

## Valneva Reports Half Year 2023 Financial Results and Provides Corporate Updates

**Product sales more than doubled in the first half of 2023 to €69.7 million compared to €33.3 million in the first half of 2022**

- Driven by IXIARO® and DUKORAL® sales, both of which benefited from a continued recovery of the travel industry as well as from price increases
- Bringing total revenues to €73.7 million in the first half of 2023

**Strong cash position of €204.4 million as at June 30, 2023**

- Excludes up to an additional \$100 million made available as part of a recent upsized financing arrangement with leading U.S. Healthcare Funds Deerfield and OrbiMed<sup>1</sup>

**Chikungunya: progressing towards delivery of the world's first chikungunya vaccine**

- Biologic License Application (BLA) currently under priority review by the U.S. Food and Drug Administration (FDA)
- Second regulatory application accepted for review by Health Canada
- Initial safety data in adolescents, required for submission to the European Medicines Agency (EMA), reported in August 2023

**2023 financial guidance confirmed**

- Expected total revenues and other income between €220 million and €260 million, including:
  - €130 million to €150 million of product sales
  - €90 million to €110 million of other income
- Expected R&D expenses between €70 million and €90 million

### Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	6 months ending June 30,	
	2023	2022
Total revenues	73.7	93.2
Product sales	69.7	33.3
Net loss	(35.0)	(171.5)
Adjusted EBITDA <sup>2</sup>	(28.3)	(136.0)
Cash	204.4	336.2

**Saint-Herblain (France), September 21, 2023 – [Valneva SE](#)** (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its consolidated financial results for the first half of the year, ended June 30, 2023. The half year financial report, including the condensed

<sup>1</sup> [Valneva Announces Extension of Existing Loan Agreement - Valneva](#)

<sup>2</sup> For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR



consolidated interim financial report and the half year management report, is available on the Company's website ([Financial Reports – Valneva](#)).

Valneva will provide a live webcast of its first half 2023 results conference call beginning at 3 p.m. CEST/9 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/qbnasrnq>

**Peter Bühler, Valneva's Chief Financial Officer**, commented, "We delivered another strong quarter of growth, leading our first half vaccine sales to more than double year-over-year, while continuing to progress our clinical studies. Our objective is to continue driving these sales in 2023 and, at the same time, continue to build a stronger commercial vaccine portfolio, notably with the potential addition of our chikungunya vaccine candidate later this year."

## Clinical Stage Vaccine Candidates

### CHIKUNGUNYA VACCINE CANDIDATE – VLA1553 BLA under priority review by the U.S. FDA

VLA1553 is a live-attenuated, single-dose vaccine candidate against the chikungunya virus (CHIKV), a mosquito-borne virus that has spread to more than 110 countries<sup>3</sup> with the potential to rapidly expand further. The Pan American Health Organization (PAHO) issued an epidemiological alert in February 2023 as the number of cases and deaths due to chikungunya continues to rise in the Americas<sup>4</sup>. With no preventive vaccine or specific treatment yet available, chikungunya is considered a major public health threat.

VLA1553 is currently the first and only chikungunya vaccine candidate worldwide for which regulatory review processes are underway. A Biologic License Application (BLA) is currently under priority review by the U.S. Food and Drug Administration (FDA)<sup>5</sup> with a Prescription Drug User Fee Act (PDUFA) action date planned for end of November 2023<sup>6</sup>. The FDA extended the PDUFA date by three months in August 2023 to allow sufficient time to align and agree on the Phase 4 program (post marketing requirements) necessary under the accelerated approval pathway<sup>7</sup>. No additional clinical data have been requested for the approval process.

Additionally, a regulatory application was filed with Health Canada at the end of May 2023<sup>8</sup> and accepted for review at the end of August 2023<sup>9</sup>.

If approved, VLA1553 could become the first licensed chikungunya vaccine available to address this unmet medical need.

The regulatory submissions with Health Canada and the FDA follow final pivotal Phase 3 data in March 2022<sup>10</sup>, final lot-to-lot consistency results in May 2022<sup>11</sup> and positive twelve-month persistence data in December 2022<sup>12</sup>. The pivotal Phase 3 data were published in *The Lancet*, the world's leading peer-reviewed medical journal, in June 2023<sup>13</sup>. The article, titled, "[Safety and](#)

<sup>3</sup> <https://www.who.int/news-room/fact-sheets/detail/chikungunya>

<sup>4</sup> <https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas>

<sup>5</sup> [FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva](#)

<sup>6</sup> [Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva](#)

<sup>7</sup> [Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva](#)

<sup>8</sup> [Valneva Files for Chikungunya Vaccine Authorization with Health Canada - Valneva](#)

<sup>9</sup> [Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review - Valneva](#)

<sup>10</sup> [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

<sup>11</sup> [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

<sup>12</sup> [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

<sup>13</sup> [Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva](#)

immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicenter, randomized, placebo-controlled phase 3 trial," provides a detailed analysis of the Phase 3 results showing that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration. This immunogenicity profile was similar in both younger and older adults, and 96% of participants maintained seroresponse six months after vaccination. VLA1553 was equally well tolerated in younger and older adults. Earlier clinical data, published in the *Lancet Infectious Diseases*, showed that the onset of the immune response after a single dose of VLA1553 is between 7- and 14-days post-vaccination<sup>14</sup>. This potential for a rapid onset of seroresponse was later confirmed in a post-hoc analysis of the Phase 1 study which showed that 100% of vaccinated individuals reached the seroresponse threshold at day 14<sup>15</sup>. Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 months with a 99% seroresponse rate and was equally durable in younger and older adults<sup>16</sup>. This dedicated antibody persistence trial (VLA1553-303) will continue to evaluate persistence for a period of at least five years. VLA1553 uses the live-attenuated virus vaccine technology, known to induce long-lasting immunity after a single dose. Examples of live-attenuated vaccines include the combined measles, mumps and rubella (MMR), yellow fever, and chickenpox (varicella) vaccines.

A clinical study in adolescents, VLA1553-321, is ongoing in Brazil, for which Valneva reported enrollment and vaccination completion in February 2023<sup>17</sup> and initial safety data in August 2023<sup>18</sup>. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and conducted in collaboration with Instituto Butantan, the VLA1553-321 adolescent trial is intended to support the label extension in this age group following a potential initial FDA approval in adults. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. Additionally, the present safety analysis is expected to enable regulatory submission to the European Medicines Agency (EMA) later this year.

Initial safety data generated from the study, Valneva's first clinical study in an endemic area and with individuals previously infected with CHIKV, show that VLA1553 was generally well tolerated in 754 adolescents aged 12 to 17 years, regardless of previous CHIKV infection. Immunogenicity data for the trial are expected in November 2023.

To make VLA1553 more accessible to Low- and Middle-Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing, and marketing of VLA1553<sup>19</sup>. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019<sup>20</sup>, which provides funding of up to \$24.6 million with support from the European Union's Horizon 2020 program.

VLA1553 received FDA Fast Track, Breakthrough Therapy and Priority Review designations in 2018, 2021 and 2023 respectively. The sponsor of the first chikungunya vaccine BLA to be approved in the United States will be eligible to receive a Priority Review Voucher, or PRV. The program was also granted PRiority MEdicine (PRIME) designation by the EMA in 2020, and Valneva plans to make regulatory submissions for VLA1553 in Europe in the second half of 2023.

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<sup>14</sup> Wressnigg N, Hochreiter R, Zoihs O, Fritzer A, Bézay N, Klingler A, Lingnau K, Schneider M, Lundberg U, Meinke A, Larcher-Senn J, Čorbic-Ramljak I, Eder-Lingelbach S, Dubischar K, Bender W. "Single-shot live-attenuated chikungunya vaccine in healthy adults: a phase 1, randomised controlled trial." *Lancet ID*, 2020: 20(10):1193-1203.

<sup>15</sup> McMahon R, Töpfer S, Schneider M, Hadl S, Hochreiter R, Kosulin K, Mader R, Zoihs O, Wressnigg N, Dubischar K, Buerger V, Eder-Lingelbach S, Jaramillo JC. "One year antibody persistence and safety of a live-attenuated chikungunya virus (CHIKV) vaccine candidate (VLA1553) in adults aged 18 years and above." *CISTM*. Basel, 2023.

<sup>16</sup> [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

<sup>17</sup> [Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

<sup>18</sup> [Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

<sup>19</sup> [Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries](#)

<sup>20</sup> [CEPI awards up to \\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine](#)

Valneva intends to commercialize VLA1553, if approved, by leveraging its existing manufacturing and commercial infrastructures. The global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032<sup>21</sup>.

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

### **Phase 3 study ongoing and first positive pediatric and adolescent booster results reported**

Valneva and Pfizer are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, 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 North America and Europe. VLA15 is the only Lyme disease vaccine program in advanced clinical development today and has received Fast Track designation from the FDA.

Valneva and Pfizer reported results for three Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which high levels of antibodies against all six strains were observed<sup>22,23,24</sup>. These include the announcement in September 2023 of positive Phase 2 pediatric and adolescent immunogenicity and safety data following a booster vaccination with VLA15. These results from the VLA15-221 Phase 2 study showed a strong anamnestic antibody response for all serotypes in pediatric (5 to 11 years of age) and adolescent participants (12 to 17 years of age), as well as in adults (18 to 65 years of age), one month after administration of a booster dose (month 19). The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies<sup>25</sup>.

In August 2022, the companies initiated a Phase 3 clinical study, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)", to investigate the efficacy, safety and immunogenicity of VLA15 in participants five years of age and older in highly endemic regions in the United States and Europe<sup>26</sup>.

The VALOR study is currently ongoing and is designed to follow vaccinated participants over two consecutive tick seasons. As communicated in February 2023, Pfizer had to discontinue approximately half of the total recruited participants in the trial following violations of Good Clinical Practice (GCP) at certain trial sites in the U.S. run by a third-party trial site operator. The clinical study remains ongoing with other sites not operated by the third party, and Pfizer has begun enrolling new participants into a second, identical cohort at those sites in addition to newly added sites in the U.S. and Canada. The original study design and endpoints previously agreed with regulators have not changed. Current projected incremental study execution costs incurred due to the agreed amount of additional enrollment will be borne by Pfizer.

Participants enrolled in the first cohort will receive their booster vaccination as planned in the second quarter of 2024 in advance of the 2024 tick season. Enrollment for primary immunization of the second cohort began in the second quarter of 2023 with overall trial continuation to include the 2025 tick season.

Pfizer is aiming to submit a BLA to the FDA and Marketing Authorization Application (MAA) to the EMA in 2026, subject to positive data.

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<sup>21</sup> *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

<sup>22</sup> *Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva*

<sup>23</sup> *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*

<sup>24</sup> *Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva*

<sup>25</sup> *Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate - Valneva*

<sup>26</sup> *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*

## ZIKA VACCINE CANDIDATE – VLA1601

### Re-initiation of clinical development with further program evaluation planned

VLA1601 is a highly purified inactivated, adjuvanted vaccine candidate against the mosquito-borne viral disease caused by the Zika virus (ZIKV). Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. Zika virus transmission persists in several countries in the Americas and in other endemic regions. To date, a total of 89 countries and territories have reported evidence of mosquito-transmitted Zika virus infection; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat.

VLA1601 is being developed on the original manufacturing platform of Valneva's licensed Japanese Encephalitis vaccine IXIARO<sup>®</sup>, which was further optimized to develop the Company's inactivated, adjuvanted COVID-19 vaccine VLA2001, the first one to receive a standard marketing authorization in Europe<sup>27</sup>.

Valneva has decided to re-initiate clinical development with further program evaluation to be conducted subject to data, medical need and market prospects. This decision is based on the persistence of Zika transmission in several countries<sup>28</sup>, the possibility to leverage the Company's existing inactivated viral platform and potentially its expertise in accelerated regulatory pathways, as well as VLA1601's compelling Target Product Profile (TPP).

## Pre-Clinical Vaccine Candidates

Valneva continues to progress selected pre-clinical assets to further strengthen its future clinical pipeline.

In preclinical R&D, the Company is currently prioritizing VLA2112, a vaccine candidate targeting the Epstein-Barr virus (EBV). EBV is a ubiquitous human pathogen that can cause infectious mononucleosis<sup>29</sup> and is strongly associated with the development of several types of cancer<sup>30</sup> and multiple sclerosis<sup>31</sup>.

Other early-stage activities include vaccine candidates against different enteric diseases.

Valneva continues to explore potential partnering opportunities for VLA1554, its vaccine candidate targeting the human metapneumovirus (hMPV), a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection<sup>32</sup>.

## Commercial Vaccines

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

IXIARO<sup>®</sup> is a Vero cell culture-derived inactivated Japanese encephalitis (JE) vaccine that is the only JE vaccine licensed and available in the United States, Canada and Europe. IXIARO<sup>®</sup> is

<sup>27</sup> [Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 - Valneva](#)

<sup>28</sup> [Zika virus disease \(who.int\)](#)

<sup>29</sup> <https://www.cdc.gov/epsteinbarr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults>.

<sup>30</sup> <https://www.cancer.org/healthy/cancer-causes/infectious-agents/infections-that-can-lead-to-cancer/viruses.html#:~:text=EBV%20infection%20increases%20a%20person's,some%20cases%20of%20stomach%20cancer>.

<sup>31</sup> <https://www.nih.gov/news-events/nih-research-matters/study-suggests-epstein-barr-virus-may-cause-multiple-sclerosis#:~:text=Infection%20with%20Epstein%20Barr%20virus,could%20help%20prevent%20multiple%20sclerosis>

<sup>32</sup> <https://www.cdc.gov/ncird/human-metapneumovirus.html>

indicated for active immunization against Japanese encephalitis, the most prevalent cause of viral encephalitis in Asia, for adults, adolescents, children and infants aged two months and older.

In the first half of 2023, IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales increased by to 147% to €30.3 million compared to €12.3 million in the first half of 2022, benefiting from a significant recovery in the private travel markets following the decline of the COVID-19 pandemic, as well as from price increases.

Valneva distributes IXIARO<sup>®</sup> directly to the U.S. Department of Defense (DoD) and the Company expects to announce a new contract with the U.S. Defense Logistics Agency (DLA) imminently.

### **CHOLERA / ETEC<sup>33</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<sup>34</sup>, 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.

In the first half of 2023, DUKORAL<sup>®</sup> sales increased by 197% to €17.1 million compared to €5.8 million in the first half of 2022, also benefiting from the significant recovery in the private travel markets and price increases.

### **THIRD-PARTY DISTRIBUTION**

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In the first half of 2023, third party product sales increased by 44% to €16.5 million from €11.5 million in the first half of 2022.

### **MANUFACTURING UPDATE**

#### **Valneva's Management Board decides on strategic direction for new Scottish manufacturing facility Almeida**

In July 2023, Valneva's Management Board took the decision to begin a staggered transfer of production for Valneva's Japanese encephalitis vaccine and chikungunya vaccine candidate to its state-of-the-art Almeida manufacturing facility, which was initially built to produce the Company's COVID-19 vaccine. As communicated in its first quarter results on May 4, 2023, the Company had been exploring options for the facility, including a possible sale of the facility. The Company will carefully balance resources across its two Scottish facilities to ensure a smooth and efficient transfer of production to Almeida.

#### **Valneva divests Swedish clinical trial manufacturing unit to NorthX Biologics**

As part of its strategy to focus on core business activities, Valneva divested its clinical trial manufacturing, or CTM, unit in Solna, Sweden, to NorthX Biologics, an established Nordic contract development and manufacturing organization (CDMO) in July 2023. The deal comprised Valneva's

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<sup>33</sup> 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.

<sup>34</sup> Enterotoxigenic *Escherichia coli* (ETEC) is a type of *Escherichia coli* and one of the leading bacterial causes of diarrhea in the developing world, as well as the most common cause of travelers' diarrhea.

CTM production facility and approximately 30 staff members in Sweden. Valneva Sweden retains 150 employees at its Swedish site, working in the Company's dedicated production unit for its cholera vaccine DUKORAL<sup>®</sup> and its center of excellence for fill and finish operations.

## First Half 2023 Financial Review

(Unaudited, consolidated under IFRS)

### Revenues

Valneva's total revenues were €73.7 million in the first half of 2023 compared to €93.2 million in the first half of 2022, a decrease of 20.9%. The decrease was related to non-recurring revenues recorded in the prior year related to the Company's COVID-19 program.

Valneva's total product sales reached €69.7 million in the first half of 2023 compared to €33.3 million in the first half of 2022, an increase of 109.0%. This was driven by a continued recovery of travel vaccine sales. Foreign currency fluctuations contributed to a €0.7 million decline in product sales. COVID-19 vaccine sales in the first half of 2023 amounted to €5.7 million compared to €3.8 million in the first half of 2022. Excluding COVID-19, product sales reached €64.0 million in the first half of 2023 compared to €29.5 million in the comparator period of 2022, an increase of 116.6%.

IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales were €30.3 million in the first half of 2023 compared to €12.3 million in the first half of 2022, an increase of 146.8% with sales benefitting from the continuing recovery of travel markets as well as price increases. Foreign currency fluctuations contributed to a €0.2 million decline in product sales. DUKORAL<sup>®</sup> sales were €17.1 million in the first half of 2023 compared to €5.8 million in the first half of 2022, an increase of 197.4%, also benefitting from the significant recovery in the private travel markets and price increases. Foreign currency fluctuations contributed to a €0.3 million decline in product sales. Third Party product sales were €16.5 million in the first half of 2023 compared to €11.5 million in the first half of 2022, an increase of 43.8%, which was mainly driven by sales under the distribution agreement with Bavarian Nordic for Rabipur<sup>®</sup>/RabAvert<sup>®</sup> and Encepur<sup>®</sup>.

Other revenues, including revenues from collaborations, licensing and services amounted to €4.1 million in the first half of 2023 compared to €59.9 million in the first half of 2022. The prior year period included €89.4 million released from the refund liability as a result of the settlement with the UK government, partially offset by €36.1 million of negative revenue resulting from an increase in the refund liability linked to the amendment to the VLA15 collaboration and license agreement with Pfizer.

### Operating Result and Adjusted EBITDA

Costs of goods and services sold (COGS) were €53.8 million in the first half of 2023. The gross margin on commercial product sales excluding COVID-19 sales was 40.0% compared to 58.3% in the first half of 2022. COGS of €18.1 million related to IXIARO<sup>®</sup> product sales yielding a product gross margin of 40.2%. COGS of €10.1 million related to DUKORAL<sup>®</sup> product sales yielding a product gross margin of 40.9%. The gross margin of IXIARO<sup>®</sup> was impacted by batch write-offs in the Scottish manufacturing site. Additionally, the gross margins of both IXIARO<sup>®</sup> and DUKORAL<sup>®</sup> were adversely impacted by high indirect sales in markets where Valneva sells through distributors. Of the remaining COGS for the first half of 2023, €10.2 million were related to the Third-Party product distribution business, €3.8 million to COVID-19 product sales and €6.1 million to initial COGS related to the launch preparations for the chikungunya vaccine candidate as well as to idle capacity costs. In the first half of 2022, overall COGS were €171.5 million, of which €167.2 million related to cost of goods and €4.3 million related to cost of services. COGS in the first half of 2022 included write-offs related to the significant reduction of COVID-19 sales volumes to EC Member States.

Research and development expenses amounted to €26.0 million in the first half of 2023 compared to €51.9 million in the first half of 2022. This decrease was exclusively driven by the lower spend on Valneva's COVID-19 vaccine VLA2001. At the same time, cost related to the Zika vaccine candidate increased as the Company has been working towards a re-initiation of clinical development. Marketing and distribution expenses in the first half of 2023 amounted to €20.0 million compared to €7.8 million in the first half of 2022. Marketing and distribution expenses in the first half of 2023 notably included €7.8 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate, VLA1553, compared to €2.2 million in the first half of 2022. In the first half of 2023, general and administrative expenses increased to €22.9 million from €16.0 million in the first half of 2022. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited in the first half of 2022 from an accrual adjustment income of €19.5 million related to the favorable effect of the Company's share price development on the employee share-based compensation programs.

Other income, net of other expenses, increased to €15.9 million in the first half of 2023 from €3.6 million in the first half of 2022. This increase was mainly driven by recognizing grant income received from Scottish Enterprise into the income statement in the first half of 2023.

Valneva recorded an operating loss of €35.0 million in the first half of 2023 compared to an operating loss of €150.4 million in the first half of 2022. Adjusted EBITDA loss in the first half of 2023 was €28.3 million compared to an Adjusted EBITDA loss of €136.0 million in the first half of 2022 (as explained further below).

### **Net Result**

In the first half of 2023, Valneva generated a net loss of €35.0 million compared to a net loss of €171.5 million in the first half of 2022.

Finance expense and foreign currency effects in the first half of 2023 resulted in a net finance expense of €3.9 million, compared to a net finance expense of €18.8 million in the first half of 2022. This was mainly a result of a foreign exchange gain amounting to €4.5 million in the first half of 2023, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange loss of €10.7 million in the first half of 2022. Interest expenses net of interest income were €8.4 million in the first half of 2023 compared to €8.2 million in the first half of 2022.

### **Cash Flow and Liquidity**

Net cash used in operating activities amounted to €65.4 million in the first half of 2023 compared to €100.2 million in the first half of 2022. Cash outflows in the first half of 2023 mainly resulted from the operating loss as well as increased working capital. Cash outflows in the first half of 2022 mainly resulted from the operating loss generated.

Cash outflows from investing activities amounted to €6.6 million in the first half of 2023 compared to €16.0 million in the first half of 2022, both mainly related to construction activities at the Scottish production site and purchases of equipment.

Net cash used in financing activities amounted to €9.5 million in the first half of 2023, which was mainly due to interest payments as well as payments of lease liabilities. Cash inflows in the first half of 2022 amounted to €105.0 million and mainly related to proceeds from the equity subscription agreement with Pfizer as well as disbursements from the credit facility provided by Deerfield & OrbiMed.

Cash and cash equivalents amounted to €204.4 million as at June 30, 2023, compared to €289.4 million as at December 31, 2022.



### Non-IFRS Financial Measures

Management uses and presents IFRS results, as well as the non-IFRS measure of Adjusted 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.

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

A reconciliation of Adjusted EBITDA to operating loss, which is the most directly comparable IFRS measure, is set forth below:

€ in million	6 months ending June 30	
	2023	2022
(unaudited results, consolidated per IFRS)		
Net Income	(35.0)	(171.5)
Add:		
Income tax expense	(3.8)	2.3
Total Finance income	(0.5)	(0.0)
Total Finance expense	8.9	8.2
Foreign exchange gain/(loss) – net	(4.5)	10.7
Result from investments in associates	-	(0.0)
Amortization	3.2	3.5
Depreciation	5.4	7.7
Impairment, excluding impairment loss of disposal	(1.9)	3.3
<b>Adjusted EBITDA</b>	<b>(28.3)</b>	<b>(136.0)</b>

### About Valneva SE

We are a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet medical needs to ensure we can make a difference to peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today, we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.



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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 product sales for full fiscal year 2023 and the expected timing for submissions to and responses by regulatory authorities. 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 or delays, 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 cancellation of existing contracts, 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.