Valneva has been awarded up to $23.4 million in funding from CEPI in relation to this partnership.

Preclinical study

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

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

Phase 1 Clinical Trial

Valneva also 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, the Company examined three doses of VLA1553: a low dose having a viral titer of 3.2 x 103, a medium dose of 3.2 x 104, and a high dose of 3.2 x 105. Participants in the low and medium dose cohorts and half of the patients in the high-dose cohort received a single dose of VLA1553 on Day 0 through intramuscular injection and a re-vaccination at 12 months. Half of the patients in the high-dose cohort received a re-vaccination at six months instead of 12 months.

The primary endpoint of the Phase 1 trial was evaluation of safety measures including frequency and severity of injection site and systemic reactions. Chikungunya virus neutralizing antibodies were observed in 100% of patients for 12 months at all three of the doses evaluated. A single vaccination was sufficient to induce sustaining high-titer neutralizing antibodies at twelve months post vaccination. Individuals that received a single high dose of VLA1553 did not exhibit an increase in antibody titers following subsequent re-vaccination at month six. Similarly, none of the dose levels that were re-vaccinated at month 12 exhibited an increase in antibody titers after re-vaccination. This result suggests that a single dose of VLA1553 could offer sufficient protection with no additional booster required

The titer of these neutralizing antibodies was assessed by determining how far the antibodies in the plasma could be diluted and still reduce *in vitro* viral infection by 50%, a commonly used parameter referred to as the neutralization titer or NT50. Seroconversion was defined as having an NT50 of 20 or greater, meaning that dilution by 20-fold or greater still resulted in inhibiting the virus-induced cytopathic effects by at least half. Valneva 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. Plasma of the trial volunteers was screened for viremia, which peaked at day three in all groups and was lower in the low-dose and medium-dose groups. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

The majority of adverse events across the dose group were assessed as mild or moderate and were reported after the single vaccination. No adverse event of special interest, meaning adverse events resembling a chikungunya like infection, and no vaccine-related SAEs were reported. Injection site reactogenicity was low, with less than 7% of individuals in the high-dose group reporting any local adverse event, all of which were mild in severity. Systemic adverse events were predominantly headache (32.5%), fever (26.7%) and fatigue (24.2%), followed by muscle pain (20%) 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.

The Company received agreement from the FDA and the EMA on its proposal to utilize the accelerated approval pathway, which will enable Valneva to potentially submit a BLA for VLA1553 based on clinical trial data on an immunological surrogate of protection, rather than observing natural rates of infection between trial participants receiving VLA1553 and the placebo. This eliminates the need to execute a time-intensive and costly field trial where a group of patients receiving a placebo is compared to groups of patients receiving VLA1553 and rates of infection are observed and compared at various points in time across each of the various trial groups. As part of the accelerated approval pathway, the Company will be required to conduct a confirmatory trial.

Phase 3 Clinical Trials

VLA1553-301 Clinical Trial

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

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 injection (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 agreed with the FDA. The seroprotective titer was agreed with the FDA to serve as a surrogate for 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 observed in the Phase 1 clinical trial.

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. Valneva expects to report final trial results in early 2022.

VLA1553-302 Clinical Trial

Valneva 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. Valneva 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.

Clinical Trial VLA1553-303

In April 2021, Valneva 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.

About chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in 72-92% of humans after 4 to 7 days following the mosquito bite.

While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash. 4.1%-78.6% of infections develop into chronic arthralgia (> 3 months).

Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating.

The highest risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia. As of September 2020, there have been more than 3 million reported cases in the Americas and the economic impact is considered to be significant (e.g. Colombia outbreak 2014: $73.6 million). The medical and economic burden is expected to grow as the primary mosquito vectors continue to further spread geographically.

There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat. It is estimated that the global market for a chikungunya vaccine, including travel and endemic markets, will exceed $500 million annually by 2032.

COVID-19 vaccine candidate, VLA2001

VLA2001 is a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe.

Valneva reported positive initial results for the Phase 1/2 clinical trial of VLA2001 in April 2021 and reported positive initial data from its pivotal, comparative immunogenicity Phase 3 clinical trial in October 2021. The results from this Phase 3 trial, Cov-Compare, demonstrated superiority against the comparator vaccine, AstraZeneca's AZD1222, in terms of geometric mean titer for neutralization antibodies as well as non-inferiority in terms of seroconversion rates at two weeks after the second vaccination. VLA2001 was generally well tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222. Valneva commenced its rolling submission and review process with the UK's Medicines & Healthcare products Regulatory Agency, or MHRA, in August 2021 and expects to incorporate the positive Phase 3 topline results in November 2021. Valneva believes it could receive MHRA approval by the end of 2021. Valneva is 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.

VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®. Valneva has commenced production in parallel to the ongoing clinical trial in order to optimize the timeline for potential deliveries of the vaccine.

Although SARS-CoV-2 vaccines are already approved, given the potential benefits often associated with inactivated whole-virus vaccines, Valneva believes its vaccine could be added to the current and future SARS-CoV-2 vaccine portfolio to meet the global need for billions of doses of the vaccine to prevent further spread of the virus.

Although vaccines against SARS-CoV-2 have already been approved, given the potential advantages often associated with inactivated whole virus vaccines, Valneva believes its 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. Additionally, the Company believes that VLA2001, if approved, could offer clear benefits compared to other vaccines that have obtained initial regulatory approvals, 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, Valneva believes its flexible approach to the clinical and manufacturing development of VLA2001 will facilitate its ability to meet the needs of future customers.

Pre-clinical Trials and Results

In pre-clinical experiments, Valneva evaluated the immunogenicity of VLA2001 using female BALB/c-strain mice, which were immunized 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.

Valneva 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 and 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), Valneva observed that the addition of CpG 1018 led to a significant shift of the immune response towards a Th1 response (ratio >1), whereas VLA 2001 formulated with alum only induced a Th2-skewed immune response.

Immunogenicity and efficacy of VLA2001 in non-human primates

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

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

Peripheral blood mononuclear cells, or PBMCs, were isolated from each animal 14 days after the second vaccination and analyzed by IFNγ ELISpot. PBMCs were restimulated with peptide pools for the spike (S) protein and the nucleoprotein (N). Both the medium and high dose of the vaccine elicited cellular immune responses.

The PBMCs were further characterized using intracellular cytokine staining to assess the Th1/Th2 bias of the response. Cells were restimulated and stained with antibodies specific for different cellular markers (e.g. CD4) and cytokines. For this analysis, the cytokines IFNγ, TNFα, and IL-2 were considered representative of a Th1 response and IL-13 of a Th2 response. Whereas cells expressing IFNγ, TNFα, or IL-2 were abundant, cells expressing IL-13 were practically not detectable. Thus, consistent with the Company's observations in mice, the non-human primate response to VLA2001 vaccination was heavily Th1-biased.

Following challenge, tracheal and nasopharyngeal swabs were taken from the animals to monitor the presence of viral subgenomic RNA using RT-qPCR. While several of the control animals showed signs of viral replication, i.e. presence of viral RNA, none of the vaccinated animals had detectable viral RNA at any time point.

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

Passive transfer data for VLA2001

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

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

VLA2001 Phase 1/2 Clinical Trial and Results

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

The trial design consists of a randomized, dose-escalation, multi-center study with three dose groups (low, medium and high dose), 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 positive data from Part A.

The primary safety endpoint of the study was the frequency and severity of solicited adverse events (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 study 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 study 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 Data Safety and Monitoring Board, or 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 study. Subjects were observed for 30 minutes post-vaccination on Day 1. An unscheduled safety telephone call was performed in case a Grade 3 adverse event or serious adverse event 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 study 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, Geometric Mean Fold Rise 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 and N protein detected in 75.6 %, 35.6% and 48.9% of study participants, respectively.

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

In Part B of the study, 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. Valneva announced in September 2021 that it has 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 Clinical Trial (Cov-Compare)

Trial Design

Based on the initial data from VLA2001-201, in April 2021, the Company 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 the Company reported initial 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 (SCR above 95% in both treatment groups) at two weeks after the second vaccination (i.e., Day 43) in adults aged 30 years and older. It will also evaluate the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults aged 18 years and older. The trial is being conducted at approximately 26 sites in the UK. 2,972 participants 30 years of age and older (through 71 years in the enrolled population) were randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=1,977) or AZD1222 (n=995) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from 990 participants (VLA2001: n=492, AZD1222: n=498) who tested sero-negative for SARS-CoV-2 at screening were analyzed. 1,040 participants that were under 30 years of age were placed in a non-randomized treatment group and received VLA2001 28 days apart.

Initial Results

In October 2021, Valneva announced positive Phase 3 initial 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).

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 fewer 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, Valneva 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. The Company 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, Valneva 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. Valneva announced the completion of recruitment for Cohort 1 in September 2021 and expects to announce topline data from this cohort in early in the first quarter of 2022.

Additional Planned Clinical Trials

The Company is in the planning stage for additional clinical trials of VLA2001.

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

The Company is also planning to continue its 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, Valneva is 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.

The Company may also consider developing new versions of VLA2001 to treat variants.

About the new coronavirus SARS-CoV-2 and COVID-19

SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of the respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. Since this outbreak was first reported, the virus has caused over 2 million reported deaths globally. It has been declared a pandemic by the World Health Organization (WHO).

Zika virus vaccine candidate, VLA1601 (program on hold)

Valneva has developed VLA1601, a highly purified inactivated vaccine candidate produced on the technology platform developed for IXIARO®, its approved Japanese encephalitis vaccine.

Valneva has completed the Phase 1 clinical trial, and the results obtained will allow Valneva to design a Phase 2 trial if it decides to pursue this program.

Valneva currently has this program on hold, as cases of Zika have significantly declined since 2016. The Group has chosen to prioritize its development programs to focus on viruses that are currently a greater health crisis, but may choose to reactivate this program in the future if warranted.

Clostridium difficile vaccine candidate, VLA84 (program on hold)

Valneva has developed VLA84, a vaccine candidate against *Clostridium difficile*, a leading cause of life-threatening, healthcare-associated infections worldwide. The Group has completed Phase 2 development of VLA84 and could advance into Phase 3 if it chooses to reactivate this program and find a suitable partner.

Other research and development assets

In addition to its clinical-stage assets, Valneva is advancing a series of pre-clinical vaccine candidates against disease targets that reflect its strategy of providing prophylactic solutions to significant diseases that lack a preventative and effective therapeutic treatment option.

Human MetaPneumoVirus (hMPV) vaccine candidate VLA1554

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.

Valneva is currently in pre-clinical proof of concept studies and expects first readouts in the second half of 2021. Valneva is also considering developing a potential combination vaccine that would protect against both hMPV and respiratory syncytial virus, or RSV. Despite the high frequency of pneumoviral infections and over 50 years of research in this field, no licensed vaccine against hMPV or RSV is currently available. This lack of effective vaccine candidates against hMPV can be explained by the recent discovery of the virus, but also by the lack of a successful vaccine against closely related RSV that could serve as a base for vaccine design.

Epstein-Barr virus (EBV) Program

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

Capitalized research and development costs

Please refer to the Group's consolidated financial statements for the year ended December 31, 2020[(1)], as well as to Section 1.3.4 of this Amendment 1.

(1) See Annex 12, within Section 4.1.5 of the 2020 URD.

(b) Intellectual Property

Section 1.3.3 (b) of the 2020 URD is replaced in its entirety by the following:

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

Valneva manages its intellectual property by :

- seeking protection for its 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 Valneva might have business interests;
- defending, and if needed, enforcing its 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 its products, product candidates and technologies, in those jurisdictions where Valneva has business interests.

Patents and patent applications

The Group considers that the protection of its technologies and products by patents and patent applications is essential to the success of its business.

As of September 30, 2021, Valneva 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 Valneva seeks 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. Valneva conducts ongoing checks to protect its inventions and to act against any infringement of its patents.

IXIARO®

In regards to its Japanese encephalitis marketed vaccine, IXIARO®, as of September 30, 2021, Valneva owns 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, Valneva was able to defend its claims to the method of preparing said composition as granted. Valneva 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 granted, and patents in this family shall 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.

Valneva also owns a pending PCT application with claims covering the manufacturing processes of IXIARO®. Patent applications claiming the benefit of this PCT application, if granted, shall 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 its DUKORAL® product, as of September 30, 2021, Valneva owns 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 granted, shall 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.

Lyme disease vaccine candidate

In regards to its *Borrelia* vaccine candidate VLA15 which is currently licensed to Pfizer, as of September 30, 2021, Valneva owns 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. Valneva further owns a second patent family which includes two issued U.S. patents and one granted European patent 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.

Valneva also owns 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. Patents, if granted, in this family shall 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, Valneva also owns three International patent applications with claims directed to compositions comprising OspA fusion proteins including uses thereof and to improved methods for producing a vaccine. Patent claiming priority to these patent applications, if granted, shall 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.

Chikungunya vaccine candidate

In regards to its chikungunya vaccine candidate, VLA1553, as of September 30, 2021, Valneva owns 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. Patents, if granted, and patents in this family shall 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.

Valneva also owns 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. Patents, if granted, in this family shall 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, Valneva also owns two pending PCT applications with claims covering formulations and manufacturing processes of VLA1553. Patent claiming the benefit of these PCT applications, if granted, shall 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.

SARS-CoV-2 vaccine candidate

In regards to its COVID-19, SARS-CoV-2 vaccine candidate, VLA2001, as of September 30, 2021, Valneva owns one International patent applications and seven foreign patent applications with claims relating to the antigen and processes preparing the antigen of VLA2001. Furthermore, Valneva co-owns together with Dynavax two International patent and three national patent applications with claims related to the 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.

Clostridium difficile vaccine candidate

In regards to its C. difficile candidate VLA84, as of September 30, 2021, Valneva owns a patent family with three granted U.S. patents with claims covering the composition of matter of VLA84 and methods of use thereof, two pending U.S. patent applications, 9 granted foreign patents in such jurisdictions as Australia, China, and Japan, and 24 pending foreign patent applications. This patent family also includes a granted European patent validated in over 35 countries that has been opposed and a second European Patent that is still in opposition period. The European Patent Office maintained its European patent in amended form, which still covers VLA84. Valneva and the opposer each filed an appeal against this decision, and the appeal procedure is currently pending. Patents, if granted, and patents in this family shall 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.

Valneva also filed an opposition in a European patent owned by a third party that has claims that might cover its *C. difficile* vaccine VLA84 candidate. The European Patent Office recently revoked this patent and an appeal has been filed and is currently pending. A further opposition was also recently filed by us against a European patent derived from the revoked patent that has claims that might cover its C. difficile vaccine VLA84 candidate and is currently pending.

Zika vaccine candidate

In regards to its Zika vaccine candidate VLA1601, as of September 30, 2021, Valneva owns 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. Patents, if granted, and patents in this family shall 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. Valneva has recently received a third party observation against the European patent application of the above case.

EB66® cell platform

Valneva obtained several patents covering (i) the establishment of embryonic derived cell lines, (ii) their use for the production of biologicals including their use in virus replication, and (iii) in some jurisdiction the cell line *per se*.

Adjuvant IC31®

Valneva's IC31® technologies have been protected by a number of Intercell proprietary patents and patent applications. A certain number of patents covering the use of the IC31® technology in various aspects are granted in several territories, including Europe and the United States.

Other protection mechanisms

Valneva's core technologies, products and many of its projects for the development of products candidates depend upon the knowledge, experience and skills of its scientific and technical personnel. In order to protect its trade secrets, proprietary know-how and technologies, Valneva generally requires all employees, contractors, advisors and collaborators to enter into confidentiality agreements. These agreements prohibit the disclosure of its 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, Valneva may still continue to reap commercial benefits from its product manufacturing secrets, even when the patents for such product have expired.

Trademarks

The trademark rights Valneva holds 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. Valneva holds the title to the names of the products used and those associated therewith.

Valneva's 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. Its key products, technologies and product candidates, namely IXIARO®, JESPECT®, DUKORAL®, EB66® and IC31®, and the number of trademarks related to these products held by the Group on September 30, 2021 are shown in the table below.

Trademarks - Number of registrations

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

Valneva also holds registrations for its different entities names, as well as the slogan and logo which constitute its graphic charter. Valneva defends its trademark rights by filling a notice of opposition against applications for identical or similar trademarks, and initiating, if necessary, legal actions to have its rights recognized.

VALNEVA trademark

Valneva SE and the company KRKA, tovarna zdravil, d.d., Novo Mesto (KRKA) signed a co-existence agreement on January 20, 2014, with respect to KRKA's earlier trademark DALNEVA covering goods of Class 5. Valneva 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, the Company also filed a notice of opposition before the European Union Intellectual Property Office (EUIPO) against the trademark application VALNECOR (application No. 13.519889) of the Company Vetpharma Animal Health SL, 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 favor of Valneva SE 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 VALNEVA, a French Simplified Joint Stock company (SASU), and Valneva SE, in order to:

- acknowledge the Company's prior rights; and
- record VALNEVA SASU's undertaking never to contest or challenge the Company name and the trademarks Valneva – registered or filed – for any goods and services.

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

Valneva and Boehringer Ingelheim International GmbH also signed a prior rights agreement on July 28, 2016. In this agreement, the Company undertakes 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"). The Company also undertakes 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. The Company filed a notice of opposition before EUIPO against the trademark application VALNOBI No.17579525 made in Class 5 in the name of Bayer AG. On February 4, 2019, the Opposition Division of the EUIPO decided in favor of Valneva SE and upheld the opposition (No. B 3 047 941) for all the contested goods in Class 5.

Valneva filed notices of opposition against the EU trademark application VALNEVA No. 017895207 and the Austrian trademark application VALNEVA 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

On September 30, 2021, the Group held 68 domain names (reserved or in the process of being reserved).

(c) Dependence of the Group on patents and licenses, on industrial, commercial or financial contracts, or on new manufacturing processes

Section 1.3.3 (c) of the 2020 URD is updated to include the information included in Section 1.5 of this Amendment 1.

1.3.4. Investments

(a) Research and development expenses

Section 1.3.4 (a) of the 2020 URD is replaced in its entirety by the following:

Research and development expenses include the costs associated with R&D conducted by the Group or for the Group by outside contractors, research partners or clinical study partners, and expenses associated with R&D carried out by Valneva in connection with strategic collaboration and licensing agreements. 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 process. By contrast, pre-clinical R&D expenses primarily during the approval depend on the number of scientific staff employed.

The following table sets forth the research and development expenses for Valneva's existing products and major product candidates, for the six months ended June 30, 2020 and 2021[(1)]:

(€ in thousands)	Six Months ended June 30,		Year ended December 31,	
	2021	**2020**	**2020**	**2019**
Lyme disease (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 programs	(2,451)	(1,615)	(3,760)	(2,799)
Total	**(78,737)**	**(33,081)**	**(84,454)**	**(38,022)**

(1) Source: Valneva internal information.

(b) Additions to intangible assets

Section 1.3.4 (b) of the 2020 URD is supplemented by the information contained in Note 8 to the condensed consolidated interim financial statements for the six months ended June 30, 2021, included within the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website and incorporated by reference in this Amendment 1[ix].

[ix] See Section 3 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/

1.4. Analysis and comments on the activities carried out during the first half of 2021

1.4.1. Business development, results and financial position of the Group

Section 1.4.1 (a) of the 2020 URD is supplemented with the financial information for the first half of 2021, set out in Section 1.3 of the Group's Half-Year Financial Report published on August 10, 2021 on Valneva's website and incorporated by reference in this Amendment 1[x].

[x] https://valneva.com/investors/financial-reports/

1.4.2. Major agreements and partnerships

(a) US Department of Defense Contracts

Section 1.4.2 (a) of the 2020 URD is replaced in its entirety by the following:

In January 2019, the Defense Logistics Agency (DLA), part of the U.S. Department of Defense, awarded Valneva USA, Inc. a contract for the supply of its Japanese encephalitis vaccine, IXIARO®. The agreement consisted of one base year for the delivery of 20,000 doses worth $59 million, and one option to purchase an additional 80,000 doses to bring the total value of the contract to $70 million. In January 2020, DLA exercised this option.

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 base year had a minimum value of approximately $53 million for 370,000 doses, and the first option year, which DLA exercised in September 2021, 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 agreements, this contract can be terminated by DLA for convenience at any time.

Valneva 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.

(b) UK Supply Agreement

Section 1.4.2 (c) of the 2020 URD is replaced in its entirety by the following:

In September 2020, Valneva SE and Valneva Austria GmbH entered into a supply agreement (the UK Supply Agreement) with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom (the UK Authority) pursuant to which Valneva is obligated to develop, manufacture and supply SARS-CoV-2 vaccines to the UK Authority in the United Kingdom of Great Britain and Northern Ireland (the UK) including an obligation for Valneva to upgrade its manufacturing facilities in Scotland. As of December 31, 2020, Valneva had 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, Valneva is 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. The UK Authority was granted priority supply over any other third party orders for the first 60 million doses, and equal priority supply for the options, In February 2021, Valneva announced that the UK Authority exercised its option to order 40 million doses for delivery in 2022. As of December 31, 2020, Valneva had received advance payments to fund certain manufacturing-related expenses and for the first payment installment in connection with the UK Supply Agreement. The UK Supply Agreement required the UK Authority to pay Valneva advance payments to fund certain manufacturing-related expenses over the life of the project, subject to Valneva's 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, Valneva is 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, Valneva received notice of the UK Authority's decision to terminate the UK Supply Agreement. Valneva had not received any indication from the UK Authority, prior to this time, of the UK Authority's intention to serve the notice. In the termination notice, the UK Authority purported to terminate the contract on one of two different bases, each with different potential or actual consequences for Valneva.

First, the UK Authority purported to terminate the supply contract on the common law (non-contractual) basis that Valneva would allegedly, at some time in the future, breach its obligations regarding the delivery schedule under

the UK Supply Contract. Valneva strongly disputes the UK Authority's purported termination based on an alleged anticipated breach of the UK Supply Agreement and does not consider such termination to be valid. However, if the UK Authority were to successfully bring proceedings for damages against Valneva in respect of the alleged anticipatory breach, it could be argued that the applicable contractual cap on Valneva's liability under the UK Supply Agreement could be as high as an amount equivalent to the sums paid to Valneva by the UK Authority prior to termination. 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, Valneva believes that it is very unlikely that any such claim by the UK Authority will be successful. In any event, the UK Authority has not notified Valneva of any specific claim for damages in connection with the purported termination for alleged anticipatory breach nor has it indicated the amount of any possible claim.

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. Valneva has 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, Valneva shall not be obliged to refund or repay any amount paid by the UK Authority. A royalty on sales and certain other obligations, as described below, survive termination of the UK Supply Agreement.

Valneva was, and still is, completing the construction of its new manufacturing facility, Almeida, at its site in Livingston, Scotland. Under the terms of the UK Supply Agreement, this project was largely funded by advance payments made by the UK Authority pursuant to the UK Supply Agreement. Unless a satisfactory resolution can be secured, Valneva may not be able to complete this construction.

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 vaccination 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 Valneva is discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and Valneva's future results of operations. The impact is uncertain as of the date of issuance of Valneva'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 Valneva's business plan resulting from the termination of the UK Supply Agreement may have an impact on Valneva'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 believes that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay Valneva certain amounts in respect of commitments that Valneva 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 Valneva's suppliers.

Valneva is currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If, before December 31, 2022, Valneva were to cease to use its COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, which were acquired with funds advanced by the UK Authority, Valneva may have certain obligations to the UK Authority, such as a partial return 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 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, Valneva is required to pay the UK Authority a royalty in respect of sales of Valneva's UK-manufactured vaccine to non-UK customers. This requirement survives 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.

1.4.3. Analysis of 2021 half-year results

Section 1.4.3 of the 2020 URD is supplemented with the following information, presenting a comparative analysis (June 30, 2020 – June 30, 2021) of the consolidated revenues as well as the consolidated income statement, and a description of the changes to the Group's segment reporting from January 1, 2021:

(a) Comparison of consolidated revenues for the six months ended June 30, 2020 and 2021

Revenues

The following table presents the major components of Valneva's revenues for the six months ended June 30, 2020 and 2021:

	Six months ended June 30,		Change from prior period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Product sales	31,762	40,942	(9,180)	(22.4)
Revenues from collaborations, licensing and services	15,740	6,965	8,775	(126.0)
TOTAL REVENUE	**47,502**	**47,907**	**(405)**	**(0.8)**

Between June 30, 2020 and June 30, 2021: 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 the Group's 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 million for the six months ended June 30, 2020. This increase was attributable to higher revenues related to the progress of the Group's collaboration with Pfizer, incremental revenues related to the Group's funding agreement with Instituto Butantan signed in January 2021 and higher revenues generated in the clinical trial materials manufacturing unit in Sweden.

Revenues by business segment

The following table presents the revenues by business segment for the six months ended June 30, 2020 and 2021:

	Six months ended June 30,		Change from prior period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Commercialized vaccines	31,772	40,942	(9,170)	(22.4)
COVID	—	—	—	—
Vaccine candidates	1,849	1,333	516	38.7
Technologies and services	13,880	5,632	8,248	146.4
TOTAL REVENUE	**47,502**	**47,907**	**(405)**	**(0,8)**

Product sales

In the six months ended June 30, 2021, IXIARO® product sales were €25.4 million, a decrease of €3 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 the Group's 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 the Group's 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 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 the Group's distribution agreement with Bavarian Nordic, which began in 2021.

The following table shows product sales by geographic area for the six months ended June 30, 2020 and 2021 and is based on the final location where Valneva's distribution partner sells the product or where the customer or partner is located:

In thousands of euros	Six months ended June 30,	
	2021	2020
United States (military)	22,289	16,748
United States (non-military)	1,300	2,319
Canada	2,006	8,126
Germany	—	4,441
Nordics	897	2,691
Austria	3,006	324
United Kingdom	1,067	1,653
Other Europe	1,181	1,539
Rest of world	15	3,099
Total product sales	**31,762**	**40,942**

Between June 30, 2020 and June 30, 2021: 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 million in the six months ended June 30, 2021, primarily as a result of decreased sales in DUKORAL® due to the pandemic impact.

Revenues from collaborations, licenses and services

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

The following table shows the breakdown by business segment of the Group's revenue from collaborations, licensing and services for the six months ended June 30, 2020 and 2021:

	Six months ended June 30,		Change from prior period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Commercialized vaccines	10	—	10	—
COVID	—	—	—	—
Vaccine candidates	1,849	1,333	516	38.7
Technologies and services	13,880	5,632	8,248	146.4
TOTAL REVENUES FROM COLLABORATIONS, LICENSING AND SERVICES	**15,740**	**6,965**	**8,775**	**126.0**

(b) Comparison of consolidated income statement for the six months ended June 30, 2020 and 2021

	Six months ended June 30,			
	2021		2020	
	In thousands of euros	% of revenues	In thousands of euros	% of revenues
Product sales	31,762	66.9	40,942	85.5
Revenues from collaborations, licensing and services	15,740	33.1	6,965	14.5
Revenues	**47,502**	**100.0**	**47,907**	**100.0**
Cost of goods and services	(34,778)	(73.2)	(22,546)	(47.1)
Research and development expenses	(78,737)	(165.8)	(33,081)	(69.1)
Marketing and distribution expenses	(9,643)	(20.3)	(10,046)	(21.0)
General and administrative expenses	(20,904)	(44.0)	(10,615)	(22.2)
Other income and expenses, net	10,389	21.9	6,453	13.5
Operating profit/(loss)	**(86,172)**	**(181.4)**	**(21,928)**	**(45.8)**
Finance income	8,962	18.9	549	1.1
Finance expense	(8,431)	(17.7)	(6,109)	(12.8)
Result from investments in associates	(90)	(0.2)	90	0.2
PROFIT/(LOSS) BEFORE INCOME TAX	**(85,730)**	**(180.5)**	**(27,398)**	**(57.2)**
Income tax	(668)	(1.4)	1,759	3.7
PROFIT/(LOSS) FOR THE PERIOD	**(86,399)**	**(181.9)**	**(25,639)**	**(53.5)**

Cost of goods and services (COGS)

Between June 30, 2020 and June 30, 2021: 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.

Research and development expenses

Research and development expenses increased by €45.7 million, or 138%, 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 the Group's COVID-19 vaccine candidate, VLA2001, as well as Phase 3 clinical study costs for the Group's 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 million external research and development services, including costs for clinical studies and external manufacturing, and €1.9 million of material consumptions.

The following table sets forth the Group's research and development expenses by product or development program for the six months ended June 30, 2020 and 2021:

	Six months ended June 30,		Change from prior period	
(In thousands of euros)	**2021**	2020	In thousands of euros	In %
Lyme (VLA15)	(2,079)	(17,384)	15,305	(88.0)
Chikungunya (VLA1553)	(26,217)	(10,223)	(15,994)	156.5
COVID-19 (VLA2001)	(46,105)	(1,548)	(44,557)	2878.4
hMPV	(1,007)	(798)	(209)	26.2
IXIARO®	(485)	(790)	305	(38.6)
DUKORAL®	(393)	(724)	331	(45.7)
Other research projects	(2,451)	(1,615)	(836)	51.8
TOTAL RESEARCH AND DEVELOPMENT EXPENSES	**(78,737)**	**(33,081)**	**(45,656)**	**138.0**

VLA15. The Group's research and development expenses related to its Lyme vaccine candidate program decreased by €15.3 million, or 88%, 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 the VLA15-201/202 studies.

VLA1553. The Group's research and development expenses related to its chikungunya vaccine candidate program increased by €16 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 this program into the Phase 3 clinical trial.

VLA2001. The Group's research and development expenses related to its 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.

The Group's research and development expenses related to its commercial products and the rest of its 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.

Marketing and distribution costs

Between June 30, 2020 and June 30, 2021: Marketing and distribution expenses decreased by €0.4 million, or 4%, to €9.6 million in the six months ended June 30, 2021 from €10 million in the six months ended June 30, 2020. Marketing and distribution expenses comprised 7.2% of the Group's total operating income (expenses) for the six months ended June 30, 2021, compared to 14.4% of its 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 the Group's direct markets due to reduced sales activity as a result of the COVID-19 pandemic. Marketing and distribution expenses in the first half of 2021 notably included €2 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first half of 2020).

Marketing and distribution expenses in the six months ended June 30, 2021 were a result of continued investments in the Group's key markets as well as launch preparation costs of the chikungunya vaccine candidate and COVID-19 candidate. 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.

General and administrative expenses

Between June 30, 2020 and June 30, 2021: 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 the Group's total operating income (expenses) for the six months ended June 30, 2021 compared to 15.2% of the Group's 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 the Group's 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.

Expenses by nature

Between June 30, 2020 and June 30, 2021: 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.

The following table summarizes the Group's cost of goods and services, research and development expenses, marketing and distribution expenses as well as general and administrative expenses by nature of cost:

	For the six months ended June 30		Change from prior period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Employee benefit expense other than share-based compensation (1)	(35,955)	(26,376)	(9,579)	36.3
Share-based compensation expense	(3,653)	(2,631)	(1,022)	38.8
Consulting and other purchased services	(76,213)	(27,860)	(48,353)	173.6
Raw materials and consumables used	(5,371)	(5,494)	123	(2.2)
Cost of services and change in inventory	(2,940)	2,257	(5,197)	(230.3)
Depreciation and amortization & impairment	(6,101)	(4,687)	(1,414)	(30.2)
Building and energy costs	(5,286)	(3,732)	(1,554)	41.6
License fees and royalties	(2,490)	(2,379)	(111)	4.7
Supply, office and IT costs	(3,308)	(1,527)	(1,781)	116.6
Advertising costs	(1,318)	(1,810)	492	(27.2)
Warehousing and distribution costs	(745)	(1,219)	474	(38.9)
Travel and transportation costs	(126)	(419)	293	(69.9)
Other expenses	(554)	(410)	(144)	35.1
OPERATING EXPENSES	**(144,062)**	**(76,288)**	**(67,774)**	**88.1**

(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).

Other income (expenses)

Between June 30, 2020 and June 30, 2021: Other operating income and expenses increased by €3.9 million, or 61%, 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 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.

The table below summarizes the other operating income (expenses) for the six months ended June 30, 2020 and 2021:

	Six months ended June 30		Change from prior period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Research and development tax credit	9,635	3,889	5,746	147.8
Grant income	1,145	2,995	(1,850)	(61.8)
Profit/(loss) on disposal of fixed assets and intangible assets, net	(21)	(7)	(14)	200.0
Profit/(loss) from revaluation of lease agreements	–	–	–	–
Taxes, duties, fees, charges, other than income tax	(133)	(116)	(17)	14.7
Other income/(expenses)	(237)	(308)	(71)	(23.1)
OTHER INCOME AND EXPENSES, NET	**10,389**	**6,453**	**3,936**	**(61.0)**

Financial income/(expense), net

Between June 30, 2020 and June 30, 2021: 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.

The following table summarizes the Group's financial income (expense), net for the six months ended June 30, 2020 and 2021:

	Six months ended June 30		Change from previous period	
(In thousands of euros)	2021	2020	In thousands of euros	In %
Financial income				
Interest income from other parties	228	74	154	208.1
Fair value gains on derivative financial instruments	—	475	(475)	(100.0)
Foreign exchange gains, net	8,735	—	8735	—
	8,962	**549**	**8,413**	**1,532.4**
Financial expense				
Interest expenses on loans	(3,820)	(2,961)	(859)	29.0
Interest expense on refund liabilities	(4,104)	(486)	(3,618)	744.4
Interest expense on lease liabilities	(419)	(447)	28	(6.3)
Other interest expense	(88)	(16)	(72)	450.0
Foreign exchange losses, net	—	(2,200)	2,200	(100.0)
Fair value losses on derivative financial instruments	—	—	—	—
	(8,431)	**(6,109)**	**(2,322)**	**38.0**
FINANCIAL INCOME/EXPENSES, NET	**532**	**(5,560)**	**6,092**	**(109.6)**

(c) Segment information

Effective 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.

The following tables present segment reporting information for the years 2020 and 2019 as if this change in segment composition had been effective from January 1, 2019:

Income statement by segment for the year ended December 31, 2019 (assuming new segment composition applied from January 1, 2019)

In thousands of euros	Commer-cialized 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)**

[(1)] For more information, see Note 5 to the Group's consolidated financial statements for the year ended December 31, 2020 in Section 4.1.5 of the 2020 URD.

Income statement by segment for the year ended December 31, 2020 (assuming new segment composition applied from January 1, 2019)

In thousands of euros	Commer-cialized vaccines	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)**

1.4.4. Group's business trends and outlook

(a) Trends

Section 1.4.4 (a) of the 2020 URD is replaced in its entirety by the following:

The factors that are most likely to have an impact on Valneva's prospects for the fiscal year 2021 are as follows:

- Signature of a supply agreement for Valneva's COVID-19 vaccine candidate with the European Commission (negotiations are still ongoing at the publication date of this Amendment 1); and
- The speed of recovery of international long-distance travel and the travel industry.

(b) Significant events after June 30, 2021

Please refer to Section 1.1.2 "Recent Events" of this Amendment 1, including the Company's announcement of positive data from the Phase 3 clinical trial of its COVID-19 vaccine candidate, and to Section 1.4.2 (b) of this Amendment 1, describing the termination of the UK Supply Agreement.

(c) Financial outlook 2021

Section 1.4.4 (c) of the 2020 URD is replaced in its entirety by the following:

As part of the management of its activities, Valneva prepares operational and financial targets for the current and subsequent fiscal years.

When preparing its targets, the Company's Management Board uses the same accounting rules as for its IFRS-compliant financial statements.

Valneva is not providing guidance related to its VLA2001 revenues and program at this time. This guidance will be material to the Company and therefore needs to be based on robust information.

With respect to non-VLA2001 activities, the Company expects for 2021:

- Total revenues, excluding VLA2001, of €80 million to €105 million;
- R&D expenses, excluding VLA2001, of €65 million to €75 million.

Taking into account the ongoing COVID-19 situation, Valneva's sales could return to 2019 levels in 2023-2024 with the expected sales recovery of its two commercial products and the marketing and distribution partnership with Bavarian Nordic announced in June 2020. The successful commercialization of a SARS-CoV-2 vaccine could accelerate that timeline.

1.4.5. Liquidity and capital resources

(a) Capital Resources

Section 1.4.5 (a) of the 2020 URD is supplemented with the following information:

Liquid funds at June 30, 2021 amounted to €329.8 million compared to €204.4 million at December 31, 2020. The main changes related to payments made by the UK government within the framework of the UK Supply Agreement as well as the proceeds from the Global Offering in May 2021.

For further information on the Company's borrowings as of June 30, 2021, see Note 18 to the Group's unaudited interim consolidated financial statements for the six months ended June 30, 2021, included in the Half-Year Financial Report published on August 10, 2021 and available on Valneva's website [(1)].

[(1)] See Section 3 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/

(b) Cash flow

Section 1.4.5 (b) of the 2020 URD is replaced in its entirety by the following:

The following table sets out the Group's condensed cash flow information for the six months ended June 30, 2020 and 2021:

	Six months ended June 30,	
(In thousands of euros)	2021	2020
NET CASH USED IN OPERATING ACTIVITIES		
Net cash generated from operating activities	**84,247**	**113,219**
CASH FLOW FROM INVESTING ACTIVITIES		
Net cash used in investing activities	**(39,902)**	**(1,831)**
NET CASH GENERATED FROM FINANCING ACTIVITIES		
Proceeds from the issuance of ordinary shares, net of costs of equity transactions	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/(used in) 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	42	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**329,766**	**200,046**

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 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 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 the Group's 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 million of repayments of borrowings to the European Investment Bank.

For further information on the Company's cash flows as of June 30, 2021, please refer to the Group's unaudited interim consolidated financial statements for the six months ended June 30, 2021, included in the Half-Year Financial Report published on August 10, 2021 and available on Valneva's website[(1)].

[(1)] See Section 3 of the Half-Year Financial Report: https://valneva.com/investors/financial-reports/

1.5. Risk Factors

A description of the most significant risks that have changed significantly since the date of filing of the 2020 URD with the AMF is provided below.

This description, together with the risk factors set out in Section 1.5 of the 2020 URD, does not constitute an exhaustive and general list of all the Group's risks in the context of its business or in consideration of the environment in which it operates. The risks presented are those identified to date as being both significant and specific to the Group, the occurrence of which could have a major adverse effect on its business, financial situation and/or results.

Risks are classified into three categories: business risks, risks related to products developed or marketed, and litigation. The risks identified as being the highest, taking into account both their probability and their impact, and this after application of mitigation measures, are indicated below by the letter M (major risks) and are presented first in each category.

1.5.1. Specific risks relating to the Group's business

(a) Risks relating to the interruption of production and supply chain (M)

Section 1.5.1 (a) of the 2020 URD is replaced in its entirety with the following:

The Group's production sites, located in Livingston, Scotland, and Solna, Sweden, play and will play an important role in revenue growth and production cost control. The manufacture of biological materials is more delicate than that of chemical substances, 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 Group may experience delays, manufacturing failures or difficulties in its ability to manufacture its vaccines, meet regulatory requirements and/or satisfy market demand. The manufacture of biological materials is subject to Good Manufacturing Practices and regular inspections by regulatory authorities. It is not possible to predict the changes that regulatory authorities may require during the life cycle of a new vaccine. Such changes could be costly and could affect the sales and revenue projections. Failure to comply with Good Manufacturing Practices, Good Distribution Practices or other regulatory requirements could result in potential actions or the suspension or revocation of manufacturing or distribution authorizations, and could hinder the supply of products by the Group. The risk of suspension or revocation of manufacturing or distribution authorizations also exists for third parties with whom the Group has entered into manufacturing, supply or distribution agreements.

The Group's production facility in Livingston, Scotland, is the sole source for the production of the IXIARO® Japanese encephalitis vaccine and chikungunya vaccine candidate and is currently the primary source of clinical materials for the COVID-19 vaccine candidate. The Group's manufacturing facility in Solna, Sweden, is the sole source of DUKORAL® vaccine production and will perform fill-finish operations for the Group's COVID-19 vaccine candidate. If one of these sites were destroyed or seriously damaged by fire or other events, the Group would no longer be able to produce the vaccine concerned and could therefore suffer considerable losses. If the site of a subcontractor or a logistics distributor can no longer operate, whether because of an accident, natural disaster or regulatory failure, the Group could be unable to deliver any of its vaccines for several months, and could therefore suffer substantial losses. Numerous measures have been put in place to minimize these risks or their impact, including annual quality and safety audits, business continuity plans, on-site storage of critical spare parts, and the establishment of safety stocks for materials used in production.

(b) Risks associated with the impact of a pandemic

Section 1.5.1(b) of the 2020 URD is replaced in its entirety with the following:

Impact on sales or on production (M):

As the Group's two commercial vaccines are used by travelers and, in the case of IXIARO®, members of the US military, their sales were strongly affected by the COVID-19 pandemic. If the resumption of travel is later or less than the assumptions made by the Company, the Company's financial results could be adversely affected. In addition, the infection of a large number of employees with COVID-19 could suspend or delay essential operations, particularly industrial production.

Impact on clinical trials (M):

Ongoing clinical trials of chikungunya or Lyme disease vaccines could be delayed if clinical sites are contaminated or if providers have to suspend their activities. Additionally, the rising rate of vaccination against COVID-19 may make recruitment for future COVID-19 trials more difficult.

Risks related to contractual minimum revenue and liquidity requirements:

Although the Group has renegotiated the minimum revenue clause contained in the financing agreement with Deerfield and OrbiMed, if the Group's cash position or consolidated revenues were to fall below the new thresholds (quarterly threshold for sales in 2021 and 2022), Valneva would be in default, which could result in additional costs (up to 10 additional interest points over the duration of the default) and/or an early repayment obligation (payment of the principal of $60 million, increased by 8%, or $4.8 million, and of an indemnity representing the interests expected until March 2023, which for example would be approximately $6 million in case of repayment at the beginning of March 2022). Compliance with these covenants may limit the Group's flexibility in operating its business and its ability to take actions that might be advantageous to the Group and its shareholders. For example, if the Group fails to meet the minimum liquidity covenants and is unable to raise additional funds or obtain a waiver or other amendment to the loan agreement, Valneva may be required to delay, limit, reduce or terminate certain of its clinical development efforts. The Group's business, financial condition and results of operations could be substantially harmed if this occurs.

(c) Risk associated with the termination of the UK Supply Agreement (M)

Section 1.5.1 of the 2020 URD is updated to include a risk factor relating to the termination of the UK Supply Agreement, as follows:

In September 2020, Valneva entered into a supply agreement, or the UK Supply Agreement, with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom, or the UK Authority, pursuant to which Valneva was 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 paid to 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 Trials Agreement. This Clinical Trials Agreement has not been terminated, and the Group reported positive initial Phase 3 clinical trial results on October 18, 2021.

Following the close of business on September 10, 2021, Valneva received notice of the UK Authority's decision to terminate the UK Supply Agreement. Valneva 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 Valneva.

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

Second, the UK Authority purported to terminate the UK Supply Agreement on 30 days' notice based on its discretionary right under the UK Supply Agreement to terminate for convenience. Valneva has 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, Valneva shall not be obliged to refund or repay any amount paid by the UK Authority. A royalty on sales and certain other obligations, as described below, survive termination of the UK Supply Agreement.

Valneva was, and still is, completing the construction of its new manufacturing facility, Almeida, at its site in Livingston, Scotland. Under the terms of the UK Supply Agreement, this project was largely funded by advance payments made by the UK Authority pursuant to the UK Supply Agreement. Unless a satisfactory resolution can be secured, Valneva may not be able to complete this construction.

Additionally, Valneva depends on funds received from the UK Authority to pay costs associated with its ongoing Cov-Compare clinical trial in the UK. Such funding has been received and is to be received pursuant to the Clinical Trials Agreement, which was executed in conjunction with the UK Supply Agreement in order to finance the cost of clinical trials associated with the development of VLA2001. The Clinical Trials Agreement has not been terminated, but the cost of the Cov-Compare trial, as a result of mutual agreement between Valneva and the UK Authority, has exceeded the amount originally budgeted for in the Clinical Trials Agreement, and it is not certain that the UK Authority will provide Valneva with the additional funding necessary to make required payments to clinical sites or other providers. Without such funding, Valneva may fail to make such payments, in a timely fashion or at all, and there is a possibility that Valneva could face litigation and disruptions to the ongoing clinical trials as a result.

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 vaccination 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 Valneva is discussing with the UK Authority, other commercial opportunities and regulatory approval of VLA2001 may significantly impact these financial positions and Valneva’s future results of operations. The impact is uncertain as of the date of issuance of Valneva’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 Valneva’s business plan resulting from the termination of the UK Supply Agreement may have an impact on Valneva’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 believes that, in accordance with the terms of the UK Supply Agreement, the UK Authority is required to pay Valneva certain amounts in respect of commitments that Valneva 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 Valneva’s suppliers.

Valneva is currently evaluating options for the production of VLA2001 following the termination of the UK Supply Agreement. If, before December 31, 2022, Valneva were to cease to use its COVID-19 vaccine manufacturing assets or facilities, such as the Almeida manufacturing facility, which were acquired with funds advanced by the UK

Authority, Valneva may have certain obligations to the UK Authority, such as a partial return 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 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, Valneva is required to pay the UK Authority a royalty in respect of sales of Valneva's UK-manufactured vaccine to non-UK customers. This requirement survives 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.

Valneva may not be able to manufacture the COVID-19 vaccine candidate in sufficient quality and quantities, which could delay or prevent the development or commercialization of this vaccine candidate.

1.5.2. Risks specific to products developed or marketed by the Group

(a) Risks related to the COVID-19 vaccine

Section 1.5.2 (b) of the 2020 URD is replaced in its entirety with the following:

Risk of development or manufacturing failure (M):

Development of the COVID-19 vaccine candidate may fail for multiple reasons, including (but not limited to) technical or scientific failures, inability to enter into agreements with key suppliers, inability or unwillingness of key suppliers (including third parties to whom Valneva may outsource production of the COVID-19 vaccine candidate) to provide equipment or products or materials on time, competition for patient recruitment for clinical trials, quality assurance failures affecting clinical trial data, rejection by health authorities of applications for clinical trials or marketing authorization, technical difficulty in manufacturing the product consistently on a large scale, difficulty in adapting development and manufacturing to meet customer demand (for example for booster doses or new formulations of the vaccine to protect against variants of the virus), etc. Approval of VLA2001 for use in boosters would require additional clinical trial data and separate regulatory approval, and there is no guarantee that such data would be positive or that such approval would be granted even if VLA2001 is approved for use in primary vaccinations.

In particular, in September 2021, Valneva learned that the MHRA had conducted an audit of Public Health England, Valneva's partner in the collection of clinical trial data, and identified a quality assurance issue relating to an assay used by Public Health England. A final assay validation required by the MHRA to verify the integrity of the VLA2001-301 data remains ongoing and is a prerequisite for final clinical study report submission for regulatory approval of VLA2001. Additionally, the Cov-Compare Phase 3 clinical trial compares Valneva's vaccine candidate to AstraZeneca's Vaxzevria vaccine. If Valneva wanted to seek regulatory approval for VLA2001 in a jurisdiction that has not yet approved the Vaxzevria vaccine, notably the United States, the Group would have to redesign the regulatory strategy, and it 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 that Valneva may eventually seek, and Valneva is in the process of collecting its own data on the effectiveness of VLA2001 as a booster. Even though the primary vaccination results from the Cov-Compare trial were positive, the results of the Cov-Boost study or booster studies conducted by Valneva may be less satisfactory, or may not compare favorably to other vaccines that are authorized or in development.

Valneva could suffer financial losses as a result of the development and manufacturing expenses incurred and will have to assume a greater amount of such expenses following the termination of the UK Supply Agreement. In addition, Valneva's share price and market capitalization have increased significantly since Valneva announced its COVID-19 program; consequently, this share price and market capitalization could be seriously affected if Valneva were to stop this development.

Commercial risk (M): The Group currently has no customer agreements in place for the supply of its COVID-19 vaccine candidate and may fail to reach an agreement with the European Union or other customers. Valneva may enter into supply agreements with governments that include obligations to refund part or all of any up-front payments received if Valneva is unable to supply the agreed quantities in time, either through its own fault or that of its subcontractors. There is no guarantee that initial demand for VLA2001 will be sustained or that Valneva will be able to remain competitive in geographies where VLA2001 is initially sold. A commercial failure would have the same type of consequences as a development failure. Additionally, the biological material that Valneva would use to manufacture certain variant-based vaccines came from Public Health England, which would need to grant Valneva a license to commercialize any vaccines derived from this material.

Intellectual Property Risk: Patent applications are confidential for a long period of time (typically 18 months) after filing. In addition, research and development work on COVID-19 is recent and has been concentrated over a relatively short period of time. As a result, many patent applications in the field of SARS-CoV-2 are still confidential, and Valneva cannot be certain that it was the first to apply for a patent on certain characteristics or properties of its COVID-19 vaccine candidate. If this vaccine were dependent on third-party patents, its supply to Valneva's customers could be delayed, and/or Valneva could be required to pay for a costly license that would affect the profitability of the product and the Group's financial performance.

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For further information about the terms of the UK Supply Agreement and its termination provisions, please refer to Section 1.4.2 (b) of this Amendment 1.

(b) Risks related to the DUKORAL® vaccine

Section 1.5.2 (c) of the 2020 URD is replaced in its entirety with the following:

Risk related to indications and recommendations (M): A reassessment of the product's indications by the Canadian federal agency supervising pharmaceutical products distributed in this country, or a reassessment of the recommendations for use of the vaccine issued by the authorities, could have a significant negative impact on the sales volumes of this product and potentially result in the product no longer being economically viable. This is particularly a risk in Canada, which remains the principal market for this vaccine. The Group received a request in July 2021 to provide further information in support of DUKORAL®'s indications and labeling in Canada, and this matter remains ongoing.

Competition: Another vaccine company has obtained a marketing authorization in Europe. The launch of this competing vaccine, if approved, will impact the sales volume of DUKORAL®.

1.5.3. Litigation

Section 1.5.3 of the 2020 URD is replaced in its entirety by the following:

(a) Vivalis SA and Intercell AG merger dispute

Following the merger between the companies Vivalis SA and Intercell AG, some former Intercell shareholders initiated legal proceedings before the Commercial Court of Vienna to revise the amount of compensation offered to existing shareholders, or the exchange ratio between Intercell and Valneva shares. If the court decides to increase the financial compensation, every former Intercell shareholder who opted for financial compensation instead of exchange would be entitled to an increase, even if he or she was not a party to the dispute. If the court decides to revise the exchange ratio, there is legal uncertainty as to whether the court could extend this revision to all former Intercell shareholders who exchanged their shares, even if they were not party to the dispute. There is therefore a risk that Valneva will be forced to compensate all former shareholders following the reevaluation of the exchange ratio. If so, these payments could have a material adverse effect on Valneva's activities, earnings and prospects. In 2016 and 2017, settlement agreements were executed with some Intercell shareholders who had held a small number of shares, which has decreased the risks associated to these proceedings. Further, 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.

On October 6, 2021, Valneva 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 the Company has 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 the Company's current litigation reserves, which pertain to this plaintiff group specifically.

(b) Litigation relating to the acquisition of Humalys SAS

In July 2016, the Company received a request for an additional payment, with a threat of lawsuit, in connection with the acquisition of the company "Humalys SAS" in 2009, a transaction by which Vivalis SA (now Valneva SE) acquired a technology that was further combined with another antibody discovery technology and contributed to the company BliNK Biomedical SAS at the beginning of 2015[(1)]. The former shareholders of Humalys are demanding an additional payment due to this transfer. This claim was followed, at the end of 2016, by a writ of summons before the Lyon District Court. A first instance decision is expected in the first half of 2022. The Company, after consultation with its external counsel, considers that this claim is unfounded and that this legal proceeding is unlikely to succeed[(2)].

(1) See Section 1.2.2.(c) of the 2020 URD.
(2) No provision has been made in the Group's financial statements in respect of this litigation.

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For a further description of litigation involving Valneva, please refer to the paragraphs "Patents and Patent Applications" and "Trademarks" in Section 1.3.3 (b) of this Amendment 1, as well as to Section 1.4.2 (p) "Trademark Coexistence Agreement with Boehringer Ingelheim" of the 2020 URD. The Company has no knowledge of any other governmental, legal or arbitration proceedings (including pending or threatened litigation) that in the future might have or in the last 12 months had a material impact on the financial position or profitability of the Company or the Group.

1.5.4. Insurance and coverage of risks

Section 1.5.4 of the 2020 URD is replaced in its entirety by the following:

The Group has taken out policies covering the main insurable risks for values it deems compatible with the nature of its business. Expenses paid by the Company and its subsidiaries for all insurance policies in the first six months of 2021 amounted to €2,968,239.57.

Main insurance policies of the Valneva SE Group :

Risks covered	Insurer	Expiration
Property Damage and Business Interruption Insurance (including storage)	HDI Versicherung AG	Renewed yearly unless terminated with one month prior notice (earliest January 1, 2022)
Marine Cargo - Transport Insurance	HDI Versicherung AG	Renewed yearly unless terminated at three months' prior notice (earliest January 1, 2022)
Public and Product Liability Insurance max coverage: €40,000,000 (per occurence, 1.5 times p.a.)(*)	XL Insurance Company SE (AXA XL Insurance) et al.	Renewed yearly unless terminated with one month prior notice (XL Insurance: earliest January 1, 2022)
Directors and Officers Insurance(**)	AGCS/AIG et al.	Validity: from April 29, 2021 to April 28, 2022 (to be renewed thereafter)
Corporate Travel Insurance	Europaeische Reiseversicherungs AG	Terminated at one month's prior notice (earliest January 1, 2022)

(*) *Valneva's SARS-Cov-2 vaccine is excluded from the scope of this policy, as of the date of this Amendment 1.*

(**) *The D&O covers any pecuniary consequences of loss or damage resulting from any claims brought against the directors and officers, binding their civil liability, whether individual or joint, and attributable to any professional misconduct, whether actual or alleged, committed by them in performing their managerial duties. This policy is also subject to certain conditions and restrictions of common practice for similar contracts.*

The Group also has other insurance policies in place, but these are less important than those described above.

The Group cannot ensure that it will always be able to keep, and if applicable, obtain, similar insurance coverage at an acceptable cost. This could lead it to accept insurance policies that are more expensive and take on a higher level of risk itself (particularly as it develops its business, especially in bio-production).

The occurrence of one or more large claims, even if covered by its insurance policies, could seriously affect the Groups' operations and its financial position, given the possible interruption to its operations that could result from such a claim, the time taken for insurance companies to pay any recovery, the damage possibly exceeding insured limits in policies, and, finally, the increase in premiums that would result.

Given the Group's listing on the NASDAQ market in May of 2021, there has been a very significant increase in the price of the premiums of its directors' and officers' liability insurance. The Group also expects a very significant increase in the price of the premium of its product liability insurance if the Group's vaccine against SARS-CoV-2 is approved and commercialized.

2. Information relating to the Company and its share capital

2.1. Share capital

2.1.1. Amount of share capital

Section 5.1.1 of the 2020 URD is completed with the following information relating to the description of the share capital and shareholding structure as at June 30 and September 30, 2021[xi]:

At June 30, 2021, Valneva SE's share capital stood at €14,986,340.70.

It was then composed of 99,908,938 shares in total, divided into :

- 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each; and
- 20,514 convertible preferred shares (XFCS00X0I9M1), also with a par value of €0.15 each.

These shares were all fully paid up.

The corresponding number of theoretical voting rights (including suspended voting rights, such as those associated with treasury shares, and double voting rights) amounted to 126,995,094. The number of net voting rights was 126,866,747.

Shareholding structure of the Company at June 30, 2021

(End of business day, to the Company's knowledge)

		Shares held (*)				
SHAREHOLDERS		Ordinary shares	Convertible preferred shares	%	Theoretical voting rights	%
Groupe Grimaud La Corbière SAS (**)		**13,704,831**	**0**	**13.72**	**27,409,661**	**21.58**
Bpifrance Participations SA		**8,971,361**	**0**	**8.98**	**16,428,146**	**12.94**
MVM Funds (MVM IV LP & MVM GP (No.4) Scottish LP)		**5,397,122**	**0**	**5.40**	**9,736,065**	**7.67**
Management Board members	**Total Management Board members**	**636,674**	**15,418**	**0.65**	**1,129,843**	**0.89**
	Mr. Franck Grimaud	485,889	5,668	0.49	968,478	0.76
	Mr. Thomas Lingelbach	139,983	8,008	0.15	145,761	0.11
	Mr. Frédéric Jacotot	10,802	1,742	0.01	15,604	0.01
	Mr Juan Carlos Jaramillo	0	0	0	0	0
Employees (non-corporate officers)		**104,837**	**5,096**	**0.11**	**189,148**	**0.15**
Other shareholders (private individuals)		**1,175,752**	**0**	**1.18**	**2,204,384**	**1.74**
Including members of the Grimaud family (including Mr. Frédéric GRIMAUD, Chairman of the Supervisory Board) and Financière Grand Champ SAS (**)		731,448	0	0.73	1,420,349	1.12
Including independent members of the Supervisory Board	Mr. James Sulat	24,117	0	0.02	45,109	0.04
	Ms. Anne-Marie Graffin	8,000	0	0.01	8,000	0.01
Other floating capital		**69,897,847**	**0**	**69.96**	**69,897,847**	**55.04**
SUBTOTAL BY CATEGORY		99,888,424	20,514	100	126,995,094	100
TOTAL			**99,908,938**	**100**	**126,995,094**	**100**

(*) Percentages in this table are calculated in reference to a share capital of 99,908,938 Valneva SE shares, divided into (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

*(**) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

[xi] Please refer also to Section 1.1.2 (u) of this Amendment 1 for a description of the current amount of share capital.

By way of comparison, at September 30, 2021, Valneva SE's share capital stood at €14,987,278.20.

It was then composed of 99,915,188 shares in total, divided into :

- 99,894,674 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each; and
- 20,514 convertible preferred shares (XFCS00X0I9M1), also with a par value of €0.15 each.

These shares were all fully paid up.

The corresponding number of theoretical voting rights (including suspended voting rights, such as those associated with treasury shares, and double voting rights) was 122,592,327. The number of net voting rights was 122,463,980.

Shareholding structure of the Company at September 30, 2021

(End of business day, to the Company's knowledge)

		Shares held (*)				
SHAREHOLDERS		Ordinary shares	Convertible preferred shares	%	Theoretical voting rights	%
Groupe Grimaud La Corbière SAS (**)		**13,704,831**	**0**	**13.72**	**27,409,661**	**22.36**
Bpifrance Participations SA		**8,971,361**	**0**	**8.98**	**16,428,146**	**13.40**
Management Board members	**Total Management Board members**	**636,674**	**15,418**	**0.65**	**1,149,143**	**0.94**
	Mr. Franck Grimaud	485,889	5,668	0.49	971,778	0.79
	Mr. Thomas Lingelbach	139,983	8,008	0.15	155,761	0.13
	Mr. Frédéric Jacotot	10,802	1,742	0.01	21,604	0.02
	Mr. Juan Carlos Jaramillo	0	0	0	0	0
Employees (non-corporate officers)		**104,337**	**5,096**	**0.11**	**188,148**	**0.15**
Other shareholders (private individuals)		**1,061,961**	**0**	**1.06**	**2,001,719**	**1.63**
Including members of the Grimaud family (including Mr Frédéric GRIMAUD, Chairman of the Supervisory Board) and Financière Grand Champ SAS (**)		701,242	0	0.70	1,359,936	1.11
Including independent members of the Supervisory Board	Mr. James Sulat	27,242	0	0.03	48,234	0.04
	Ms. Anne-Marie Graffin	8 000	0	0.01	8,000	0.01
Other floating capital		**75,415,510**	**0**	**75.48**	**75,415,510**	**61.52**
SUBTOTAL BY CATEGORY		99,894,674	20,514	100	122,592,327	100
TOTAL			**99,915,188**	**100**	**122,592,327**	**100**

(*) Percentages in this table are calculated in reference to a share capital of 99,915,188 Valneva SE shares, divided into (a) 99,894,674 ordinary shares (ISIN FR0004056851) with a par value of €0.15 euro, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

*(**) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

2.1.2. Potential capital

(a) Company stock option plans

Section 5.1.4 (a) of the 2020 URD is completed with the following information relating to a detailed description, as at June 30, 2021, of the Company's stock option plans. This description is accompanied by an additional statement setting out the changes in each of these plans as at September 30, 2021:

At June 30, 2021, there were 3,990,885 stock options outstanding, under all of the Company's plans combined.

The maximum number of new Valneva SE ordinary shares that could result from the exercise of these options was 4,054,937[(1)] (*i.e.* a potential nominal increase in the share capital of €608,240.55, representing a maximum potential dilution of 4.06%[(2)] of the Company's share capital).

*

A detailed description of the Company's stock option plans in force at June 30, 2021 is provided on the following pages:

[(1)] Provided that all stock options become available for exercise.
[(2)] Rate calculated in reference to a total share capital of 99,908,938 Valneva SE shares, divided into (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

Plan 7 (ESOP 2013)

Grant decision date	**General Meeting:** June 28, 2013 **Management Board meeting:** October 2, 2013
Number of beneficiaries at launch of plan	293
Duration of plan (as from the date of the decision of the Board of Directors or Management Board)	Until October 2, 2023
Maximum amount authorized by the General Meeting	Authorization to grant an amount of stock options conferring a right to subscribe to a total number of shares representing 4% maximum of the Company's share capital on the date the capital increase is adopted under the terms of the 9th resolution of Valneva's Combined General Meeting of March 7, 2014(1)
Exercise price for one new ordinary share	€2.919(2)
Option/share conversion ratio	1: 1.099617653 (then rounded up for each beneficiary)(3)
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	1,052,950
Starting date for the exercise of options	October 2, 2015 & October 2, 2017(4)
Stock options exercised at June 30, 2021	0
New ordinary shares issued as of June 30, 2021 resulting from exercise of stock options	0
Outstanding stock options not yet exercised as of June 30, 2021	642,200 (all available for exercise)
Of which outstanding stock options held by corporate officers	*210,000* ▪ *Mr. Thomas Lingelbach: 100,000* ▪ *Mr. Franck Grimaud: 100,000* ▪ *Mr. Frédéric Jacotot : 10,000*
New ordinary shares potentially resulting from stock option exercise as of June 30, 2021	706,252
Stock options having lapsed as of June 30, 2021	410,750
Stock options remaining to be granted at June 30, 2021 under the General Meeting's authorization – Authorization status	0 - Authorization declared null and void by the Combined General Meeting of June 26, 2014
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

(1) At the Supervisory Board's meeting of the Company held on August 29, 2013, the number of stock options was set at 2,231,356.
(2) Subscription price has been revised in accordance with the decision of the Company's Management Board of February 25, 2015.
(3) Conversion ratio has been revised in accordance with the decision of the Company's Management Board of February 25, 2015.
(4) 50% of options may be exercised after being held for 2 years by their beneficiary; the remaining 50% becoming available for exercise after being held for 4 years.

- **Changes in the plan since June 30, 2021**: as of September 30, 2021, no options had been exercised under this plan. The number of outstanding stock options at that time was 636,000. The number of new ordinary shares that may be issued upon exercise of the remaining options was 699,433. The total number of stock options that have lapsed has been increased to 416,950.

Plan 8 (ESOP 2015)

Grant decision date	**General Meeting:** June 26, 2014 **Management Board meeting:** July 28, 2015
Number of beneficiaries at launch of plan	259
Duration of plan (as from the date of the decision of the Board of Directors or Management Board)	Until July 28, 2025
Maximum amount authorized by the General Meeting	Authorization to grant an amount of stock options conferring a right to subscribe to a total number of shares representing 4% maximum of the Company's share capital on the date of the stock option grant
Exercise price for one new ordinary share	€3.92
Option/share conversion ratio	1 : 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	712,000
Starting date for the exercise of options	July 28, 2017 & July 28, 2019(1)
Stock options exercised at June 30, 2021	0
New ordinary shares issued as of June 30, 2021 resulting from exercise of stock options	0
Outstanding stock options not yet exercised as of June 30, 2021	528,000 (all available for exercise)
Of which outstanding stock options held by corporate officers	*100,000 (Mr. Thomas LINGELBACH)*
New ordinary shares potentially resulting from stock option exercise as of June 30, 2021	528,000
Stock options having lapsed as of June 30, 2021	184,000
Stock options remaining to be granted at June 30, 2021 under the General Meeting's authorization – Authorization status	0 – Authorization declared null and void by the Combined General Meeting of June 30, 2016
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

(1) 50% of options may be exercised after being held for 2 years by their beneficiary; the remaining 50% becoming available for exercise after being held for 4 years.

- **Changes in the plan since June 30, 2021**: as of September 30, 2021, no options had been exercised under this plan. The number of outstanding stock options at that time was 524,000 (entitling the holder to an equivalent number of new ordinary shares). The total number of stock options that have lapsed has been increased to 188,000.

Plan 9 (ESOP 2016)

Grant decision date	**General Meeting:** June 30, 2016 **Management Board meeting:** October 7, 2016
Number of beneficiaries at launch of plan	402
Duration of plan (as from the date of the decision of the Board of Directors or Management Board)	Until October 7, 2026
Maximum amount authorized by the General Meeting	Authorization to grant an amount of stock options conferring a right to subscribe to a total number of shares representing 4% maximum of the Company's share capital on the date of the stock option grant
Exercise price for one new ordinary share	€2.71
Option/share conversion ratio	1 : 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	584,250
Starting date for the exercise of options	October 7, 2018 & October 7, 2020(1)
Stock options exercised at June 30, 2021	363,050
New ordinary shares issued as of June 30, 2021 resulting from exercise of stock options	363,050
Outstanding stock options not yet exercised as of June 30, 2021	36,200 (all available for exercise)
Of which outstanding stock options held by corporate officers	*0*
New ordinary shares potentially resulting from stock option exercise as of June 30, 2021	36,200
Stock options having lapsed as of June 30, 2021	185,000
Stock options remaining to be granted at June 30, 2021 under the General Meeting's authorization – Authorization status	0 – Authorization declared null and void by the Combined General Meeting of June 28, 2018
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

(1) 50% of options may be exercised after being held for 2 years by their beneficiary; the remaining 50% becoming available for exercise after being held for 4 years.

- **Changes to the plan since June 30, 2021**: there has been no change to this plan.

Plan 10 (ESOP 2017)

Grant decision date	**General Meeting:** June 30, 2016 **Management Board meeting:** December 7, 2017
Number of beneficiaries at launch of plan	424
Duration of plan (as from the date of the decision of the Board of Directors or Management Board)	Until December 7, 2027
Maximum amount authorized by the General Meeting	Authorization to grant an amount of stock options conferring a right to subscribe to a total number of shares representing 4% maximum of the Company's share capital on the date of the stock option grant
Exercise price for one new ordinary share	€2.85
Option/share conversion ratio	1 : 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	1,269,500
Starting date for the exercise of options	December 7, 2019 & December 7, 2021(1)
Stock options exercised at June 30, 2021	427,025
New ordinary shares issued as of June 30, 2021 resulting from exercise of stock options	427,025
Outstanding stock options not yet exercised as of June 30, 2021	559,725 (including 71,975 stock options available for exercise)
Of which outstanding options held by corporate officers	*0*
New ordinary shares potentially resulting from stock option exercise as of June 30, 2021	559,725 (including 71,975 shares which can be issued from stock options available for exercise)
Stock options having lapsed as of June 30, 2021	282,750
Stock options remaining to be granted at June 30, 2021 under the General Meeting's authorization – Authorization status	0 – Authorization declared null and void by the Combined General Meeting of June 28, 2018
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

(1) 50% of options may be exercised after being held for 2 years by their beneficiary; the remaining 50% becoming available for exercise after being held for 4 years.

- **Changes in the plan since June 30, 2021**: as of September 30, 2021, the number of outstanding stock options was 554,475 (entitling the holder to an equivalent number of new ordinary shares). The total number of stock options that have lapsed has been increased to 288,000.

Plan 11 (ESOP 2019)

Grant decision date	**General Meeting:** June 28, 2018 **Management Board meeting:** September 30, 2019
Number of beneficiaries at launch of plan	467
Duration of plan (as from the date of the decision of the Board of Directors or Management Board)	Until September 30, 2029
Maximum amount authorized by the General Meeting	Authorization to grant an amount of stock options conferring a right to subscribe to a total number of shares representing 4% maximum of the Company's share capital on the date of the stock option grant
Exercise price for one new ordinary share	€3.05
Option/share conversion ratio	1 : 1
Stock options granted to employees and/or corporate officers by the Management Board at launch of plan	2,671,510
Starting date for the exercise of options	September 30, 2020, September 30, 2021 & September 30, 2022(1)
Stock options exercised at June 30, 2021	0
New ordinary shares issued as of June 30, 2021 resulting from exercise of stock options	0
Outstanding stock options not yet exercised as of June 30, 2021	2,224,760 (including 1,483,022 stock options available for exercise)
Of which outstanding options held by corporate officers	*0*
New ordinary shares potentially resulting from stock option exercise as of June 30, 2021	2,224,760 (including 1,483,022 shares which can be issued upon stock options available for exercise)
Stock options having lapsed as of June 30, 2021	446,750
Stock options remaining to be granted at June 30, 2021 under the General Meeting's authorization – Authorization status	0 – Authorization declared null and void by the Combined General Meeting of June 17, 2020
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

(1) 1/3 of options may be exercised after being held for 1 year by their beneficiary; then another 1/3 after being held for 2 years, and the remainder after being held for 3 years.

- **Changes in the plan since June 30, 2021**: as of September 30, 2021, the number of options remaining in circulation amounted to 2,205,260 (entitling the holder to an equivalent number of new ordinary shares). The number of options that have become available for exercise has been increased to 1,470,024. The total number of stock options that have lapsed has been increased to 466,250.

(b) Free share plans (ordinary shares and convertible preferred shares)

Section 5.1.4 (b) of the 2020 URD is supplemented with the information set out below, relating to a detailed description, as at June 30, 2021, of the Company's free share plans (ordinary shares or convertible preferred shares). This description is accompanied by an additional statement reporting on the change of these plans since June 30, 2021:

Free ordinary share plan - Status as of June 30, 2021

At June 30, 2021, 1,842,404 free ordinary shares granted by the Company in 2019 were under vesting (*i.e.*, a potential nominal increase in the share capital of €276,360.60, representing a maximum potential dilution of 1.84%[(1)] of the Company's share capital).

*

A detailed description of the free share plan in force at June 30, 2021 is set out in the following table:

FREE SHARE PLAN 2019-2023

General Meeting date	June 27, 2019
Management Board decision	December 19, 2019
Maximum amount authorized by the General Meeting	Maximum three percent (3%) of the Company's share capital on the grant date, without exceeding the maximum legal amount applicable on the grant date
Number of beneficiaries	14
Total number of free ordinary shares granted	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 shares will be rounded down for the first two tranches and rounded up for the third tranche.
Corporate officers beneficiaries	*Mr. Thomas Lingelbach : 331,667* *Mr. Franck Grimaud: 262,570* *Mr. Frédéric Jacotot : 262,570*
Date of full vesting	The tranches will vest in the beneficiaries as follows: First tranche after two (2) years as from December 19, 2019, Second Tranche after three (3) years as from December 19, 2019, Third Tranche after four (4) years as from December 19, 2019. The vesting ("*attribution définitive*") of each tranche will be subject to performance and employment conditions.
Date of availability	Following free shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees. However, in accordance with section II (4th paragraph) of Article L. 225-197-1 of the French Commercial Code, the Supervisory Board decided that the Management Board members should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer.
Free ordinary shares fully vested at June 30, 2021	0
Free ordinary shares being vested at June 30, 2021	1,842,404 (including 856,807 by corporate officers)
Ordinary shares lapsed on 30 June 2021	349,543 - *Following former Management Board members leaving the Company*
Performance and employment conditions	Concerning non-corporate officers employees, the vesting of each tranche will be contingent upon the beneficiary's performance in the Relevant Year having been rated not lower than "Meets Expectations" (regardless of any qualifying sign), as assessed by his/her supervisor under the Company's employee performance appraisal rules. Concerning corporate officers, the vesting of each tranche will be contingent upon the level of achievement of 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.

[(1)] Rate calculated in reference to a total share capital of 99,908,938 Valneva SE shares, divided into (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

FREE SHARE PLAN 2019-2023

Performance and employment conditions *(continued)*	***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, the beneficiaries must continuously remain a corporate officer or employee (full time or not less than 80%) of the Company or a direct or indirect subsidiary of the Company until vesting, subject to the retirement exception below or any individual exemption.
Provisions relating to retirement	Beneficiaries who will retire in accordance with the age requirements of their applicable retirement regime before complete vesting will remain entitled to a prorated amount of shares, for each unvested tranche, based on the period from the initial grant date until retirement, as compared to the total duration of the tranche in question (2, 3 or 4 years); provided, however, that the performance condition stated above was met in the performance appraisal immediately preceding the retirement. For Management Board members (including the CEO), the level of performance will also affect the amount of shares kept.
Provisions relating to a change of control	If (a) a Change of Control (as defined below) occurs not earlier than December 19, 2021, and (b) the performance condition stated above was met for the calendar year immediately preceding the year of Change of Control (or for the year of Change of Control if already assessed), all tranches will vest immediately. For Management Board members (including the CEO), their level of performance will also affect the amount of shares that will be the subject of accelerated vesting. If a Change of Control takes place before December 19, 2021, and Article L. 225-197-1, III of the French Commercial Code does not apply, the plan will be cancelled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the cancelled plan, subject however to the above-mentioned performance conditions, and for the Management Board (including the 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 ordinary shares which may be granted at June 30, 2021 under the General Meeting's authorization - Authorization status	0 - Authorization declared null and void by the Combined General Meeting of June 17, 2020.
Theoretical number of shares available for take up at June 30, 2021, if the Management Board makes use of the remainder amount under the General Meeting authorization	0

- **Changes in the plan since June 30, 2021**: there has been no change to this plan.

Free convertible preferred share program 2017-2021 – Status as of June 30, 2021

At June 30, 2021, 32,463 free convertible preferred shares granted by the Company in 2017 (***FCPS***) were under vesting (including 14,898 by corporate officers[1]).

The maximum number of new Valneva SE ordinary shares that could result from the full vesting and conversion of these free convertible preferred shares was then 2,012,706[2] (*i.e.*, a potential nominal increase in the share capital of €301,905.90, representing a maximum potential dilution of 2.01%[3] of the Company's share capital).

*

A detailed description of the free convertible preferred share program in force at June 30, 2021 is provided in the following table:

FREE CONVERTIBLE PREFERRED SHARE PROGRAM 2017-2021

General Meeting date	June 29, 2017
Management Board decision	December 7, 2017
FCPS granted by the Management Board	34,017, by Management Board decision on December 15, 2017 ▪ 5,596 to the Chair of the Management Board ▪ 4,651 to the other Management Board members serving at that time, and ▪ 1,157 for each of the other Executive Committee *(now "Management Committee")* members also serving at that time, 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	The FCPS will be fully vested after a period of 4 years as from 15 December 2017, subject to certain employment conditions.
Date of availability	Management Board members who are beneficiaries of the plan shall keep and retain under registered form at least 10% of the ordinary shares resulting from the conversion of their FCPS.
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 - *Following former Management Board members leaving the Company*
Applicable conditions for the conversion of FCPS into ordinary shares	The free convertible preferred shares will be convertible into Valneva SE ordinary shares 4 years after their initial granting, 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 (it being specified that the FCPS cannot give rights to more than 2,363,000 ordinary shares of the Company). The ***Final Share Price*** will be the volume-weighted average stock market price of the Company's ordinary shares 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[4]. If any of the transactions listed in of Article 13.3, subparagraph 3, (iii) of the Articles of Association of the Company, including but not limited to any share capital increase by public offering with preferential subscription rights, takes place, the Management Board will adjust the conversion ratio and the conversion table provided above in the manner set forth in the Articles of Association so as to protect the rights of the program beneficiaries.

- **Changes in the plan since June 30, 2021**: see footnote (4) below.

[1] 1,554 FCPS in total have lapsed, following former Management Board members leaving the Company.

[2] Based on a maximum conversion ratio of 1 FCPS for 62 ordinary shares, according to the rules of the plan.

[3] Rate calculated in reference to a total share capital of 99,908,938 Valneva SE shares, divided into (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

[4] Certain foreign beneficiaries have been individually authorized to postpone the deadline for conversion of their FCPS up to a maximum of 12 months after full vesting of their FCPS, for reasons relating to the tax rules applicable to their country of residence.

(c) Equity warrants (BSA)

Section 5.1.4 (c) of the 2020 URD is supplemented with the following information relating to a detailed description of the Company's equity warrant plan in force at June 30, 2021. This description is accompanied by an additional statement reporting on the change of this plan since June 30, 2021:

BSA 27	
Date of grant	Management Board dated December 15, 2017
Number of BSAs authorized by the General Meeting	125,000 (Extraordinary General Meeting dated June 30, 2016)
Number of BSAs issued by the Management Board	87,500
Beneficiaries and number of BSAs granted	▪ 25,000 BSA 27 to the Chairman of the Supervisory Board, Mr. Frédéric Grimaud ▪ 12,500 BSA 27 for each of : - Mr. Alain Munoz - Ms. Anne-Marie Graffin - Mr. James Sulat - Mr. Alexander von Gabain - Mr Ralf Clemens, Supervisory Board members at the time of launching the plan.
Number of BSAs lapsed at June 30, 2021	15,625
Number of BSAs exercised at June 30, 2021	31,250
Number of outstanding BSAs at June 30, 2021	40,625
Number of potential Valneva SE ordinary shares to be issued upon exercise of outstanding BSAs at June 30, 2021	40,625 (1 BSA for 1 Valneva SE ordinary share)
Exercise price per share	€2.574
Expiry date of the plan	December 15, 2022

- **Changes in the plan since June 30, 2021**: as of September 30, 2021, the number of outstanding BSA 27 was 34,375 (entitling the holder to an equivalent number of new ordinary shares). The number of BSA 27 exercised has been increased to 37,500.

(d) Information on the fully-diluted Company's share capital

Section 5.1.4 (d) of the 2020 URD is supplemented with the following information relating to the Company's shareholder structure before and after exercise or full vesting (and, if applicable, conversion) of the dilutive instruments in force on June 30 and September 30, 2021:

Status as of June 30, 2021

Valneva SE shareholding structure before exercise or full vesting (and, if applicable, conversion) of dilutive instruments

		Shares held (*)			Dilutive instruments Number of ordinary shares to be issued (***)			
SHAREHOLDERS		Ordinary shares	Convertible preferred shares	%	Stock options	BSA	Free ordinary shares	Free convertible preferred shares
Groupe Grimaud La Corbière SAS (**)		**13,704,831**	**0**	**13.72**	**0**	**0**	**0**	**0**
Bpifrance Participations SA		**8,971,361**	**0**	**8.98**	**0**	**0**	**0**	**0**
MVM Funds (MVM IV LP & MVM GP (No.4) Scottish LP)		**5,397,122**	**0**	**5.40**	**0**	**0**	**0**	**0**
Management Board members	**Total Management Board members**	**636,674**	**15,418**	**0.65**	**330,921**	**0**	**856,807**	**923,676**
	Mr. Franck Grimaud	485,889	5,668	0.49	109,962	0	262,570	288,362
	Mr. Thomas Lingelbach	139,983	8,008	0.15	209 962	0	331,667	346,952
	Mr. Frédéric Jacotot	10,802	1,742	0.01	10,997	0	262,570	288,362
	Mr. Juan Carlos Jaramillo	0	0	0	0	0	0	0
Employees (non-corporate officers)		**104,837**	**5,096**	**0.11**	**3,724,016**	**0**	**810,000**	**608,654**
Other shareholders (private individuals)		**1,175,752**	**0**	**1.18**	**0**	**40,625**	**175,597**	**480,376**
Including members of the Grimaud family (including Mr. Frédéric Grimaud, Chairman of the Supervisory Board) and Financière Grand Champ SAS (**)		731,448	0	0.73	0	12,500	0	0
Including independent members of the Supervisory Board	Mr. James Sulat	24,117	0	0.02	0	6,250	0	0
	Ms. Anne-Marie Graffin	8,000	0	0.01	0	6,250	0	0
Other floating capital		**69,897,847**	**0**	**69.96**	**0**	**0**	**0**	**0**
SUBTOTAL BY CATEGORY		99,888,424	20,514	100	4,054,937	40,625	1,842,404	2,012,706
TOTAL			**99,908,938**	**100**		**7,950,672**		

(*) Percentages in this table are calculated in reference to a share capital of 99,908,938 Valneva SE shares, divided into (a) 99,888,424 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

*(**) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

(***) The conversion ratios of the various dilutive instruments are set as follows:

- *Stock options: for plan 7, 1 stock option entitles to 1.099617653 Valneva SE ordinary shares (then rounded up for each beneficiary), while for plans 8, 9, 10 and 11, 1 option entitles to 1 Valneva SE ordinary share;*
- *BSA 27: 1 BSA entitles to 1 Valneva SE ordinary share;*
- *Free convertible preferred shares: the conversion of free convertible preferred shares into ordinary shares is carried out by multiplying the number of FCPS granted by 62 (maximum conversion ratio according to the rules of the Free convertible preferred share program 2017-2021).*

Valneva SE shareholding after exercise or full vesting (and, if applicable, conversion) of dilutive instruments

		Valneva SE ordinary shares	%
Groupe Grimaud La Corbière SAS(*)		**13,704,831**	**12.71**
Bpifrance Participations SA		**8,971,361**	**8.32**
MVM Funds (MVM IV LP & MVM GP (No.4) Scottish LP)		**5,397,122**	**5**
Management Board members	**Total Management Board members**	**2,748,078**	**2.55**
	Mr. Franck Grimaud	1,146,783	1.06
	Mr. Thomas Lingelbach	1,028,564	0.95
	Mr. Frédéric Jacotot	572,731	0.53
	Mr. Juan Carlos Jaramillo	0	0
Employees (non-corporate officers)		**5,247,507**	**4.87**
Other shareholders (private individuals)		**1,872,350**	**1.73**
Including members of the Grimaud family (including Mr. Frédéric Grimaud, Chairman of the Supervisory Board) and Financière Grand Champ SAS(*)		743,948	0.69
Including independent members of the Supervisory Board	Mr. James Sulat	30,367	0.03
	Ms. Anne-Marie Graffin	14,250	0.01
Other floating capital		**69,897,847**	**64.82**
TOTAL		**107,839,096**	**100**

*(*) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

Status as of September 30, 2021

Valneva SE shareholding structure before exercise or full vesting (and, if applicable, conversion) of dilutive instruments

		Shares held (*)			Dilutive instruments Number of ordinary shares to be issued(***)			
SHAREHOLDERS		Ordinary shares	Convertible preferred shares	%	Stock options	BSA	Free ordinary shares	Free convertible preferred shares
Groupe Grimaud La Corbière SAS(**)		**13,704,831**	**0**	**13.72**	**0**	**0**	**0**	**0**
Bpifrance Participations SA		**8,971,361**	**0**	**8.98**	**0**	**0**	**0**	**0**
Management Board members	**Total Management Board members**	**636,674**	**15,418**	**0.65**	**330,921**	**0**	**856,807**	**923,676**
	Mr. Franck Grimaud	485,889	5,668	0.49	109,962	0	262,570	288,362
	Mr. Thomas Lingelbach	139,983	8,008	0.15	209 962	0	331,667	346,952
	Mr. Frédéric Jacotot	10,802	1,742	0.01	10,997	0	262,570	288,362
	Mr. Juan Carlos Jaramillo	0	0	0	0	0	0	0
Employees (non-corporate officers)		**104,337**	**5,096**	**0.11**	**3,688,447**	**0**	**810,000**	**608,654**
Other shareholders (private individuals)		**1,061,961**	**0**	**1.06**	**0**	**34,375**	**175,597**	**480,376**
Including members of the Grimaud family (including Mr. Frédéric Grimaud, Chairman of the Supervisory Board) and Financière Grand Champ SAS(**)		701,242	0	0.70	0	12,500	0	0
Including independent members of the Supervisory Board	Mr. James Sulat	27,242	0	0.03	0	3,125	0	0
	Ms. Anne-Marie Graffin	8,000	0	0.01	0	6,250	0	0
Other floating capital		**75,415,510**	**0**	**75.48**	**0**	**0**	**0**	**0**
SUBTOTAL BY CATEGORY		99,894,674	20,514	100	4,019,368	34,375	1,842,404	2,012,706
TOTAL			**99,915,188**	**100**		**7,908,853**		

(*) Percentages in this table are calculated in reference to a share capital of 99,915,188 Valneva SE shares, divided into (a) 99,894,674 ordinary shares (ISIN FR0004056851) with a par value of €0.15 each, and (b) 20,514 preferred shares convertible into ordinary shares (XFCS00X0I9M1), also with a par value of €0.15 each.

*(**) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

(***) The conversion ratios of the various dilutive instruments are set as follows:

- *Stock options: for plan 7, 1 stock option entitles to 1.099617653 Valneva SE ordinary shares (then rounded up for each beneficiary), while for plans 8, 9, 10 and 11, 1 option entitles to 1 Valneva SE ordinary share;*
- *BSA 27: 1 BSA entitles to 1 Valneva SE ordinary share;*
- *Free convertible preferred shares: the conversion of free convertible preferred shares into ordinary shares is carried out by multiplying the number of FCPS granted by 62 (maximum conversion ratio according to the rules of the Free convertible preferred share program 2017-2021).*

Valneva SE shareholding after exercise or full vesting (and, if applicable, conversion) of dilutive instruments

		Valneva SE ordinary shares	%
Groupe Grimaud La Corbière SAS(*)		**13,704,831**	**12.71**
Bpifrance Participations SA		**8,971,361**	**8.32**
Management Board members	**Total Management Board members**	**2,748,078**	**2.55**
	Mr. Franck Grimaud	1,146,783	1.06
	Mr. Thomas Lingelbach	1,028,564	0.95
	Mr. Frédéric Jacotot	572,731	0.53
	Mr. Juan Carlos Jaramillo	0	0
Employees (non-corporate officers)		**5,211,438**	**4.83**
Other shareholders (private individuals)		**1,752,309**	**1.63**
Including members of the Grimaud family (including Mr. Frédéric Grimaud, Chairman of the Supervisory Board) and Financière Grand Champ SAS (*)		713,742	0.66
Including independent members of the Supervisory Board	Mr. James Sulat	30,367	0.03
	Ms. Anne-Marie Graffin	14,250	0.01
Other floating capital		**75,415,510**	**69.96**
TOTAL		**107,803,527**	**100**

*(*) The **Groupe Familial Grimaud** is comprised of the company Groupe Grimaud La Corbière SAS, the private shareholders of the Grimaud family and the company Financière Grand Champ SAS.*

2.1.3. Share capital changes

Section 5.1.6 of the 2020 URD is completed with the following information:

DATE	Nature of the share capital change	Share composing the share capital	Share capital after capital change
05/06/2021	**Capital increase by way of cash contribution** ▪ **Issuance of 7,082,762 Valneva SE ordinary shares** with a par value of €0.15 each ▪ **Total amount paid to the Company: €77,910,382** (including €1,062,414.30 in par value and €76,847,967.70 as issue premium)	**98,846,524 Valneva SE shares** Including: ▪ 98,826,010 ordinary shares with a par value of €0.15 each ▪ 20,514 preferred shares convertible into ordinary shares, with a par value of €0.15 each	**€14,826,978.60**
05/07/2021	**Capital increase by way of cash contribution** ▪ **Issuance of 1,062,414 Valneva SE ordinary shares** with a par value of €0.15 each ▪ **Total amount paid to the Company: €11,686,554** (including €159,362.10 in par value and €11,527,191.90 as issue premium)	**99,908,938 Valneva SE shares** Including: ▪ 99,888,424 ordinary shares with a par value of €0.15 each ▪ 20,514 preferred shares convertible into ordinary shares, with a par value of €0.15 each	**€14,986,340.70**
08/26/2021	**Capital increase by cash contribution on August 19, 2021** ▪ **Issuance of 3,125 Valneva SE ordinary shares** with a nominal value of €0.15 each ▪ **Total amount paid to the Company: €8,043.75** (including €468.75 in par value and €7,575 as issue premium)	**99,912,063 Valneva SE shares** Including: ▪ 99,891,549 ordinary shares with a par value of €0.15 each ▪ 20,514 preferred shares convertible into ordinary shares, with a par value of €0.15 each	**€14,986,809.45**
09/03/2021	**Capital increase by cash contribution on September 2, 2021** ▪ **Issuance of 3,125 Valneva SE ordinary shares** with a nominal value of €0.15 each ▪ **Total amount paid to the Company: €8,043.75** (including €468.75 in par value and €7,575 as issue premium)	**99,915,188 Valneva SE shares** Including: ▪ 99,894,674 ordinary shares with a par value of €0.15 each ▪ 20,514 preferred shares convertible into ordinary shares, with a par value of €0.15 each	**€14,987,278.20**
10/04/2021	**Capital reduction by cancellation of shares** ▪ **Cancellation of 4,025 Valneva SE ordinary shares** with a nominal value of €0.15 each ▪ **Capital reduction in nominal value: €603.75**	**99,911,163 Valneva SE shares** Including: ▪ 99,890,649 ordinary shares with a par value of €0.15 each ▪ 20,514 preferred shares convertible into ordinary shares, with a par value of €0.15 each	**€14,986,674.45**

2.2. Main shareholders

2.2.1. Shareholding structure

Section 5.2.1 of the 2020 URD is completed with the information included in Section 2.1.1 of this Amendment 1.

2.2.2. Direct or indirect shareholdings in the Company's share capital, of which the Company has been informed pursuant to Articles L. 233-7 and L. 233-12 of the French Commercial Code

Section 5.2.2 of the 2020 URD is completed with the following information:

Groupe Grimaud La Corbière

On June 10, 2021, the *Groupe Familial Grimaud* declared that on June 7, 2021, it had crossed below the threshold of 15% of the Company's share capital and held, on that date and on June 10, 2021, 14,436,278 Valneva SE shares representing 28,830,009 voting rights, *i.e.*, 14.45% of the capital and 22.70% of the voting rights of the Company[1], distributed as follows:

	Ordinary shares	%	Theoretical Voting rights	%
Groupe Grimaud La Corbière SAS	13,704,830	13.72	27,409,660	21.58
Frédéric Grimaud	264,246	0.26	519,190	0.41
Financière Grand Champ SAS	193,977	0.19	387,954	0.31
Joseph Grimaud	137,831	0;14	244,346	0.19
Marie-Thérèse Grimaud	69,230	0.07	138,460	0.11
Renée Grimaud	64,135	0.06	128,270	0.10
Agnès Grimaud	1,022	ns	1,022	ns
Anne-Marie Grimaud	779	ns	779	ns
Thomas Grimaud	100	ns	200	ns
Bruno Grimaud	66	ns	66	ns
Odile Grimaud	62	ns	62	ns
TOTAL GRIMAUD FAMILY GROUP	**14,436,278**	**14.45**	**28,830,009**	**22.70**

This threshold crossing was the result of a capital increase by Valneva SE.

[1] Based on a share capital of 99,908,938 shares, representing 126,995,096 voting rights.
[2] See Section 1.1.2 (r) of this Amendment 1.

MVM Fund

On April 12, 2021, MVM IV LP and MVM GP (No. 4) Scottish LP (together, the ***MVM Funds***) declared that on April 6, 2021, through MVM Partners LLP, they had crossed below the threshold of 10% of the Company's voting rights and held 5,950,617 Valneva SE shares representing 10,843,382 voting rights, *i.e.*, 6.48% of the share capital and 8.93% of the voting rights of the Company[1], distributed as follows:

	Ordinary share	%	Theoretical voting rights	%
MVM IV LP	5,770,295	6.29	10,514,794	8.66
MVM GP (No. 4) Scottish LP	180,322	0.20	328,588	0.27
TOTAL MVM PARTNERS LLP	**5,950,617**	**6.48**	**10,843,382**	**8.93**

This threshold was crossed as a result of an off-market sale of Valneva SE shares.

On September 3, 2021, the MVM Funds declared that on August 16, 2021, through MVM Partners LLP, they had crossed below the threshold of 5% of the Company's voting rights and that, on that date, they held 5,297,122 Valneva SE shares representing the same number of voting rights, *i.e.*, 5.30% of the share capital and 4.17% of the voting rights of the Company[2], distributed as follows:

	Ordinary shares	%	Theoretical voting rights	%
MVM IV LP	5,136,602	5.14	5,136,602	4.04
MVM GP (No. 4) Scottish LP	160,520	0.16	160,520	0.13
TOTAL MVM PARTNERS LLP	**5,297,122**	**5.30**	**5,297,122**	**4.17**

This threshold crossing resulted from the loss of double voting rights following the conversion of Valneva SE shares into bearer shares.

As a result of this loss of double voting rights, as of August 25, 2021, the MVM Funds held 4,797,122 Valneva SE shares representing the same number of voting rights, *i.e.* 4.80% of the share capital and 3.78% of the voting rights of the Company[3], distributed as follows:

	Ordinary shares	%	Theoretical voting rights	%
MVM IV LP	4,651,754	4.66	4,651,754	3.66
MVM GP (No. 4) Scottish LP	145,368	0.15	145,368	0.11
TOTAL MVM PARTNERS LLP	**4,797,122**	**4.80**	**4,797,122**	**3.78**

Finally, the MVM Funds have indicated that, as of September 3, 2021, they held 2,628,141 Valneva SE shares representing the same number of voting rights, *i.e.* 2.63% of the share capital and 2.07% of the voting rights of the Company[4], distributed as follows:

	Ordinary shares	%	Theoretical voting rights	%
MVM IV LP	2,548,500	2.55	2,548,500	2.01
MVM GP (No. 4) Scottish LP	79,641	0.08	79,641	0.06
TOTAL MVM PARTNERS LLP	**2,628,141**	**2.63**	**2,628,141**	**2.07**

[1] Based on a share capital of 91,763,762 shares, representing 121,400,867 voting rights.
[2] Based on a share capital of 99,908,938 shares, representing 126,993,094 voting rights.
[3] *Idem.*
[4] *Idem.*

2.2.3. Changes in share ownership over the past three fiscal years

Section 5.2.3 of the 2020 URD is completed with the information included in Section 2.1.1 of this Amendment 1.

2.3. Information and history of the Company during the fiscal year

The paragraph "Significant events in the development of the issuer's activities" in Section 5.4 of the 2020 URD is updated with the information included in Sections 1.1.2, 1.3 and 1.4 of this Amendment 1.

3. Additional information

3.1. Declaration by the persons responsible for the French version of the Amendment to the Universal Registration Document

"We hereby declare that to the best of our knowledge, the information contained in this Amendment 1 to the 2020 Universal Registration Document is in accordance with the facts and contains no omission likely to affect its import."

Thomas LINGELBACH

President & CEO

Franck GRIMAUD

President & CBO

3.2. Documents publicly available

The information published on the website referred to below does not form part of this Amendment 1. As such, it has not been reviewed or approved by the AMF.

- https://www.cdc.gov/lyme/stats/humancases.html (see page 23)

3.3. Table of concordance with the Universal Registration Document (Commission Delegated Regulation (EC) 2019/980 of March 14, 2019)

This table of concordance lists the headings provided for in Annexes I and II of the Commission Delegated Regulation (EC) 2019/980 of March 14, 2019 and refers to the Sections and pages of the 2020 URD, as well as of this Amendment 1, where the information relating to each of these headings is provided.

Required disclosure (pursuant to Delegated Regulation (EC) 2019/980		Section(s) of the 2020 URD	Page(s)	Section(s) of this Amendment 1 to the 2020 URD	Page(s)
1. RESPONSIBLE PERSONS, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL					
1.1.	Persons responsible for the information provided in this URD.	6.1.1 & 6.1.2	348	3.1	88
1.2.	Responsibility statement.	6.1.1	348	3.1	88
1.3. 1.4.	Third party information, expert reports and declarations of interest.	6.2	349	n.a.	
1.5.	Approval by the competent authority.	n.a.		n.a.	
2. STATUTORY AUDITORS					
2.1.	Names and addresses of the Statutory auditors.	6.1.3	348	n.a.	
2.2.	Changes of Statutory auditors.	n.a. (no change in 2020)	348	n.a.	
3. RISK FACTORS		1.5	62	1.5	57
4. INFORMATION ABOUT THE ISSUER					
4.1.	Legal and commercial name of the issuer.	5.4	334	n.a.	
4.2.	Place of registration of the issuer, its registration number and legal entity identifier (LEI).	5.4	334	n.a.	
4.3.	Date of incorporation and length of life of the issuer.	5.4	334	n.a.	
4.4.	Registered office (including related contact details), legal form, applicable legislation, website (and related disclaimer) of the issuer.	5.4	334	n.a.	
5. BUSINESS OVERVIEW					
5.1.	Principal activities:				
5.1.1.	Nature of the issuer's operations and its principal activities.	1.3.1	23	1.2.1 and 1.3.1	14 and 17
5.1.2.	Significant new products and/or services launched on the market.	1.1.2, 1.1.3 & 1.3.1	10, 15 & 23	1.1.2 and 1.3.1	8 and 17
5.2.	Principal markets.	1.3.2 (a) Notes 4.2 and 5.1 to the Group's consolidated financial statements for the fiscal year 2020, in Section 4.1.5	25 218 & 221	n.a.	
5.3.	Significant events in the development of the issuer's activity.	1.1.2, 1.1.3, 1.2.2 (b), 1.3.1, 1.3.2 (a) & 1.4.4 - upon referral by Sections 1.2.1 (b) & 5.4	10, 15, 20, 23, 25 & 57	1.1.2 (upon referral by Section 1.4.4 (b)), 1.3.2 and 1.4.2	8, 18 and 43
5.4.	Strategy and objectives.	1.3.2 (b), 1.4.4 (a) & 1.4.4 (c)	27 & 57	1.4.4 (c)	54
5.5.	Dependence of the Group on patents, licenses, industrial, commercial or financial agreements, or on new manufacturing processes.	1.5 - upon referral by Section 1.3.3 (c)	62	1.5 – upon referral by Section 1.3.3 (c)	57
5.6.	Competitive position.	1.3.2 (a)	25	n.a.	

Required disclosure (pursuant to Delegated Regulation (EC) 2019/980		Section(s) of the 2020 URD	Page(s)	Section(s) of this Amendment 1 to the 2020 URD	Page(s)
5.7.	Investments:				
5.7.1.	Material investments made by the issuer.	1.3.4 (a) & (b)	40	1.3.4	41
5.7.2.	Material investments in progress or firm commitments taken in this respect.	1.3.4 (c)	40	n.a.	
5.7.3.	Joint ventures and significant shareholding affecting the issuers' situation.	n.a.		n.a.	
5.7.4.	Environmental issue that may affect the issuer's use of the tangible fixed assets.	3	161	n.a.	
6. ORGANIZATIONAL STRUCTURE					
6.1.	Summarized description of the Group.	1.2.2	19	1.2.2	15
6.2.	List of issuer's significant subsidiaries.	1.2.2 (b)	20	1.2.2	15
7. OPERATING AND FINANCIAL REVIEW					
7.1.	Financial condition:				
7.1.1.	Fair review of the development and performance of the issuer's business.	1.4.1 & 1.4.3	41 & 50	1.4.1 and 1.4.3	42 and 46
7.1.2.	Issuer's likely future development, research and development activities.	1.3.3, 1.4.4	28 & 57	1.3.2, 1.3.3 and 1.4.2 (b)	18, 19 and 43
7.2.	Operating results:				
7.2.1.	Significant factors materially affecting the issuer's operating results.	1.4.1 & 1.4.3	41 & 50	1.4.1 and 1.4.3	42 and 46
7.2.2.	Explanation of material changes in the financial statements.	1.4.1 & 1.4.3	41 & 50	1.4.1 and 1.4.3	42 and 46
8. CAPITAL RESOURCES					
8.1.	Issuer's capital resources (short-term and long-term).	1.4.5 (a)	58	1.4.5 (a)	55
8.2.	Sources, amounts and description of the issuer's cash flows.	1.4.5 (b)	58	1.4.5 (b)	55
8.3.	Borrowing requirements and funding structure of the issuer.	1.4.5 (a) & (c)	58 & 59	1.4.5 (a)	55
8.4.	Restriction on the use of capital resources.	1.4.5 (a)	58	n.a.	
8.5.	Anticipated sources of funds needed to fulfil commitments of item 5.7.2 above.	1.4.5 (c)	59	n.a.	
9. REGULATORY ENVIRONMENT					
9.1.	Description of the regulatory environment and of the factors having an impact on the issuer's activities.	1.2.1 (c)	17	1.2.1 (c)	14
10. TRENDS					
10.1.	Most significant recent trends. Significant changes in the Group's financial performance since end of the last fiscal year.	1.1.3 - upon referral by Section 1.4.4 (b) Note 34 to the Group's consolidated financial statements for the fiscal year 2020, in Section 4.1.5	15 259	1.4.4	54
10.2.	Information on any known trends that may have affect the issuer's prospects, for at least the current fiscal year.	1.1.3 & 1.4.4 Note 34 to the Group's consolidated financial statements for the fiscal year 2020, in Section 4.1.5	15 & 57 259	1.1.2 and 1.4.4	8 and 54

Required disclosure (pursuant to Delegated Regulation (EC) 2019/980		Section(s) of the 2020 URD	Page(s)	Section(s) of this Amendment 1 to the 2020 URD	Page(s)
11. PROFIT FORECAST OR ESTIMATE					
11.1.	Forecast or estimate in progress, published.	n.a.		n.a.	
11.2.	Principal assumptions.	n.a.		n.a.	
11.3.	Statement on published forecasts or estimates.	n.a.		n.a.	
12. MANAGEMENT AND SUPERVISORY BODIES, EXECUTIVE MANAGEMENT					
12.1	Information on the Management and Supervisory Board members.	2.1.1, 2.1.2 & 2.1.4	75, 79 & 94	1.1.2 (s)	13
12.2.	Conflicts of interest. Arrangement or agreement for selection as a member of a management or supervisory body or as a member of executive management. Details of any agreed restrictions of their holdings in the issuer's share capital.	2.1.4	94	n.a.	
13. REMUNERATION AND BENEFITS					
13.1.	Remuneration and benefits paid or granted.	2.6.2	104	n.a.	
13.2.	Accruals to provide retirement or other similar benefits.	2.6.2.1 (b) & (d)	110 & 128	n.a.	
14. MANAGEMENT AND SUPERVISORY BODIES OPERATION					
14.1.	Date of expiration of current terms of office.	2.1	75	n.a.	
14.2.	Service agreements.	2.1.3 (c)	94	n.a.	
14.3.	Information about the issuer's special Committees.	2.2.5	98	n.a.	
14.4.	Compliance with the applicable incorporation corporate governance regime.	2 (Preliminary statements)	74	n.a.	
14.5.	Potential significant impacts and future changes on corporate governance.	n.a. - however on the prospect of a change in governance structure, see Section 2.6.1	106	n.a.	
15. EMPLOYEES					
15.1.	Breakdown of employees.	1.2.2 (b) & 1.4.1 (b)	20 & 44	n.a.	
15.2.	Shareholdings and stock options.	2.6.2.1 (c) & 5.7.1	117 & 343	2.1.2	68
15.3.	Arrangement involving the employees in the capital of the issuer.	5.7.2	344	n.a.	
16. MAIN SHAREHOLDERS					
16.1.	Shareholdings declared in accordance with Articles L. 233-7 and L. 233-12 of the French Commercial Code.	2.7.3 - upon referral by Section 5.2.2	146	2.2.2	83
16.2.	Principal shareholders of the issuer with different voting rights.	5.2.1	325	2.1.1 – upon referral by Section 2.2.1	66
16.3.	Direct or indirect ownership or control of the issuer.	5.2.5	326	n.a.	
16.4.	Arrangements which could result in a change of control of the issuer.	2.7.9 - upon referral by Sections 5.2.6 & 5.3.6	155	n.a.	

Required disclosure (pursuant to Delegated Regulation (EC) 2019/980		Section(s) of the 2020 URD	Page(s)	Section(s) of this Amendment 1 to the 2020 URD	Page(s)
17. RELATED PARTY TRANSACTIONS		Section 4.2.5 (b) of the parent entity financial statements for the fiscal year 2020 Note 33 to the Group's consolidated financial statements for the fiscal year 2020, in Section 4.1.5 - upon referral by Section 5.6.3	300 258	Statement in Section 1.6 of the Group's Half-Year Financial Report published on August 10, 2021; Note 26 to the condensed consolidated interim financial statements for the six months ended June 30, 2021	
18. FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES					
18.1.	Historical financial information:				
18.1.1.	Audited historical financial information.	4.1 & 4.2 Incorporation by reference of information with respect to the fiscal years 2018 and 2019	202 & 265	n.a.	
18.1.2.	Change of accounting reference date.	n.a. (none)		n.a. (none)	
18.1.3.	Accounting standards.	4.1 & 4.2	202 & 265	n.a.	
18.1.4.	Change of accounting framework.	n.a. (none)		n.a. (none)	
18.1.5.	Parent entity financial statements.	4.2	265	n.a.	
18.1.6.	Consolidated financial statements.	4.1	202	n.a.	
18.1.7.	Latest financial information.	4.1 & 4.2	202 & 265	n.a.	
18.2.	Interim and other financial information.	n.a.		Sections 2 and 3 of the Group's Half-Year Financial Report published on August 10, 2021	
18.3.	Audit of historical annual financial information:				
18.3.1.	Independent audit of historical annual financial information.	4.1.6 & 4.2.6	260 & 307	n.a.	
18.3.2.	Other audits conducted on this URD.	n.a. - However, see Section 3.13 for the Independent Third Party Auditor's report on the CSR report	197	n.a.	
18.3.3	Unaudited financial information.	1.3.4 (a)	40	n.a.	
18.4.	Pro forma financial information.	4.3 (none)	311	n.a.	
18.5.	Policy on dividend:				
18.5.1.	Applicable policy and restrictions.	n.a. (see Section 1.4.9)	61	n.a.	
18.5.2.	Amount of dividend per share.	n.a. (see Section 1.4.9)	61	n.a.	
18.6.	Legal and arbitration proceedings.	1.5.3	66	1.5.3	63
18.7.	Significant change in the Group's financial position which has occurred since the end of the last financial period for which either audited financial statements or interim financial information have been published.	1.1.3 - upon referral by Section 1.4.4 (b) Note 34 to the Group's consolidated statements for the fiscal year 2020, in Section 4.1.5 Section 4.2.5 (f) of the parent entity financial statements for the fiscal year 2020	15 259 306	1.4.4 (b)	54

Required disclosure (pursuant to Delegated Regulation (EC) 2019/980		Section(s) of the 2020 URD	Page(s)	Section(s) of this Amendment 1 to the 2020 URD	Page(s)
19. ADDITIONAL INFORMATION					
19.1.	Share capital:				
19.1.1.	Information of the amount of issued capital.	2.7.1 & 5.1.1 Note 22 to the Group's consolidated statements for the fiscal year 2020, in Section 4.1.5	142 & 314 243	2.1.1	66
19.1.2.	Non-equity shares.	5.1.2	314	n.a.	
19.1.3.	Treasury stock.	5.1.3	314	1.1.2 (u)	13
19.1.4.	Convertible securities, exchangeable securities or securities with warrants.	2.6.2.1 (c) & 2.6.2.2 (b) -upon referral by Section 5.1.4	117 & 138	2.1.2	68
19.1.5.	Information about and terms of any acquisition rights and/or obligations over authorized, but not fully paid, capital or an undertaking to increase the capital.	2.6.2.1 (c) - upon referral by Section 5.1.4, 2.7.8.1 & 2.7.8.3 - upon referral by Section 5.1.5	117 150 & 152	2.1.2	68
19.1.6.	Information about any capital of any member of the Group which is under option or agreed to be put under option.	2.6.2.1 (c) - upon referral by Section 5.1.4 (a)	117	2.1.2	68
19.1.7.	Share capital history.	5.1.6	322	2.1.3	82
19.2.	Memorandum and Articles of Association:				
19.2.1.	Issuer's corporate purpose.	5.3.1	327	n.a.	
19.2.2.	Rights, preferences and restrictions attached to each category of shares.	5.3.3	327	n.a.	
19.2.3.	Any provision of the issuer's articles of association that would have an effect of delaying, deferring or preventing a change in control of the issuer.	5.3.6	333	n.a.	
20. MATERIAL AGREEMENTS		1.4.2	45	1.4.2	43
21. AVAILABLE DOCUMENTS		6.3	349	3.2	89

A European Company *(Societas Europaea)*
with a Management Board and a Supervisory Board
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Nantes Trade and Companies Registry (R.C.S.) No. 422 497 560