**VALNEVA SE**
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# Valneva Reports FY 2020 Results and Major Corporate Achievements

- **Excellent progress on clinical programs**
  - Unprecedented partnering deal signed with Pfizer for Lyme disease vaccine candidate VLA15, including $130 million upfront payment as part of over $300 million for upfront and milestone payments
    - Positive initial Phase 2 results
    - Acceleration of pediatric development announced
  - Acceleration of chikungunya vaccine candidate VLA1553 into Phase 3
    - Only Phase 3 chikungunya vaccine program to date worldwide
    - Potentially eligible for Priority Review Voucher (PRV)[1] - for first company to receive Biologics License Application (BLA) approval
- **Commercial business adversely affected by pandemic impact on travel industry**
  - New US military / Department of Defense (DoD) contract for IXIARO® worth up to $166 million over three years
- **Valneva contributing to the global effort against the COVID-19 pandemic**
  - Only whole-virus inactivated vaccine candidate in clinical development in Europe
    - Commercial manufacturing commenced
  - Major Partnership with U.K. government, worth up to €1.4 billion including investment in manufacturing plant and clinical trials in the UK
    - Advanced discussions with European Commission
- **FY 2020 cash and cash equivalents of €204.4 million underlining strong balance sheet**
- **EGM passes resolutions to allow preparation for possible Nasdaq listing and US IPO**

**Thomas Lingelbach, Chief Executive Officer,** commented, *"2020 was a transformational year for Valneva, marked by major partnerships with Pfizer and the UK government as well as substantial progress across all of our clinical programs. Our company has responded very well to the challenges presented to us by the COVID pandemic. With over €200 million of cash, Valneva is in a strong position to continue to focus on execution of our key programs which could result in even greater transformation in 2021 and beyond."*

**FY 2020 financial highlights (unaudited)**

- **FY 2020 cash and cash equivalents of €204.4 million, exceeding guidance of between €180 million and €200 million[1]**
  - FY 2020 cash and cash equivalents include $130 million from the Lyme disease collaboration with Pfizer[2] and €96.7 million from the UK COVID-19 vaccine partnership[3]
  - $60 million drawn down from the $85 million debt financing arrangement with leading US healthcare funds Deerfield Management Company and OrbiMed[4]

[1] *https://priorityreviewvoucher.org/*
[2] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[3] *Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government*
[4] *Valneva Announces New $85 Million Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed*

- **Total revenue of €110.3 million in 2020 compared to €126.2 million in 2019;**
  - Product sales of €65.9 million in 2020 (€129.5 million in 2019) adversely affected by the COVID-19 pandemic impact on the travel industry.
  - FY 2020 total revenue includes €31.6 million resulting from the Lyme vaccine partnership with Pfizer and €12.8 million of Technology and Service revenues.
- **EBITDA[5] loss of €45.2 million in 2020 reflecting increased R&D investment and lower sales (compared to EBITDA profit of €7.8 million in 2019)**
  - FY 2020 EBITDA reflects planned increase in R&D investment of €84.5 million in 2020 compared to €38.0 million in 2019
    - Lyme disease, chikungunya and COVID-19 vaccine programs all advanced in 2020
    - €19.0 million of COVID-19 R&D investment is included in the 2020 results
    - Gross margin adversely affected by inventory provisions and idle capacity costs in manufacturing plants caused by the impact of the ongoing COVID-19 pandemic
      - 4.2% negative impact due to reporting changes
  - G&A costs include additional share option costs given share price appreciation during 2020 as well as one-off costs related to corporate project expenses

**FY 2021 financial guidance**

The Company is not providing guidance related to its VLA2001 revenues and program at this time. This guidance will be material to the Company, therefore needs to be based on robust information. As far as the non – VLA2001 related business is concerned, the Company expects for 2021:

- Total revenues, excluding VLA2001, of €100 million to €115 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million

**David Lawrence, Valneva's Acting Chief Financial Officer**, commented, *"Valneva's response to the COVID-19 pandemic has been outstanding. We have more than overcome the adverse impact in product sales with the partnerships on Lyme and our own COVID-19 vaccine program including the major partnership with the U.K. The 2020 financial results reflect the downturn in the travel industry and the great progress made across our R&D pipeline. 2021 is likely to see major development in our revenues and the prospect of a US IPO underlines our strategy to continue to build significant shareholder value."*

## Financial Information[6]

(2020 unaudited results, consolidated per IFRS)

| **€ in million** | **12 months ending December 31** | |
|---|---|---|
| | **2020** | **2019** |
| Product sales | 65.9 | 129.5 |
| Total revenues | 110.3 | 126.2 |
| Net profit/(loss) | (64.4) | (1.7) |
| EBITDA | (45.2) | 7.8 |
| Cash | 204.4 | 64.4 |

[5] *2020 EBITDA was calculated by excluding €9.9 million of depreciation, amortization and impairment (€8.6 million in 2019) from the €55.1 million operating loss (€0.8 million in 2019) as recorded in the consolidated financial statements under IFRS.*

[6] *Financial statements are not audited. The audit procedures by the Statutory Auditors are underway. The Company plans to publish its audited annual financial report on March 24, 2021.*

**Saint Herblain (France), February 25, 2021** – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention against diseases with major unmet needs, reported today its full year unaudited consolidated financial results for the year ending December 31, 2020 and summarized its key achievements in 2020. A brief unaudited report, including the profit and loss statement and the balance sheet, is available on the Company's website, www.valneva.com.

Valneva will provide a live webcast of its full-year 2020 unaudited 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/yz28diuy

## Commercial Vaccines

### JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

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

Sales of IXIARO® were €48.5 million in 2020 compared to €94.1 million in 2019. Sales in 2020 were significantly impacted by the COVID-related decline in travel.

In September 2020, the US Defense Logistics Agency (DLA), awarded Valneva a new contract for the supply of IXIARO®[7]. The terms of the agreement contemplate an initial base year followed by two option years, each with a range of minimum and maximum potential dose orders. The current base year has a minimum value of approximately $54 million for 370,000 doses, and the option years have minimum values of $46 million for 320,000 doses and $36 million for 250,000 doses, respectively, if DLA exercises those options.

### CHOLERA / ETEC[8]-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[8].

Valneva acquired DUKORAL® in 2015 and recorded sales of €13.3 million in 2020 compared to €31.5 million in 2019. DUKORAL® sales in 2020 have been significantly impacted by the COVID-related decline in travel.

### OVERALL SALES OUTLOOK

Taking into account the ongoing COVID-19 situation, Valneva's sales could return to 2019 levels in 2023-2024 with the expected sales recovery of its two commercial products and the marketing and distribution partnership with Bavarian Nordic announced in June 2020[9]. The successful development of a SARS-CoV-2 vaccine could accelerate that timeline.

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[7] *Valneva Announces New IXIARO® Supply Contract with the US Government worth up to $166 million*

[8] *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.*

[9] *Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership*

## Clinical Stage Vaccine Candidates

### LYME DISEASE VACCINE CANDIDATE – VLA15
**Collaboration agreement with Pfizer**; **Positive initial results reported for the two Phase 2 studies; Acceleration of pediatric development**

Valneva has developed VLA15, a vaccine candidate against Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States 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[10]. Valneva has reported positive initial results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults.

As part of this collaboration, Valneva announced in December 2020[11], that it had accelerated the pediatric development of VLA15 with an additional Phase 2 clinical trial anticipated to commence in March 2021. The dosing of the first subject in this trial will trigger a milestone payment from Pfizer of $10 million. Initial pediatric data are expected by mid-2022.

Together with Pfizer, Valneva expects that its Phase 3 clinical trial will start in the third quarter of 2022 to ensure administration of VLA15 in time for the pivotal, placebo-controlled field efficacy trial that the parties are planning for the 2023 tick season. Clinical readout, based on one tick season, is projected for end 2023.

If the results from these clinical trials are positive and, subject to regulatory approval, first licensure is anticipated for the first half of 2025. VLA15 has received Fast Track designation from the U.S. Food and Drug Administration (FDA)[12].

### CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
**Phase 3 initiated; EMA PRIME designation granted**

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.

[10] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[11] *Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate*
[12] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*

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 in approximately 4,000 participants aged 18 years or above. Valneva has also initiated a clinical lot-to-lot consistency Phase 3 trial in February 2021[13] to show manufacturing consistency of the vaccine. These two Phase 3 trials will run in parallel.

Valneva has received confirmation that it may seek licensure through the FDA's accelerated approval pathway. Via this pathway, the Company plans to seek licensure of the vaccine based on a surrogate of protection, subject to agreement with the FDA that this surrogate endpoint is reasonably likely to predict protection from chikungunya infection. Current clinical activities are affected by the ongoing pandemic but, with more than 80% of the study enrolled to date, Valneva now projects primary endpoint read-out around mid-2021.

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

To make VLA1553 also accessible to Low and Middle Income Countries, Valneva and the Butantan Institute in Brazil signed a collaboration agreement in January 2021 for the development, manufacturing and marketing of VLA1553[14]. 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[15].

**SARS-CoV-2 VACCINE CANDIDATE – VLA2001**
**Major COVID-19 Vaccine Partnership with U.K. Government**

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. The Phase 1/2 clinical trial is fully enrolled and is expected to report initial results in April 2021.

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

Assuming positive results from the ongoing Phase 1/2 trial and subject to regulatory approval Valneva plans to progress expeditiously into Phase 3 clinical development. Valneva is currently discussing Phase 3 design with the UK Medicines and Healthcare Products Agency (MHRA).

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

[13] *Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate*
[14] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[15] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

can be incorporated into the current and future portfolio of SARS-CoV-2 vaccines to address the global need for billions of doses of vaccines to prevent further spread of the virus.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025[16]. Following an initial order for 60 million doses to be delivered in 2021, the UK Government exercised an option in February 2021 to order 40 million doses for supply in 2022[17]. This brings the total volume of the Valneva vaccine ordered by UK Government to 100 million doses and the UK Government retains options over a further 90 million doses for supply between 2023 and 2025. The total value of the 190 million doses, if all options are exercised, is up to €1.4 billion. Valneva also announced in January 2021, it is in advanced discussions with the European Commission to supply up to 60 million doses of its COVID-19 vaccine[18].

## Full Year 2020 Financial Review

(Unaudited, consolidated under IFRS)

### Revenues

Valneva's total revenues in 2020 were €110.3 million compared to €126.2 million in 2019.

Product sales declined by 49.1% to €65.9 million in 2020 compared to €129.5 million in 2019. On a CER basis[19] 2020 product sales declined by 48.2% compared to 2019 with both commercial vaccines impacted by COVID-19 related consequences on the travel market. The sales decline was caused by a 48.5% (47.2% at CER) decrease in IXIARO®/JESPECT® sales and a 57.7% (57.9% at CER) decrease in DUKORAL® sales while sales of Third Party products grew by 6.7% (8.5% at CER) compared to 2019.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €44.4 million in 2020 and included revenues related to the Lyme R&D collaboration agreement with Pfizer amounting to €31.6 million. In 2019, negative Other Revenues amounted to €3.3 million, including the effect of the termination of the SAA with GSK. Excluding the termination effect, other revenues would have amounted to €7.4 million in 2019.

### Operating result and EBITDA

Costs of goods and services sold (COGS) were €54.3 million in 2020. Gross margin on product sales was 36.6% compared to 63.1% in 2019, with the decline mainly related to provisions taken for excess stock driven by reduced demand (due to the COVID-19 pandemic) and idle capacity costs in both of Valneva's manufacturing sites. COGS of €24.8 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 48.9%. COGS of €14.3 million were related to DUKORAL® sales, yielding a negative product gross margin of 7.3%. Of the remaining COGS in 2020, €2.8 million were related to the Third Party Product distribution business and

[16] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*
[17] *Valneva Announces UK Government Exercise of Option for 40 Million Doses of its Inactivated, Adjuvanted COVID-19 Vaccine*
[18] *Valneva in Advanced Discussions with European Commission to Supply up to 60 Million Doses of Inactivated, Adjuvanted COVID-19 Vaccine Candidate*
[19] *CER: Constant Exchange Rate; Full Year 2019 actuals restated to Full Year 2020 average exchange rates*

€12.5 million were related to cost of services. In 2019, overall COGS were €52.8 million, of which €47.8 million related to cost of goods and €5.0 million related to cost of services.

Research and development investments in 2020 continued to increase as planned, more than doubling to €84.5 million compared to €38.0 million in 2019. This was driven by investments into Valneva's clinical stage vaccine candidates, notably Lyme and chikungunya, and was also impacted by spending related to the Company's SARS-CoV-2 vaccine candidate. Marketing and distribution expenses in 2020 amounted to €18.3 million compared to €24.1 million in 2019. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity further to the COVID-19 pandemic. In 2020, general and administrative expenses increased to €27.5 million from €18.4 million in 2019, mainly driven by increased costs to support corporate transactions and projects as well as costs related to Valneva's employee share option program.

Other income, net of other expenses in 2020 increased to €19.1 million from €6.3 million in 2019. This increase was mainly driven by increased R&D tax credit directly resulting from increased R&D spending along with income from the CEPI funding for Valneva's chikungunya R&D program.

Valneva recorded an operating loss of €55.1 million in 2020 compared to an operating loss of €0.8 million in 2019. EBITDA loss in 2020 was €45.2 million compared to an EBITDA profit of €7.8 million in 2019.

**Net result**

In 2020, Valneva generated a net loss amounting to €64.4 million compared to a net loss of €1.7 million in 2019.

Finance costs and currency effects in 2020 resulted in a net finance expense of €10.0 million, compared to a net finance expense of €1.6 million in 2019. The increase of expenses was mainly the result of increased interest charges related to the financing arrangement with US healthcare funds Deerfield and OrbiMed entered into in 2020 as well as interest charges of €3.2 million related to the re-payment obligation to Pfizer for Valneva's contribution to the Lyme VLA15 Phase 3 costs.

**Cash flow and liquidity**

Net cash generated by operating activities in 2020 amounted to €137.7 million compared to €5.5 million in 2019 mainly driven by the $130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement as well as funds received related to the COVID supply agreement concluded with the UK Government in September 2020.

Cash outflows from investing activities in 2020 amounted to €19.3 million compared to €10.7 million in 2019 mainly as a result of purchases of equipment.

Cash inflows from financing activities amounted to €21.7 million in 2020 and consisted mainly of €48.8 million net proceeds from the financing arrangement with US healthcare funds Deerfield and OrbiMed, offset by €20 million repayments of borrowings to the European Investment Bank (EIB). Cash outflows from financing activities amounted to €7.7 million in 2019, which included the repayment of the Biopharma (Pharmakon) loan of €11.3 million in early 2019.

Liquid funds on December 31, 2020 strongly increased and stood at €204.4 million compared to €64.4 million on December 31, 2019. The main changes resulted from the $130.0 million upfront payment related to the Lyme collaboration agreement with Pfizer, proceeds from the new debt line net of loan repayment to the EIB in March 2020 and 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 prevention of infectious diseases with significant unmet medical need. The Company has several vaccines in development including unique vaccines against Lyme disease, COVID-19 and chikungunya. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with approximately 580 employees.

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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 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, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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.