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

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE  
ACT OF 1934**

**Date of Report: May 21, 2021**

Commission File Number: **001-40377**

**Valneva SE**

(Translation of registrant's name into English)

**6 rue Alain Bombard**

**44800 Saint-Herblain, France**

**(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F [  ]    Form 40-F [  ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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On May 19 and 20, 2021, the Registrant issued press releases and a presentation, copies of which are attached hereto as Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3 and are incorporated herein by reference.

**Exhibits**

[99.1](#) [Press release dated May 19, 2021](#)

[99.2](#) [Press release dated May 20, 2021](#)

[99.3](#) [Presentation dated May 20, 2021](#)

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Valneva SE  
(Registrant)

Date: May 21, 2021

/s/ Thomas Lingelbach  
Thomas Lingelbach  
Chief Executive Officer and President

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

**Saint-Herblain (France), May 19, 2021** – Valneva SE, a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced it will participate in a UK government-funded clinical trial looking at different COVID-19 ‘booster’ vaccines that launches today.

The Cov-Boost trial, led by University Hospital Southampton NHS Foundation Trust, will look at seven different COVID-19 vaccines, including Valneva’s inactivated vaccine VLA2001, as potential boosters. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus.

The vaccines will be given at least three months after a second dose as part of the ongoing vaccination programme. One booster will be provided to each volunteer and could be a different brand to the one they were originally vaccinated with. The trial will also include a control group.

Initial results from the trial, expected in September, will help inform decisions by the UK Joint Committee on Vaccination and Immunisation (JCVI) on any potential booster programme from autumn this year, ensuring the UK’s most vulnerable people are given the strongest possible protection over the winter period.

**Thomas Lingelbach, Chief Executive Officer of Valneva**, commented, “*We are pleased to be involved in this new Cov-Boost trial. Valneva has the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe and we believe our VLA2001 vaccine has an important role to play in the ongoing pandemic, including as a booster. We remain fully committed to completing development and bringing our inactivated vaccine solution to the market.*”

In parallel to the Cov-Boost trial, Valneva will continue working on its pivotal Phase 3 clinical trial “Cov-Compare”, (VLA2001-301) which the Company launched in April 2021<sup>1</sup>. This trial compares Valneva’s SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca’s conditionally approved vaccine, Vaxzevria<sup>2</sup>. Recruitment for the trial, conducted in the U.K. and supported by the National Institute for Health Research (NIHR), is ongoing (<https://www.ukcovid19study.com/>). Subject to successful Phase 3 data, Valneva aims to make regulatory submissions for initial approval in the autumn of 2021.

### About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines. VLA2001 is produced on Valneva’s established Vero-cell platform, leveraging the manufacturing technology for Valneva’s licensed Japanese encephalitis vaccine, IXIARO<sup>®</sup>. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. This adjuvant combination has consistently induced higher antibody levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. CpG 1018 adjuvant, supplied by Dynavax Technologies Corporation (Nasdaq: DVAX), is a component of the US FDA- and EMA-approved HEPLISAV-B<sup>®</sup> vaccine. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

### About Valneva SE

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

### Valneva Investor and Media Contacts

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### Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates and estimates for future performance. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be sustained in the future. In some cases, you can identify forward-looking statements by words such as “could,” “should,” “may,” “expects,” “anticipates,” “believes,” “intends,” “estimates,” “aims,” “targets,” or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

<sup>1</sup> Valneva Initiates Phase 3 Clinical Trial for its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

<sup>2</sup> Approved by MHRA under reg. 174 and by the European Commission as conditional approval

## Valneva Reports Q1 2021 Financial Results and Business Update

### Excellent progress on clinical programs in the first quarter of 2021 for:

- VLA15, currently the only clinical stage vaccine candidate against Lyme disease
  - Initiation of additional Phase 2 trial to accelerate pediatric development
- VLA2001, currently the only inactivated, adjuvanted vaccine candidate for COVID-19 in clinical trials in Europe:
  - Initiation of pivotal Phase 3 clinical trial
  - Participation in the world's first COVID-19 vaccine booster trial in the UK
  - Publication of Phase 1/2 results
- VLA1553, currently the only Phase 3 chikungunya vaccine program worldwide
  - Recruitment completion for pivotal Phase 3 trial
- **Successful Nasdaq listing (Q2 event); \$107.6 million of gross proceeds raised in a US initial public offering and a concurrent private placement in Europe**
- **Cash and cash equivalents of €235.9 million at March 31, 2021**
  - Q1 2021 cash and cash equivalents do not include proceeds of \$107.6 million from the Company's recent Global Offering
- **Total revenue of €23.2 million in the first quarter of 2021 compared to €35.2 million in the first quarter of 2020**
  - Product sales of €16.1 million in the first quarter of 2021 (€32.7 million in the first quarter of 2020), affected by the COVID-19 pandemic impact on the travel industry
  - €7.1 million of Other Revenues (revenues from collaborations, licensing and services) in the first quarter of 2021 (€2.5 million in the first quarter of 2020)
- **EBITDA<sup>1</sup> loss of €28.3 million in the first quarter of 2021 reflecting increased R&D investment in clinical stage programs, and lower sales (compared to EBITDA profit of €2.4 million in Q1 2020)**
  - R&D investment increased to €27.7 million in the first quarter of 2021 compared to €13.3 million in the first quarter of 2020

### FY 2021 financial guidance updated

Updated guidance, excluding VLA2001 related activities (including revenue, costs of goods sold, R&D investments), for full-year 2021:

- Total revenues, excluding VLA2001, of €80 million to €105 million
  - Range modified noting that, despite initial signs of recovery in travel vaccine sales being seen, the 2021 outlook remains soft
- R&D expenses, excluding VLA2001, of €65 million to €75 million

**Thomas Lingelbach, Valneva's Chief Executive Officer**, commented, "*Valneva continues to achieve significant R&D milestones thanks to the huge efforts of our team and our partners. Our recent successful Nasdaq listing marks a significant strategic step for Valneva as we look forward. I would like to take this opportunity to thank our existing and new shareholders, partners and employees for their support and contribution to our journey. We are now in a strong position to continue to execute our key programs and continue to build shareholder value.*"

### Financial Information

(unaudited results, consolidated under IFRS)

€ in million	3 months ending March 31	
	2021	2020
Total revenues	23.2	35.2
Product sales	16.1	32.7
Net profit/(loss)	(27.7)	(1.2)
EBITDA	(28.3)	2.4
Cash	235.9	80.8

**Saint Herblain (France), May 20, 2021** – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, reported today its first quarter financial results ending March 31, 2021. The condensed consolidated interim financial results are available on the Company's website [www.valneva.com](http://www.valneva.com).

Valneva will provide a live webcast of its first quarter financial results conference call beginning at 3 p.m. CET today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/bhohhzn6>

### Commercial Vaccines

#### JAPANESE ENCEPHALITIS VACCINE (IXIARO<sup>®</sup>/JESPECT<sup>®</sup>)

IXIARO<sup>®</sup> is the only Japanese encephalitis vaccine licensed and available in the United States, Canada and Europe.

Sales of IXIARO<sup>®</sup> were €13.3 million in the first quarter of 2021 compared to €22.9 million in the first quarter of 2020. First quarter 2021 sales were affected by the COVID-19 pandemic's impact on the travel industry.

#### CHOLERA / ETEC<sup>2</sup>-DIARRHEA VACCINE (DUKORAL<sup>®</sup>)

DUKORAL<sup>®</sup> is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. DUKORAL<sup>®</sup> is authorized for use in the European Union and Australia to protect against cholera and in Canada, Switzerland, New Zealand and Thailand to protect against cholera and ETEC<sup>8</sup>.

DUKORAL<sup>®</sup> recorded sales of €0.1 million in the first quarter of 2021 compared to €9.7 million in the first quarter of 2020. First quarter 2021 sales were significantly affected by the COVID-19 pandemic impact on the travel industry.

### Clinical Stage Vaccine Candidates

## **LYME DISEASE VACCINE CANDIDATE – VLA15**

### **Acceleration of pediatric development**

Valneva is developing VLA15, a vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is the only vaccine undergoing clinical trials against Lyme disease.

Valneva announced a collaboration with Pfizer for late phase development and, if approved, commercialization of VLA15<sup>3</sup>. Valneva has reported positive initial results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults.

As part of the collaboration with Pfizer, Valneva announced in December 2020<sup>4</sup> that it had accelerated VLA15's pediatric development with the initiation of an additional Phase 2 clinical trial, VLA15-221. The dosing of the first trial participant in March 2021<sup>5</sup> triggered a milestone payment from Pfizer of \$10 million that was received in the second quarter of 2021. Initial pediatric data are expected by mid-2022.

## **SARS-CoV-2 VACCINE CANDIDATE – VLA2001**

### **Pivotal Phase 3 clinical trial initiated**

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.

In April 2021, Valneva reported initial data from the Phase 1/2 clinical trial in which VLA2001 showed high immunogenicity and was generally well tolerated, with no safety concerns identified.

The Company initiated a pivotal Phase 3 clinical trial in April 2021 and aims to make initial regulatory licensure submissions in the autumn of 2021. In parallel, Valneva has developed viral seed banks, including South African and Kent, to be in a position to manufacture variant-based vaccines.

Valneva also announced yesterday that it is participating in a UK government-funded clinical trial looking at different COVID-19 'booster' vaccines. The Cov-Boost trial, led by University Hospital Southampton NHS Foundation Trust, will look at seven different COVID-19 vaccines, including Valneva's inactivated vaccine VLA2001, as potential boosters. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus.

The vaccines will be given at least three months after a second dose as part of the ongoing vaccination programme. One booster will be provided to each volunteer and could be a different brand to the one they were originally vaccinated with. The trial will also include a control group.

Initial results from the trial, expected in September, will help inform decisions by the UK Joint Committee on Vaccination and Immunisation (JCVI) on any potential booster programme from autumn this year, ensuring the UK's most vulnerable people are given the strongest possible protection over the winter period.

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 will play a role in the overall portfolio of SARS-CoV-2 vaccines that will address the global need during the pandemic and in the future.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025<sup>6</sup>. So far, the UK Government has ordered 100 million doses for supply in 2021 and 2022.

VLA2001 is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO<sup>®</sup>. Valneva has commenced production in parallel to the ongoing clinical development in order to prepare for deliveries of VLA2001 following approval, if received.

## **CHIKUNGUNYA VACCINE CANDIDATE – VLA1553**

### **Pivotal Phase 3 clinical trial initiated**

VLA1553 is a vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available and, to Valneva's knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials worldwide.

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.

The pivotal Phase 3 trial, VLA1553-301, was initiated in September 2020. The primary objective of the trial is to evaluate the immunogenicity and safety of VLA1553 at 28 days following a single immunization. A total of 4,131 adults aged 18 or above have been recruited across 44 sites in the United States<sup>7</sup>. Valneva has also initiated a clinical lot-to-lot consistency trial to show manufacturing consistency of the vaccine and an antibody persistence trial that will follow the immunogenicity subset for a period of up to five years.

The FDA has confirmed that Valneva can seek licensure through the FDA's accelerated approval pathway. Therefore, the Company plans to seek licensure of the vaccine based on a surrogate of protection that is expected to reasonably predict protection from chikungunya infection.

VLA1553 received Fast Track designation from the FDA and PRIME designation from the European Medicines Agency. The sponsor of the first chikungunya vaccine Biologics License Application to be approved in the United States may be eligible to receive a Priority Review Voucher.

To make VLA1553 accessible to Low and Middle Income Countries (LMIC), Valneva and the Butantan Institute in Brazil entered into a collaboration agreement in January 2021 for the development, manufacturing and marketing of VLA1553<sup>8</sup>. The collaboration falls within the framework of the \$23.4 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019<sup>9</sup>.

## **First Quarter 2021 Financial Review**

(Unaudited, consolidated under IFRS)

### **Revenues**

Valneva's total revenues were €23.2 million in the first quarter of 2021 compared to €35.2 million in the first quarter of 2020.

Product sales declined by 50.7% to €16.1 million in the first quarter of 2021 compared to €32.7 million in the first quarter of 2020. On a CER basis<sup>10</sup>, product sales declined by 47.8% in the first quarter of 2021 compared to the first quarter of 2020 due to the COVID-19 pandemic impact on the travel industry. IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales declined by 41.8% (37.2% at CER) to

€13.3 million and DUKORAL<sup>®</sup> sales by 98.9% (98.8% at CER) to €0.1 million in the first quarter of 2021 compared to €22.9 million and €9.7 million respectively in the first quarter of 2020. Third Party product sales grew to €2.7 million in the first quarter of 2021 from €0.1 million in the first quarter of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur/RabAvert and Encepur in certain territories that commenced in 2021.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €7.1 million in the first quarter of 2021 compared to €2.5 million in the first quarter of 2020. This increase is primarily attributable to the €2.6 million of revenues related to the Lyme R&D collaboration agreement with Pfizer which was the main driver for the increase in collaboration and licensing revenues.

### **Operating result and EBITDA**

Costs of goods and services sold (COGS) were €14.6 million in the first quarter of 2021. Gross margin on product sales was 41.7% compared to 67.3% in the first quarter of 2020. The decline was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €5.9 million were related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 55.9%. COGS of €1.7 million were related to DUKORAL<sup>®</sup> sales, causing a negative product gross margin. Of the remaining COGS in the first quarter of 2021, €1.9 million were related to the Third Party Product distribution business and €5.1 million were related to cost of services. In the first quarter of 2020, overall COGS were €12.8 million, of which €10.7 million related to cost of goods and €2.1 million related to cost of services.

Research and development investments continued to increase as planned in the first quarter of 2021, growing to €27.7 million compared to €13.3 million in the first quarter of 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine VLA2001 as well as Phase 3 clinical study costs for Valneva's chikungunya vaccine program VLA1553. Excluding COVID-19, research and development investments amounted to €12.1 million in the first quarter of 2021 compared to €13.1 million in the first quarter of 2020. Marketing and distribution expenses in the first quarter of 2021 amounted to €4.9 million compared to €6.0 million in the first quarter of 2020. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity as a result of the COVID-19 pandemic. Marketing and distribution expenses in the first quarter of 2021 notably included €1.2 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first quarter of 2020). In the first quarter of 2021, general and administrative expenses increased to €10.0 million from €5.2 million in the first quarter of 2020, mainly driven by increased costs to support corporate transactions and projects.

Other income, net of other expenses, increased to €3.0 million in the first quarter of 2021 from €2.2 million in the first quarter of 2020. This increase was mainly driven by increased R&D tax credits directly resulting from increased R&D spending.

Valneva recorded an operating loss of €31.1 million in the first quarter of 2021 compared to an operating profit of €0.1 million in the first quarter of 2020. EBITDA loss in the first quarter of 2021 was €28.3 million compared to an EBITDA profit of €2.4 million in the first quarter of 2020.

### **Net result**

In the first quarter of 2021, Valneva generated a net loss amounting to €27.7 million compared to a net loss of €1.2 million in the first quarter of 2020.

Finance costs and currency effects in the first quarter of 2021 resulted in a net finance income of €3.1 million, compared to a net finance expense of €2.2 million in the first quarter of 2020. This was mainly a result of foreign exchange gains amounting to €7.7 million in the first quarter of 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss of €1.0 million in the first quarter of 2020. Interest charges increased to €4.6 million in the first quarter of 2021 compared to €1.3 million in the same period of 2020. This growth was driven by increased interest charges related to the financing agreement with US healthcare funds Deerfield & Orbimed entered into in 2020 as well as interest charges related to refund liabilities.

### **Cash flow and liquidity**

Net cash generated by operating activities amounted to €47.6 million in the first quarter of 2021 compared to €3.0 million in the first quarter of 2020 mainly driven by milestone payments related to the COVID supply agreement concluded with the UK Government in September 2020.

Cash outflows from investing activities amounted to €16.9 million in the first quarter of 2021 compared to €0.6 million in the first quarter of 2020 mainly as a result of purchases of equipment related to the site expansion activities related to COVID manufacturing in both Scotland and Sweden.

Cash outflows from financing activities amounted to €1.6 million in the first quarter of 2021 and consisted of €3.4 million of interest payments as well as €2.2 million of cash proceeds related to issuance of new shares related to employee stock option programs. Cash inflows in the first quarter of 2020 amounted to €14.5 million and consisted of net proceeds from the financing arrangement with US healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank (EIB).

Liquid funds increased to €235.9 million as of March 31, 2021 compared to €204.4 million as of December 31, 2020. The main changes related to payments made by the UK Government within the framework of the UK COVID-19 partnership.

### **About Valneva SE**

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 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.

### **Valneva Investor and Media Contacts**

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### **Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to expected total revenues and R&D expenses for full fiscal year 2021, the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates and estimates for future performance. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future performance. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be

materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

## Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful as an aid to further understand Valneva's current performance, performance trends, and financial condition.

EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth below:

€ in million	3 months ending March 31	
	2021	2020
Operating (loss)/Profit	(31.1)	0.1
Add:		
Amortization	1.5	1.5
Depreciation	1.3	0.8
<b>EBITDA</b>	<b>(28.3)</b>	<b>2.4</b>

1 EBITDA is a non-IFRS financial measure. See "Non-IFRS Financial Measures" section included herein for more information regarding our use of EBITDA and a reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS.

2 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

3 Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

4 Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

5 Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate

6 Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program

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

8 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

9 CEPI awards up to \$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

10 CER: Constant Exchange Rate; First quarter 2020 actuals restated to first quarter 2021 average exchange rates



# Valneva Reports Q1 2021 Financial Results and Business Update

Analyst Presentation  
May 20, 2021





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### **Non-IFRS Financial Measures**

Management uses and presents IFRS results as well as the non-IFRS measure of EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful as an aid to further understand Valneva's current performance, performance trends, and financial condition.

EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth in this presentation.



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- **Excellent progress on clinical programs**
  - Initiation of additional Phase 2 trial to accelerate pediatric development for Lyme vaccine
  - Initiation of pivotal Phase 3 clinical trial for COVID-19 vaccine; participation in COVID-19 vaccine booster trial
  - Chikungunya pivotal Phase 3 trial recruitment completion
- **Successful Nasdaq listing (Q2); \$107.6 million of gross proceeds**
- **Cash / cash equivalents of €235.9 million at end of March (excluding proceeds from Global Offering)**
- **Q1 2021 total revenue of €23.2 million compared to €35.2 million in Q1 2020**





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# VLA15 – Multivalent Lyme Disease Vaccine Candidate

## Only Program in Advanced Clinical Development Today



1

FDA Fast Track Designation granted

2

Initial results reported from Phase 2 trials<sup>1, 2</sup>  
Accelerated pediatric trial (VLA15-221) initiated in March 2021<sup>3</sup>

3

Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe

4

Follows proven Mechanism of Action for a Lyme disease vaccine

5

Exclusive, worldwide partnership with Pfizer

<sup>1</sup>Valveva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate. <sup>2</sup>Valveva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. <sup>3</sup>Valveva announces acceleration of pediatric development for Lyme Disease vaccine candidate.



### **Phase 2 trial (VLA15-221) in adults and pediatric subjects initiated<sup>1</sup>**

- Trial to include participants from 5-65 years of age and a reduced immunization schedule (Month 0-6 compared to Month 0-2-6)
- The trial triggered a milestone payment of \$10 million, upon dosing of the first subject, from Pfizer to Valneva
- Initial pediatric population data expected in Q2 2022<sup>1</sup>
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the six Month dose<sup>1</sup>

### **Phase 3 pivotal efficacy trial planned to commence pending positive readout from VA15-221 in 2022<sup>1</sup>**

- Clinical readout, based on one tick season, projected end 2023

### **First licensure anticipated H1 2025, subject to regulatory approval**

<sup>1</sup>[Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate.](#)

# VLA2001 – The Only Inactivated Vaccine in Clinical Development in Europe : Adjuvanted with CpG1018



1

**UK government deal worth up to €1.4 billion<sup>1</sup> with development and manufacturing funding; ongoing dialogue with other potential customers**

2

**Program acceleration enabled through use of Valneva's FDA-registered facility in UK; commercial manufacturing commenced January 2021<sup>3</sup>**

3

**Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant<sup>4</sup>**

4

**Phase 1/2 clinical trial results reported<sup>5</sup>, Phase 3 ongoing**

5

**Regulatory submission to MHRA planned in autumn 2021, deliveries thereafter, subject to approval**

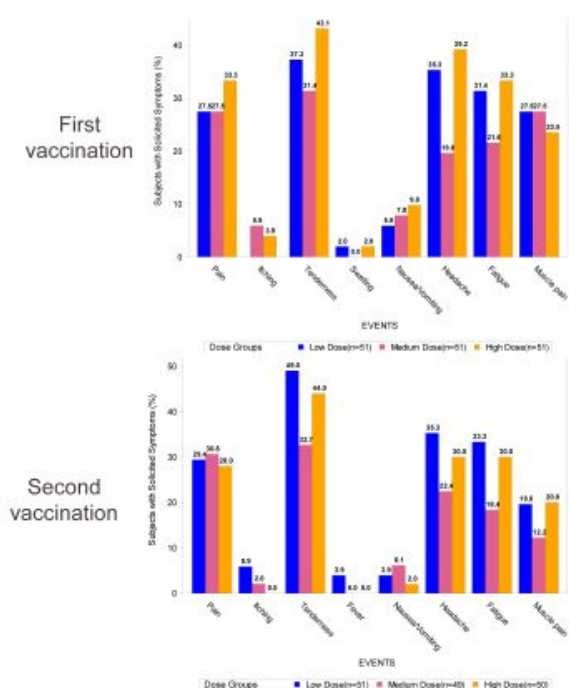
Note: Photo credit: CDC/Aissa Eckert, MSMI; Dan Higgins, MAM. <sup>1</sup> Valneva announces major COVID-19 vaccine partnership with U.K. Government. <sup>2</sup> Valneva in advanced discussion with European Commission to supply up to 60m doses of Inactivated, Adjuvanted COVID-19 vaccine candidate. <sup>3</sup> Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. <sup>4</sup> Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine. <sup>5</sup> Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001





## VLA2001 Was Well Tolerated in Phase 1/2

### Safety Profile Within the Expected Range for an Inactivated Vaccine



Safety Analysis Set, Figure 1.1.1 and 1.1.2, Table 14.2.1.2 and 14.2.1.3

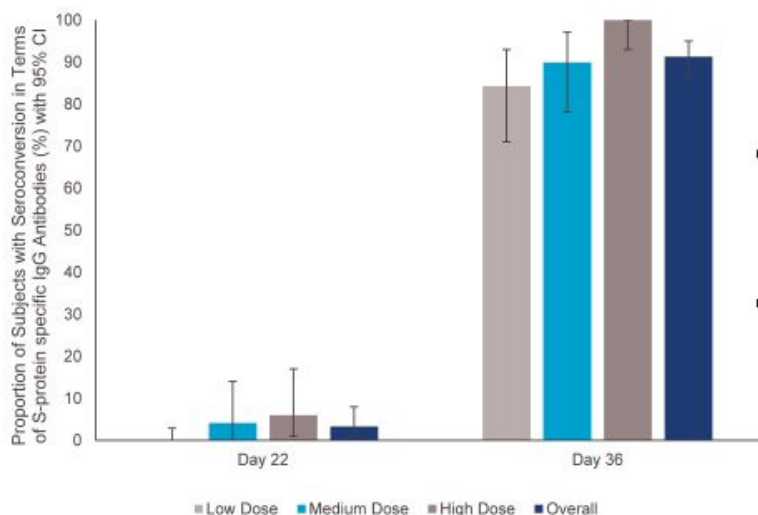
- Generally well tolerated across all dose groups tested, no safety concerns identified by an independent Data Safety Monitoring Board.
- No statistically significant differences between dose groups and no differences between first and second vaccinations in terms of reactogenicity.
- Majority of Adverse Events (AEs) were mild or moderate and only two subjects reported severe solicited AEs (headache and fatigue).
- All solicited AEs were transient.
- Only 17.6% of unsolicited AEs up to day 36 were considered related to the vaccine and no severe unsolicited AEs were reported.
- No serious related AEs.



## VLA2001 Was Highly Immunogenic in Phase 1/2

> 90% of Trial Participants Developed Significant Levels of Antibodies

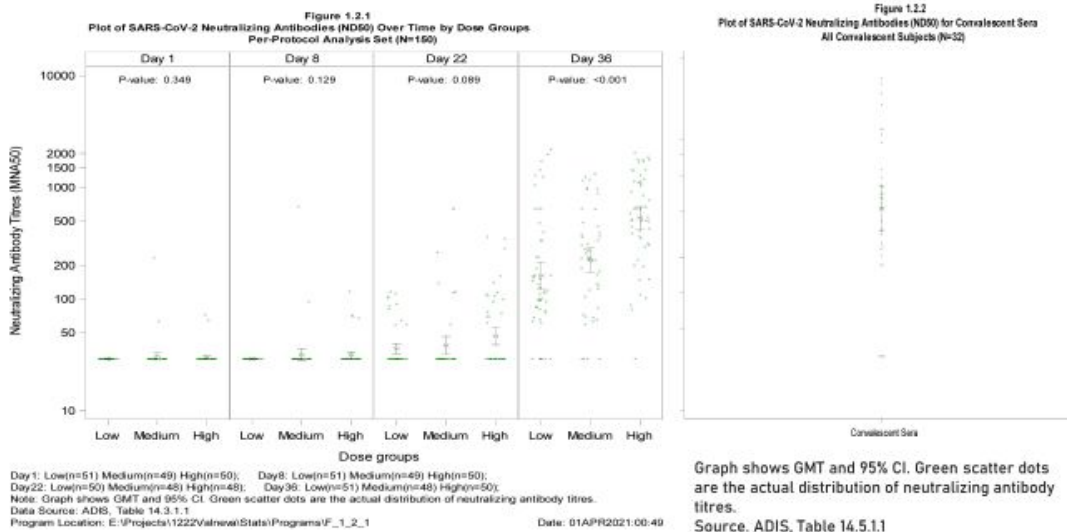
### Seroconversion as Measured by IgG Against S-protein (ELISA)



- More than 90% of all trial participants developed significant levels of antibodies to the SARS-CoV-2 virus spike protein across all dose groups tested.
- Seroconversion Rates (SCR) 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 Rises (GMFRs) from baseline were 26 in the medium dose and 86 in the high dose group.

Per-Protocol Analysis Set, Table 14.3.5.1, Table 14.3.6.1

# VLA2001 Generated Neutralizing Antibody Titers at or Above Levels Generally Seen in Convalescent Sera in Phase 1/2



- Dose dependent response, statistically significant higher Geometric Mean Titers (GMTs) in high dose group compared to low and medium dose groups.
- In high dose group, GMT of neutralizing antibody titers of 530.4 (95% CI: 421.49, 667.52).
- With a GMT ratio of vaccine vs. convalescent sera  $\geq 1$  vaccine efficacy has been reported above 80% for other vaccines.

## Immunogenicity Summary – Cellular Response Induced



Exploratory endpoints evaluated T-cell responses by IFN $\gamma$  ELISpot analysis against **S**-protein, **M**embrane-protein and **N**ucleocapsid-protein.

At Day 36, in the high dose group:

- 76% of study participants (34/45) were reactive<sup>1</sup> against peptide pools spanning the full-length **S**-protein
- 36% (16/45) against the **M**-protein
- 49% (22/45) against the **N**-protein

**S-protein**



■ Reactive ■ Non-reactive

**M-protein**



■ Reactive ■ Non-reactive

**N-protein**



■ Reactive ■ Non-reactive

<sup>1</sup>Sample is considered **reactive** against individual stimulation panel (peptide pools) if normalized spot counts (Nil control counts subtracted) per  $2.10 \times 10^5$  PBMCs  $\geq 6$

## **VLA2001: Development Outlook**

Pivotal Phase 3 Trial Ongoing



**Pivotal Phase 3 is a randomized, observer-blind, controlled, comparative immunogenicity trial in ~ 4,000 adults**

- Immunological comparison against a licensed vaccine to reasonably predict efficacy (superiority of VLA2001 in a two-dose immunization schedule four weeks apart - GMTs of neutralising antibodies, at two weeks after the second vaccination)
- Study conducted in UK supported by DHSC/NIHR, including funding
- Protocol agreed with MHRA; discussion with other regulatory bodies ongoing

**Valneva participates in the world's first COVID-19 vaccine booster trial in the UK**

**Additional booster studies planned (including reduced booster dose)**

**Valneva has developed viral seed banks, including South African and Kent, to be in a position to manufacture variant-based vaccines**





## VLA1553 – Only Chikungunya Vaccine Candidate in Phase 3 Today



- 1 Phase 3 trial VLA1553-301 fully enrolled<sup>1</sup>; Use of surrogate marker for Ph3 endpoint confirmed by FDA<sup>2</sup>; Accelerated Approval Pathway confirmed<sup>3</sup>
- 2 Potentially eligible for Priority Review Voucher<sup>4</sup>; FDA Fast Track<sup>5</sup> and EMA PRIME<sup>6</sup> designation granted
- 3 Single shot, live attenuated<sup>7</sup> prophylactic vaccine targeting chikungunya virus neutralization
- 4 Up to \$23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs<sup>8</sup>
- 5 Excellent fit with existing commercial and manufacturing capabilities

Note: Photo credit: James Gathany. 1 Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial. 2 Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates. 3 Valneva reports positive End-of-Phase 2 Chikungunya meeting with the U.S. FDA and sets stage for Phase 3 Study. 4 <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>. 5 Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate. 6 Valneva's Chikungunya vaccine candidate awarded EMA prime designation. 7 CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase). 8 Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-income countries.



## VLA1553: Development Outlook

### Pivotal Phase 3 Trial - Topline Read-out Expected Mid-2021

#### Phase 3 Clinical Development Program underway

- Pivotal Phase 3 safety and immunogenicity trial in 4,131 healthy volunteers fully enrolled<sup>1</sup>
- Topline read-out on Day 29 (based on surrogate of protection) mid-2021
- Lot-to-Lot consistency trial initiated (VLA1553-302) in ~400 volunteers<sup>2</sup>
- Antibody persistence follow-up trial initiated (VLA1553-303) – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization<sup>1</sup>
- Adolescents' clinical trial in 750 volunteers in Brazil planned to commence in 2021<sup>3</sup>
- **Accelerated approval pathway agreed with FDA<sup>4</sup>**

#### VLA1553 may be eligible for Priority Review Voucher upon FDA approval<sup>5</sup>

<sup>1</sup> Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial. <sup>2</sup> Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate. <sup>3</sup> In collaboration with development partner Instituto Butantan, under CEPI funding. <sup>4</sup> Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates. <sup>5</sup><https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>



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## Strong Cash Position of €235.9 million at End of March to be Complemented by Proceeds from Global Offering

### Cash and cash equivalents of €235.9 million at March 31, 2021

- The increase in liquid funds compared to December 31, 2020 results from payments made by the UK Government within the framework of the UK COVID-19 partnership.



### Successful Nasdaq listing in May 2021

- \$107.6 million of gross proceeds raised in a US initial public offering and a concurrent private placement in Europe.



**Total revenues, excluding VLA2001, expected in range of €80 million to €105 million**

**Revenue guidance, excluding COVID-19, updated taking into account ongoing impacts of COVID-19 on travel industry**

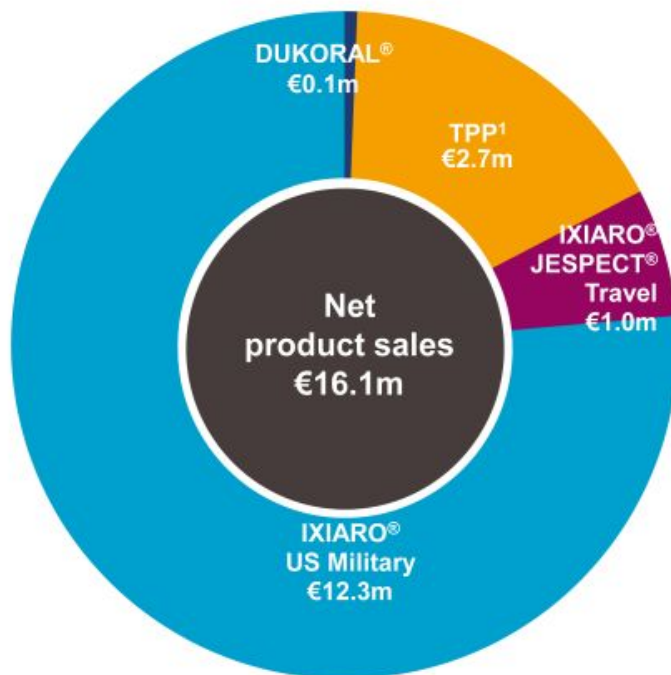
- Variants causing havoc in some key destinations (e.g. India)
- Ongoing pandemic setting in others such as Brazil
- Inconsistent vaccine program roll out in some key markets (e.g. Canada)

**COVID-19 revenue guidance to be provided in due course but still early days**

- Ongoing Phase 3 and regulatory discussions outside the UK
- Role of VLA2001 as a booster
- Potential switch to variant
- Ongoing discussions with EC

# Q1 2021 Sales Adversely Affected by the COVID-19 Pandemic

## Q1 2021 Product Sales (unaudited)



**Product sales<sup>2</sup>**  
-51% AER / -48% CER

**Direct sales**  
98%

**Gross margin<sup>3</sup>**  
41.7%

AER: Actual exchange rates, CER: Constant exchange rates; 1 Third party products sold by Valneva's commercial organization, 2 YoY comparison for same period, 3 Gross margin on product sales

# EBITDA Loss Reflecting Increasing R&D Expenses / Lower Sales



## Q1 2021 Profit & Loss Report (unaudited)

€m	Q1 2021	Q1 2020
Product sales	16.1	32.7
Revenues from collaboration, licensing and services	7.1	2.5
<b>Revenues</b>	<b>23.2</b>	<b>35.2</b>
Cost of goods	(9.6)	(10.7)
Cost of services	(5.1)	(2.1)
Research and development expenses	(27.7)	(13.3)
Marketing and distribution expenses	(4.9)	(6.0)
General and administrative expenses	(10.0)	(5.2)
Other income / (expense), net	3.0	2.2
<b>Operating profit / (loss)</b>	<b>(31.1)</b>	<b>0.1</b>
Finance, investment in associates & income taxes	3.4	(1.3)
<b>Loss for the period</b>	<b>(27.7)</b>	<b>(1.2)</b>
<b>EBITDA<sup>1</sup></b>	<b>(28.3)</b>	<b>2.4</b>

<sup>1</sup> EBITDA is a non-IFRS financial measure. A reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS, is included herein. Q1 2021 EBITDA was calculated by excluding €2.8 million (Q1 2020: €2.3 million) of depreciation and amortization from the €31.1 million operating loss (Q1 2020: €0.1 million operating profit) as recorded in the consolidated income statement under IFRS.



## Effect of SARS-CoV-2 program on Group P&L

COVID-19 Program Reported as Separate Segment as of 2021

€m	Q1 2021 Group	Q1 2021 COVID only	Q1 2021 excl. COVID
Product sales	16.1		16.1
Revenues from collaboration, licensing and services	7.1		7.1
<b>Revenues</b>	<b>23.2</b>		<b>23.2</b>
Cost of goods	(9.6)	(0.2)	(9.4)
Cost of services	(5.1)		(5.1)
Research and development expenses	(27.7)	(15.7)	(12.1)
Marketing and distribution expenses	(4.9)	(0.1)	(4.8)
General and administrative expenses	(10.0)	(5.4)	(4.6)
Other income / (expense), net	3.0	-	3.0
<b>Operating profit / (loss)</b>	<b>(31.1)</b>	<b>(21.4)</b>	<b>(9.8)</b>
Finance, investment in associates & income taxes	3.4		3.4
<b>Loss for the period</b>	<b>(27.7)</b>	<b>(21.4)</b>	<b>(6.4)</b>
<b>EBITDA<sup>†</sup></b>	<b>(28.3)</b>	<b>(20.3)</b>	<b>(8.0)</b>

<sup>†</sup> EBITDA is a non-IFRS financial measure. A reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS, is included herein. Q1 2021 EBITDA was calculated by excluding €2.8 million of depreciation, amortization and impairment from the €31.1 million operating loss as recorded in the consolidated financial statements under IFRS.



## Balance Sheet Statement

Per March 31, 2021 – before US IPO effects on Cash & Equity

ASSETS	Mar 31, 2021	Dec 31, 2020
<b>NON-CURRENT ASSETS</b>	<b>157,132</b>	<b>140,737</b>
+ Intangible Assets	35,156	35,409
+ Right Of Use Assets	42,592	43,374
+ Property, plant & equipment	51,030	34,779
+ Other non-current assets	28,353	27,176
<b>CURRENT ASSETS</b>	<b>416,981</b>	<b>308,427</b>
+ Inventories	97,400	26,933
+ Trade receivables	25,100	19,232
+ Other current assets	58,568	57,828
+ Cash & current financial assets	235,913	204,435
<b>TOTAL ASSETS</b>	<b>574,112</b>	<b>449,164</b>
<b>EQUITY &amp; LIABILITIES</b>	<b>Mar 31, 2021</b>	<b>Dec 31, 2020</b>
<b>EQUITY</b>	<b>52,355</b>	<b>77,422</b>
<b>NON-CURRENT LIABILITIES</b>	<b>201,401</b>	<b>195,872</b>
+ Borrowings, long term	48,868	46,375
+ Refund Liabilities	99,637	97,205
+ Other long term liabilities, including Lease Liabilities	52,897	52,292
<b>CURRENT LIABILITIES</b>	<b>320,357</b>	<b>175,870</b>
+ Trade payables and accruals	60,878	36,212
+ Borrowings, short term	5,944	6,988
+ Contract Liabilities	204,956	89,578
+ Refund Liabilities	18,818	14,222
+ Other current liabilities, including Lease Liabilities	29,760	28,871
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>574,112</b>	<b>449,164</b>





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### Lyme disease vaccine candidate VLA15

- Further Phase 2 milestones and read-outs during 2021; Phase 2 study VLA15-221, including pediatric development, initiated March 2021

### Chikungunya vaccine candidate VLA1553

- Initial Phase 3 data expected mid-2021; Phase 3 now fully recruited

### COVID-19 vaccine candidate VLA2001

- Phase 1/2 initial data reported, Phase 3 data expected in Q3 2021
- Regulatory submissions planned autumn 2021 assuming clinical data positive
- Further trial initiations to strengthen the product candidate's differentiation
- Further supply deals subject to negotiations and capacity



## Supplemental Disclosures Regarding Non-IFRS Financial Measures



EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth below:

€ in million	3 months ending March 31	
	2021	2020
Operating (loss)/Profit	(31.1)	0.1
Add:		
Amortization	1.5	1.5
Depreciation	1.3	0.8
<b>EBITDA</b>	<b>(28.3)</b>	<b>2.4</b>



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Thank you  
Merci  
Danke  
Tack

 valneva