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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: March 24, 2022**

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 [ X ]    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 March 24, 2022, 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.

**Exhibit**

[99.1 Valneva Reports Full Year 2021 Results and Provides Corporate Updates](#)

[99.2 Valneva Announces Filing of 2021 Universal Registration Document and US Form 20-F](#)

[99.3 Analyst Presentation](#)

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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.

Valveva SE  
(Registrant)

Date: March 24, 2022

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

## Valneva Reports Full Year 2021 Results and Provides Corporate Updates

Excellent progress on clinical programs**Lyme Disease Vaccine Candidate VLA15**

- Further positive Phase 2 results, including booster response
- Phase 3 expected to commence in the third quarter of 2022

**Inactivated COVID-19 Vaccine Candidate VLA2001**

- Positive pivotal Phase 3 results
- Purchase Agreements approved by European Commission (EC) and Kingdom of Bahrain for up to 60 million doses and one million doses, respectively, in 2022 and 2023
- Positive homologous booster results between seven to eight months after primary vaccination
- Confirmed neutralization of ancestral virus, Delta and Omicron variants in laboratory studies
- Emergency Use Authorization granted in Bahrain; reviews ongoing with the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA)

**Single-Shot Chikungunya Vaccine Candidate VLA1553**

- Final positive pivotal Phase 3 results
- Pre-submission process expected to commence in the second quarter of 2022

Strong full-year 2021 revenues and cash position**Total revenues of €348.1 million in 2021 compared to €110.3 million in 2020 – an increase of 216%**

- Includes €94.8 million of product and other revenues (excluding COVID), at the higher end of the Company's previously communicated guidance of €85 to €100 million, and
- €253.3 million of COVID-related revenues under the terminated UK agreement

**Cash position of €346.7 million at December 31, 2021**

- Reflects \$209.6 million of combined gross proceeds from Nasdaq initial public offering (IPO) and European placement in May 2021, plus November 2021 follow-on offering, and
- Pre-payments under the EC COVID-19 vaccine supply agreement

2022 financial guidance

- Total revenues between €430 to €590 million expected, including:
  - €350 to €500 million of COVID-19 vaccine sales subject to regulatory approvals and deliveries of VLA2001<sup>1</sup>
  - €60 to €70 million of other vaccine sales
  - Approximately €20 million of Other Revenues (revenues from collaborations, licensing and services)
- R&D expenses expected between €160 million to €200 million

**Financial Information**

(2021 audited results, consolidated per IFRS)

€ in million	12 months ending December 31,	
	2021	2020
Product sales	63.0	65.9
Total revenues	348.1	110.3
Net profit/(loss)	(73.4)	(64.4)
EBITDA	(47.1)	(45.2)
Cash	346.7	204.4

**Saint-Herblain (France), March 24, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its audited consolidated financial results for the year ending December 31, 2021 and provided corporate updates. The 2021 audited consolidated financial statements are available on the Company's website (Financial Reports – Valneva).

Valneva will provide a live webcast of its full-year 2021 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/qieuu6at>

**Peter Bühler, Valneva's Chief Financial Officer**, commented, "2021 was an exceptional year for Valneva, marked by unprecedented R&D progress and our successful Nasdaq listing. We reported positive Phase 3 results for two vaccine candidates (COVID-19 and chikungunya) and we expect both vaccines, if approved, to make a positive change to people's lives. With close to €350 million in cash, we entered 2022 in a strong position and will continue to focus on gaining regulatory approvals and preparing market entry for our key late-stage programs."

**Clinical Stage Vaccine Candidates****LYME DISEASE VACCINE CANDIDATE – VLA15****Further positive Phase 2 results reported**

Valneva and Pfizer<sup>2</sup> are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. The vaccine candidate covers the six OspA serotypes expressed by *Borrelia burgdorferi* sensu lato species that are prevalent in North America and Europe.

In February 2022, Valneva and Pfizer reported further positive Phase 2 data for VLA15<sup>3</sup> confirming the robust immunogenicity profile observed for adults (18-65 years) in previous Phase 2 studies. The companies are also evaluating VLA15 in pediatric participants aged 5 to 17 years, with first data expected in the second quarter of 2022. Based on the latest Phase 2 results, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule for adults (18-65 years) in a planned Phase 3 clinical trial, which they expect to initiate in the third quarter of 2022, subject to regulatory approval.

**SARS-CoV-2 VACCINE CANDIDATE – VLA2001****First Emergency Use Authorization granted**

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for the Company's commercial Japanese encephalitis vaccine, IXIARO<sup>®</sup>.

Valneva remains focused on achieving regulatory approvals of VLA2001. In March 2022, VLA2001 was granted emergency use authorization from the Kingdom of Bahrain<sup>4</sup>. Valneva now expects to deliver the first VLA2001 shipments to Bahrain at the end of March 2022 as per the purchase agreement signed in December 2021<sup>5</sup>.

VLA2001 is in advanced review processes with the EMA and UK MHRA, as recently communicated<sup>6</sup>. Subject to acceptance of Valneva's responses by the EMA's Committee for Medicinal Products for Human Use (CHMP), Valneva anticipates receiving a positive CHMP recommendation for conditional approval of VLA2001 for primary immunization in adults 18 to 55 years of age in April 2022. Following such conditional approval, the Company would expect to start delivering planned doses of VLA2001 to European countries in the second quarter of 2022. Valneva signed an agreement with the European Commission (EC) in November 2021 to supply up to 60 million doses of VLA2001 over two years, including 24.3 million doses in 2022<sup>7</sup> and the remainder via options in 2023.

In order to gradually expand the label and indications of VLA2001 to further age groups, Valneva is currently conducting additional clinical studies, including for potential use as a homologous and heterologous booster vaccine in the course of 2022.

**CHIKUNGUNYA VACCINE CANDIDATE – VLA1553****Final Positive Phase 3 Results reported**

Valneva is developing a single-dose vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to over 120 countries.

In March 2022, Valneva announced successful completion of the Phase 3 pivotal trial of VLA1553<sup>8</sup>. The final six-month analysis confirmed the very high level of seroprotection reported in August 2021. Six months after receiving a single vaccination, 96.3% of participants showed protective CHIKV neutralizing antibody titers. VLA1553's good safety and tolerability profile was also consistent with topline Phase 3 data. Valneva now expects to commence the pre-submission process with the U.S. Food and Drug Administration (FDA) in the second quarter of 2022.

The Company also previously reported positive topline lot-to-lot manufacturing consistency results for VLA1553<sup>9</sup>. This is one of the standard requirements for vaccine licensure, and final lot-to-lot results are expected in the second quarter of 2022.

Valneva also initiated a Phase 3 trial in adolescents in January 2022. The trial, conducted in Brazil by Instituto Butantan, is designed to support label extension to this age group following a potential initial regulatory approval in adults in the U.S.<sup>10</sup>. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

## 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 U.S., Canada and Europe.

Sales of Ixiaro<sup>®</sup> were €45.1 million in 2021 compared to €48.5 million in 2020. While the COVID-19 pandemic continued to adversely impact the travel industry and vaccine sales to the private market, the impact on Ixiaro<sup>®</sup> sales was mitigated by the Company's contract with the U.S. Government's Department of Defense (DoD).

### CHOLERA / ETEC<sup>11</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.

Dukoral<sup>®</sup> recorded sales of €2.4 million in 2021 compared to €13.3 million in 2020. 2021 sales continued to be significantly affected by the COVID-19 pandemic's impact on the travel industry.

## Full Year 2021 Financial Review

(Audited, consolidated under IFRS)

### Revenues

Valneva's total revenues were €348.1 million in 2021 compared to €110.3 million in 2020, an increase of 216%.

Product sales decreased by 4.5% to €63.0 million in 2021 compared to €65.9 million in 2020 as the travel industry continued to be impacted by the COVID-19 pandemic. On a constant exchange rate (CER) basis, product sales also decreased by 4.5% in 2021 as compared to 2020.

Ixiaro<sup>®</sup>/Jespect<sup>®</sup> product sales decreased by 6.9% (5.7% at CER) to €45.1 million in 2021 compared to €48.5 million in 2020. The impact of the COVID-19 pandemic was mitigated by sales to the U.S. Government's Department of Defense (DoD) during the period. Dukoral<sup>®</sup> product sales declined by 81.7% (82.4% at CER) to €2.4 million in 2021 compared to €13.3 million in 2020. Third Party product sales grew by 271.0% to €15.4 million in 2021 from €4.2 million in 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<sup>®</sup>/RabAvert<sup>®</sup> and Encepur<sup>®</sup>, which commenced in certain territories in 2021.

Other Revenues amounted to €285.1 million in 2021 compared to €44.4 million in 2020. This increase was attributable to revenues recognized in relation to the terminated UK COVID-19 vaccine supply agreement for non-refundable payments received up to December 31<sup>st</sup>, 2021.

### Operating Result and EBITDA

Costs of goods and services sold (COGS) were €187.9 million in 2021. Gross margin on product sales was 36.5% compared to 36.6% in 2020. COGS of €22.6 million were related to Ixiaro<sup>®</sup>/Jespect<sup>®</sup> product sales, yielding a product gross margin of 50.0%. COGS of €7.6 million were related to Dukoral<sup>®</sup> product sales, causing a negative product gross margin. Of the remaining 2021 COGS, €9.9 million were related to the Third-Party product distribution business, €122.8 million to the COVID-19 business and €25.1 million to cost of services. COGS for the COVID-19 business in 2021 included write-offs of materials and onerous purchase agreements resulting from the termination of the UK VLA2001 supply agreement. In 2020, overall COGS were €54.3 million, of which €41.8 million related to cost of goods and €12.5 million related to cost of services.

Research and development investments continued to increase in 2021, growing to €173.3 million compared to €84.5 million in 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine candidate, 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 €59.4 million in 2021 compared to €65.5 million in 2020. Marketing and distribution expenses in 2021 amounted to €23.6 million compared to €18.3 million in 2020. Marketing and distribution expenses in 2021 notably included €3.8 million of expenses (compared to €0.6 million in 2020) related to the launch preparation costs of the chikungunya vaccine candidate, VLA1553, and also included higher expenses related to the Company's employee share-based compensation programs, which offset cost containment measures taken as a result of the pandemic's impact on the travel vaccine business. General and administrative expenses increased to €47.6 million in 2021 from €27.5 million in 2020, mainly driven by increased costs to support corporate transactions such as the Company's initial public offering on Nasdaq, increased resources in support of incremental COVID-19 activities, and higher costs related to the Company's employee share-based compensation programs.

Other income, net of other expenses, increased to €23.0 million in 2021 from €19.1 million in 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 €61.4 million in 2021 compared to an operating loss of €55.1 million in 2020. EBITDA loss in 2021 was €47.1 million compared to an EBITDA loss of €45.2 million in 2020.

### Net Result

In 2021, Valneva generated a net loss of €73.4 million compared to a net loss of €64.4 million in 2020.

Finance expense and currency effects in 2021 resulted in a net finance expense of €8.6 million, compared to a net finance expense of €10.0 million in 2020. This was mainly a result of foreign exchange gains amounting to €8.1 million in 2021, primarily driven by revaluation gains of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain (including gains on derivative financial instruments) of €0.6 million in 2020. Interest charges increased to €17.0 million in 2021 compared to €10.7 million in 2020. This growth was mainly driven by increased interest charges related to refund liabilities.

### Cash Flow and Liquidity

Net cash generated by operating activities amounted to €76.9 million in 2021 compared to €137.7 million in 2020, mainly driven by pre-payments related to the vaccine supply agreement signed with the EC. Net cash generated by operating activities in 2020 was mainly derived from the \$130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement, as well as payments received from the UK government in relation to the UK VLA2001 supply agreement.

Cash outflows from investing activities amounted to €93.1 million in 2021 compared to €19.3 million in 2020, mainly as a result of COVID manufacturing related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €154.5 million in 2021, which was mainly a result of proceeds from the issuance of new shares in the U.S. initial public offering and European private placement (Global Offering). Cash inflows in 2020 amounted to €21.7 million and mainly consisted of net proceeds from the financing arrangement with U.S. healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank.

Liquid funds increased to €346.7 million as of December 31, 2021, compared to €204.4 million as of December 31, 2020. The cash increase resulted from significant cash in-flows most notably COVID related payments received from UK government and EC member states as well as net proceeds from the Global Offering in May and October 2021.

### 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 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 provides 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 loss, which is the most directly comparable IFRS measure, is set forth below:

€ in million	12 months ending December 31,	
	2021	2020
Operating Loss	(61.4)	(55.1)

Add:		
Amortization	6.6	6.0
Depreciation	7.7	3.8
Impairment of Tangible Assets	-	0.1
<b>EBITDA</b>	<b>(47.1)</b>	<b>(45.2)</b>

#### About Valneva SE

Valneva is a specialty vaccine company focused on the development, production 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.

#### 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 2022. 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 results. 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 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, the ability to obtain or maintain patent or other proprietary intellectual property protection, the terms and cancellation of existing contracts, including but not limited to the supply agreement with the UK government, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. 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 this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

*1 Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001*

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

*3 Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate – Valneva*

*4 Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

*5 Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001 – Valneva*

*6 Valneva Provides Regulatory Update on its COVID-19 Vaccine Candidate – Valneva*

*7 Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001*

*8 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva*

*9 Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate*

*10 Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*

*11 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.*

**Valneva Announces Filing of 2021 Universal Registration Document and US Form 20-F**

**Saint-Herblain (France), March 24, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announced today the filing of its 2021 Universal Registration Document (URD) with the French Financial Markets Authority (AMF) on March 23, 2022 under the filing number D.22-0140 and its Form 20-F with the U.S. Securities and Exchange Commission (SEC) on March 24, 2022.

Valneva's 2021 Universal Registration Document includes the Company's 2021 Annual Financial Report, Management Board Report, the Supervisory Board's report on Corporate Governance and the Group's Corporate Social Responsibility Report.

The 2021 URD and Form 20-F also include a description of the Group's major agreements, including obligations, timelines and remedies related to product approval and delivery under the Advance Purchase Agreement with the European Commission.

These documents are available on Valneva's website (<https://valneva.com/investors/financial-reports/>) and will also be available on the AMF ([www.amf-france.org](http://www.amf-france.org)) and SEC ([www.sec.gov](http://www.sec.gov)) websites, respectively. Hard copies of these documents may be obtained from the Company, free of charge, upon request at the following address: 6 rue Alain Bombard, 44800 Saint-Herblain, France.

**About Valneva SE**

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# Valneva Reports Full Year 2021 Results and Provides Corporate Updates

Analyst Presentation  
March 24, 2022







This presentation does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva SE shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful.

Valneva is a European company. Information distributed is subject to European disclosure requirements that are different from those of the United States. Financial statements and information may be prepared according to accounting standards which may not be comparable to those used generally by companies in the United States.

This presentation includes only summary information provided as of the date of this presentation only and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time without notice. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of its affiliates, directors, officers, advisors and employees is under any obligation to update such information or shall bear any liability for any loss arising from any use of this presentation. The information has not been subject to independent verification and is qualified in its entirety by the business, financial and other information that Valneva is required to publish in accordance with the rules, regulations and practices applicable to companies listed on Euronext Paris and the NASDAQ Global Select Market, including in particular the risk factors described in Valneva's universal registration document filed with the French Financial Markets Authority (Autorité des Marchés Financiers, or AMF) on March 23, 2022 and the Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 23, 2022, as well as the information in any other periodic report and in any other press release, which are available free of charge on the websites of Valneva ([www.valneva.com](http://www.valneva.com)) and/or the AMF ([www.amf-france.org](http://www.amf-france.org)) and SEC ([www.sec.gov](http://www.sec.gov)).

Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including statements with respect to revenue guidance, the progress, timing, completion results of research, development and clinical trials for product candidates and estimates for future performance. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.



**Introduction**

**Business Update**

**Financial Report FY 2021**

**Financial Outlook**

**Newsflow**

**Q&A**



## Excellent progress in all clinical programs

- **Lyme disease:** Further positive Phase 2 results reported, including booster response; Phase 3 dose and schedule selected
- **COVID-19:** Positive Phase 3 results reported; EUA granted in Bahrain; reviews ongoing with EMA and MHRA
- **Chikungunya:** Final positive Phase 3 results and topline lot-to-lot data reported; Adolescent Phase 3 trial initiated

## Strong full-year 2021 revenues and cash position

- Total revenues of €348.1m in 2021 compared to €110.3m in 2020 – an increase of 216%
- Cash position of €346.7m (December 31, 2021)

## Successful Nasdaq Initial Public Offering (IPO), European placement and follow-on offering





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# VLA15: Multivalent Lyme Disease Vaccine Candidate



Only Lyme Disease Program in Advanced Clinical Development Today



- 1 FDA Fast Track Designation granted
- 2 Exclusive, worldwide partnership with Pfizer
- 3 Topline results reported from Phase 2 trials<sup>1,2,3</sup>, incl. booster response<sup>4</sup>; Phase 3 schedule selected; Topline pediatric data expected in Q2 2022
- 4 Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe
- 5 Follows proven Mechanism of Action for a Lyme disease vaccine
- 6 Global market to exceed \$1bn in sales annually according to Valneva estimates

1 Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate; 2 Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15; 3 Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; 4 Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate



## VLA15: Development Progress and Outlook

Positive Topline Phase 2 Results<sup>1</sup> in Adults Reported; Topline Pediatric Data Expected in Q2

### VLA15-221 recruited 625 randomized participants, 5 to 65 years of age<sup>2</sup>

- Three-dose priming schedule selected for use in adults for Phase 3, based on stronger immune response vs. two-dose schedule; sub-analysis reported February 2022<sup>3</sup>
- Topline pediatric data are expected in the second quarter of 2022
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the six-month dose<sup>1</sup>

### VLA15-202 results and topline booster data announced in Sep. 2021<sup>4</sup>

- VLA15 immunogenic across all dose groups; elicited high antibody responses across all serotypes one month after primary vaccination series (primary endpoint)
- Booster dose elicited strong anamnestic response

### Phase 3 pivotal efficacy trial planned to commence in Q3 2022<sup>1</sup>

- Clinical readout, based on one tick season, projected by end of 2023
- \$25m milestone payment due to Valneva upon trial initiation


### Initial submission for regulatory approval anticipated in H2 2024, assuming positive data

<sup>1</sup> Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate, <sup>2</sup> Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate, <sup>3</sup> Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate, <sup>4</sup> Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate



# VLA1553: Single Shot Chikungunya Vaccine Candidate

## Most Advanced Chikungunya Vaccine Program worldwide



- 1 Final positive pivotal Phase 3 results<sup>1</sup> and topline lot-to-lot data<sup>2</sup> reported; Adolescent Phase 3 trial initiated in January 2022<sup>3</sup>
- 2 FDA Breakthrough Therapy<sup>5</sup>, Fast Track<sup>6</sup> and EMA PRIME<sup>7</sup> designations granted; Potentially eligible for Priority Review Voucher<sup>4</sup>; FDA Pre-submission process expected in Q2 2022
- 3 Single shot, live attenuated<sup>8</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>9</sup>
- 5 Excellent fit with existing commercial and manufacturing capabilities
- 6 Global market, including endemic regions, estimated to exceed \$500 million annually by 2032<sup>10</sup>

Note: Photo credit: James Gathany. 1 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; 2 Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; 3 Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate; 4 <https://www.fda.gov/about-fda/center-for-evaluation-and-research-otermopca-disease-priority-review-voucher-program>; 5 Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate; 6 Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate; 7 Valneva's Chikungunya vaccine candidate awarded EMA prime designation; 8 CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus replicase); 9 Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-income countries; 10 VacZineAnalytics Chikungunya virus vaccines Global demand analysis, February 2020.



#### First and only program to have reported positive Phase 3 results worldwide

- Six-month follow-up completed - all Phase 3 immunogenicity and safety endpoints met - seroprotection in 98.9% of participants after one month and 96.3% after six months - good safety and tolerability profile confirmed
- Positive topline lot-to-lot consistency trial results reported (VLA1553-302)<sup>2</sup>, final data expected in Q2 2022
- Antibody persistence follow-up trial (VLA1553-303) ongoing: up to 375 volunteers from the VLA1553-301 trial will be followed annually for five years
- Adolescent Phase 3 trial initiated in January 2022 to support potential label expansion, funded by the Coalition for Epidemic Preparedness Innovations (CEPI)<sup>3</sup>

#### Pre-submission process with FDA expected to commence in Q2 2022

#### The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher<sup>4</sup>

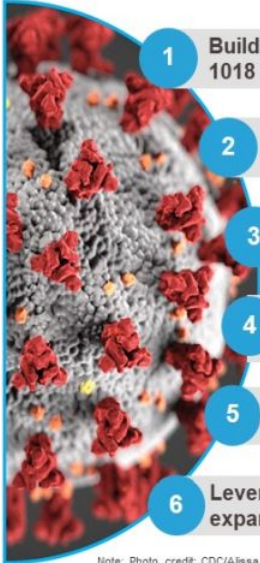
<sup>1</sup> Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; <sup>2</sup> Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; <sup>3</sup> Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate; <sup>4</sup> <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>



# VLA2001: Inactivated whole virus COVID-19 Vaccine Candidate

## Only Inactivated COVID-19 Vaccine Program in the Clinics in Europe



- 
- 1 Builds on Valneva's IXIARO® manufacturing technology combined with Dynavax's CpG 1018 adjuvant<sup>1</sup>
  - 2 Bahraini NHRA Emergency Use Authorization received March 2022<sup>2</sup>; EMA and UK MHRA rolling reviews ongoing
  - 3 Advance purchase agreements for up to 60 million doses with European Commission<sup>3</sup> and for one million doses with Bahrain<sup>4</sup>:
  - 4 Pivotal Phase 3 showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability<sup>5</sup>; Positive topline homologous booster data reported<sup>6</sup>; Shown to neutralize Omicron and Delta variants in laboratory studies<sup>7</sup>
  - 5 Ongoing clinical trials aiming to gradually extend target product profile (label) and geographical reach
  - 6 Leveraging Valneva's manufacturing sites in Scotland and Sweden; capacity being expanded, including CMO<sup>8</sup> – targeting >100m doses per annum<sup>9</sup>

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. <sup>1</sup> Valneva and Dynavax announce commercial supply agreement for inactivated, adjuvanted COVID-19 vaccine; <sup>2</sup> Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; <sup>3</sup> Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001; <sup>4</sup> Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; <sup>5</sup> Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001; <sup>6</sup> Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva; <sup>7</sup> Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant; <sup>8</sup> Valneva and DT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001; <sup>9</sup> Based on a combination of in-house capacity and external contracted manufacturing.



### Immunogenicity

- VLA2001 met its co-primary endpoints vs AZD1222, demonstrating:
  - Superiority in terms of **geometric mean titer** for neutralization antibodies (GMT ratio = 1.39,  $p < 0.0001$ ), as well as
  - **Non-inferiority** in terms of **seroconversion rate**
- VLA2001 induced **broad** antigen-specific IFN-gamma producing **T-cells reactive against the S (74.3%), N (45.9%) and M (20.3%) proteins**

### Safety and Tolerability

- VLA2001 was generally well tolerated:
  - **Significantly more favorable profile** compared to AZD1222
  - Participants 30 years and above reported **significantly fewer solicited adverse events**, including **injection site reactions**, and **systemic reactions**
- Participants **18-29 years** old showed an **overall safety profile comparable to the older age group**

### COVID-19 Cases

- The **occurrence of COVID-19 cases** (exploratory endpoint) was **similar between treatment groups** (age 30+)
- The **complete absence of any severe COVID-19 cases** could suggest that **both vaccines** used in the study **prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta)**

## VLA2001: Current Purchase Agreements and Grants

First EU Deliveries expected in Q2 2022, subject to EMA approval



### European Commission: Up to 60 million doses of VLA2001 to be supplied in 2022-23<sup>1</sup>

- 24.3 million doses to be supplied in the second and third quarters of 2022; EC has the option to increase its initial purchase, the remainder of which would be delivered in 2023

### Bahrain: One million doses of VLA2001 to be supplied in 2022-23<sup>2</sup>

- NHRA Emergency Use Authorization received; first deliveries expected at the end of March 2022<sup>3</sup>

### Up to £20 Million awarded by Scottish Enterprise to advance vaccine development<sup>4</sup>

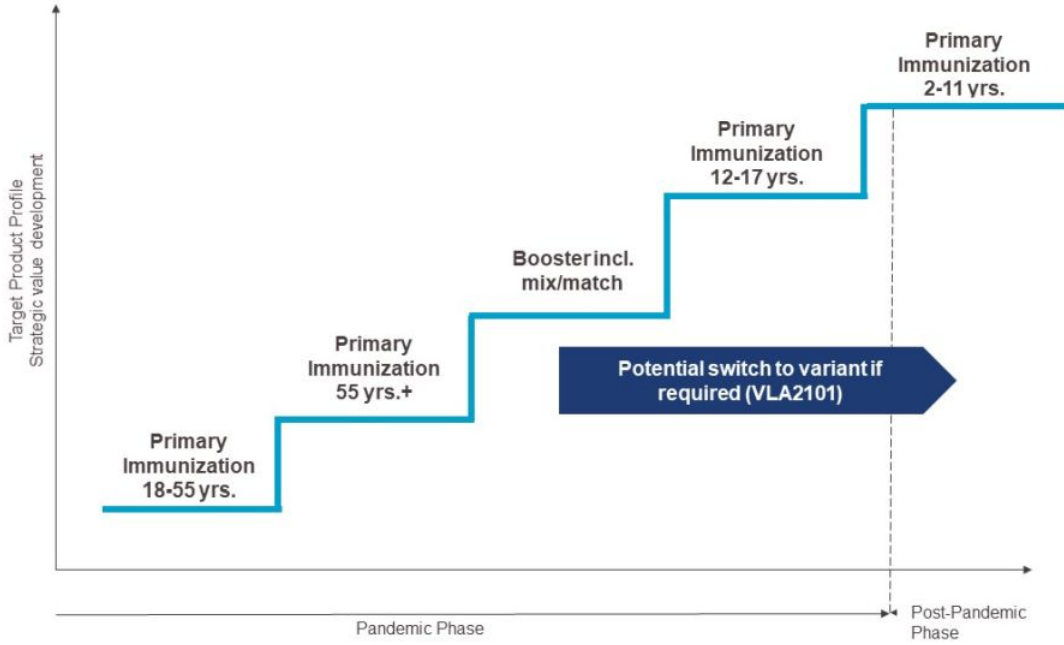
- Grants totaling up to £20 million expected to be received over the next three years, commencing March 2022
- The first grant of up to £12,500,000 will support R&D related to VLA2001 manufacturing; the second grant of up to £7,500,000 will support R&D connected to manufacturing of Valneva's other vaccine candidates

<sup>1</sup> Valneva Announces European Commission Approval of Advance Purchase Agreement for up to 60 Million Doses of Inactivated COVID-19 Vaccine VLA2001; <sup>2</sup> Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; <sup>3</sup> Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; <sup>4</sup> Valneva Awarded Up to £20 Million by Scottish Enterprise to Advance Vaccine Development

# VLA2001: Planned Label Extensions



Ongoing and Future Clinical Studies Expected To Strengthen Product Profile





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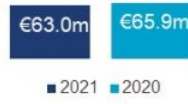
# Full Year 2021 Financials: Total Revenues of €348m



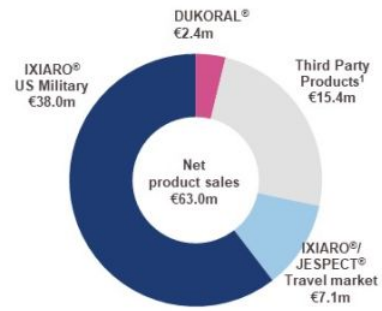
Growth attributed to recognized revenues from terminated UK agreement



**Total Revenues**  
+215.5%



**Product sales<sup>2</sup>**  
-4.5%



**Direct sales**  
98%

<sup>1</sup> Third party products sold by Valneva, <sup>2</sup> YoY comparison for same period  
Valneva FY 2021 Analyst Presentation

## Full Year 2021 Financials: Product Sales of €63m



Continued pandemic impact on travel industry, strong increase in third party product sales

€m	FY 2021 (audited)	FY 2020 (audited)	%
IXIARO®/JESPECT®	45.1	48.5	-6.9%
DUKORAL®	2.4	13.3	-81.7%
Third party products	15.4	4.2	+271.0%
<b>Total</b>	<b>63.0</b>	<b>65.9</b>	<b>-4.5%</b>

## Full year 2021 Financials: EBITDA of -€47.1m



Reflects Pandemic Impact on Sales and Significant R&D Investments

€m (2020 unaudited)	FY 2021	FY 2020
Product sales	63.0	65.9
Other Revenues	285.1	44.4
<b>Revenues</b>	<b>348.1</b>	<b>110.3</b>
Cost of goods and services	(187.9)	(54.3)
Research and development expenses	(173.3)	(84.5)
Marketing and distribution expenses	(23.6)	(18.3)
General and administrative expenses	(47.6)	(27.5)
Other income / (expense), net	23.0	19.1
<b>Operating loss</b>	<b>(61.4)</b>	<b>(55.1)</b>
Finance, investment in associates & income taxes	(12.0)	(9.3)
<b>Profit/loss for the period</b>	<b>(73.4)</b>	<b>(64.4)</b>
<b>EBITDA<sup>1</sup></b>	<b>(47.1)</b>	<b>(45.2)</b>

<sup>1</sup> FY EBITDA was calculated by excluding €14.3 million (2020: €9.9 million) of depreciation and amortization from the €61.4 million (2020: €55.1 million) operating loss as recorded in the consolidated income statement under IFRS.



**Full Year 2021 Financials: Impact of COVID-19 Program on P&L**  
 COVID-19 reported as separate segment as of 2021



€m (2021 audited)	FY 2021	FY2021	FY 2021
	Group	COVID only	excl. COVID
Product sales	63.0		63.0
Other Revenues	285.1	253.3	31.8
<b>Revenues</b>	<b>348.1</b>	<b>253.3</b>	<b>94.8</b>
Cost of goods and services	(187.9)	(122.8)	(65.1)
Research and development expenses	(173.3)	(113.9)	(59.4)
Marketing and distribution expenses	(23.6)	(1.2)	(22.5)
General and administrative expenses	(47.6)	(23.0)	(24.6)
Other income / (expense), net	23.0	11.5	11.4
<b>Operating loss</b>	<b>(61.4)</b>	<b>3.9</b>	<b>(65.3)</b>
Finance, investment in associates & income taxes	(12.0)		(12.0)
<b>Profit/loss for the period</b>	<b>(73.4)</b>	<b>3.9</b>	<b>(77.4)</b>
<b>EBITDA<sup>1</sup></b>	<b>(47.1)</b>	<b>11.6</b>	<b>(58.7)</b>

<sup>1</sup> FY EBITDA was calculated by excluding €14.3 million (2020: €9.9 million) of depreciation and amortization from the €61.4 million (2020: €55.1 million) operating loss as recorded in the consolidated income statement under IFRS.

## Full Year 2021 Financials: Balance Sheet 2020/2021



Net Assets impacted by COVID as well as cash proceeds from public offerings

€m (2021 audited)	December 31st,	December 31st,
	2021	2020
<b>NON-CURRENT ASSETS</b>	<b>231.5</b>	<b>140.7</b>
- Property, Plant & Equipment	125.5	34.8
- Other Non-current Assets	106.0	106.0
<b>CURRENT ASSETS</b>	<b>585.8</b>	<b>308.4</b>
- Inventory	124.1	26.9
- Trade Receivables & Other current assets	115.0	77.1
- Cash & Cash Equivalents	346.7	204.4
<b>TOTAL ASSETS</b>	<b>817.4</b>	<b>449.2</b>

## Full Year 2021 Financials: Balance Sheet 2020/2021 (cont.)



Liabilities & Equity increased due to COVID contracts and public offerings

€m (2021 audited)	December 31st,	December 31st,
	2021	2020
<b>EQUITY</b>	<b>170.6</b>	<b>77.4</b>
<b>NON-CURRENT LIABILITIES</b>	<b>277.8</b>	<b>195.9</b>
- Refund Liabilities	159.0	97.2
- Other Non-Current Liabilities	118.7	98.7
<b>CURRENT LIABILITIES</b>	<b>369.0</b>	<b>175.9</b>
- Trade Payables & Accruals	68.1	36.2
- Contract Liabilities	124.0	89.6
- Refund Liabilities	95.6	14.2
- Provisions	48.7	10.2
- Other Current Liabilities	32.5	25.7
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>817.4</b>	<b>449.2</b>



## Full year 2021 Financials: Impact of Terminated UK Agreement

Terminated Supply Agreement Impacted Revenue Recognition and Balance Sheet

<b>Total cash considerations received *</b>	<b>€ 420m</b>
<b>Reported as Other Revenue in 2021</b>	<b>€ 253m</b>
<b>Remaining on December 2021 Balance Sheet as Refund Liability</b>	<b>€ 167m</b>
- Refund Liability on Royalty Payments	€ 87m
- Refund Liability on CAPEX advances	€ 80m

\*) Cash receipts originating from a) terminated UK COVID-19 vaccine supply agreement for non-refundable payments received during the duration of the contract, b) Clinical Trial Agreement payments; includes €7.8m of outstanding payments; includes EUR / GBP FX effects on funds received



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## Valneva 2022 Financial Guidance

Substantial growth expected from anticipated COVID business



### **Total revenues expected between €430 to €590 million, including:**

- €350 to €500 million of COVID-19 vaccine sales subject to regulatory approvals and deliveries of VLA2001<sup>1</sup>,
- €60 to €70 million of other vaccine sales
- Approximately €20 million of Other Revenues (revenues from collaborations, licensing and services)

### **R&D investments expected between €160 million and €200 million**

- R&D investments reflecting pipeline progression



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### Lyme disease vaccine candidate VLA15

- First pediatric data expected in Q2 2022
- Phase 3 trial initiation expected in Q3 2022

### Chikungunya vaccine candidate VLA1553

- Pre-submission process expected to commence in Q2 2022
- Final lot-to-lot Phase 3 data expected in Q2 2022

### COVID-19 vaccine candidate VLA2001

- Possible regulatory approvals
- Supplies and further supply contracts
- Further clinical trials and data expected



Thank you  
Merci  
Danke  
Tack

 valneva