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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[1]
  - €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

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

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[2] 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[3] 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

[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*

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®.

Valneva remains focused on achieving regulatory approvals of VLA2001. In March 2022, VLA2001 was granted emergency use authorization from the Kingdom of Bahrain[4]. 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[5].

VLA2001 is in advanced review processes with the EMA and UK MHRA, as recently communicated[6]. 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[7] 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[8]. 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

[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*

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[9]. 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[10]. 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®/JESPECT®)

IXIARO® is the only Japanese encephalitis vaccine licensed and available in the U.S., Canada and Europe.

Sales of IXIARO® 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® sales was mitigated by the Company's contract with the U.S. Government's Department of Defense (DoD).

CHOLERA / ETEC[11]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® 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® 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® 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.

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[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.*

IXIARO®/JESPECT® 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® 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®/RabAvert® and Encepur®, 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 31st, 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®/JESPECT® product sales, yielding a product gross margin of 50.0%. COGS of €7.6 million were related to DUKORAL® 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
EBITDA	**(47.1)**	**(45.2)**

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.

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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.