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Valneva Reports Full Year 2023 Results and Provides Business Updates and Outlook

Total revenues of €153.7 million, including product sales of €144.6 million

- Product sales surpassed pre-pandemic (2019) sales by 12% and 2022 sales by 26%
- Excluding COVID-19 vaccine sales, product sales grew by 63% compared to 2022

Cash position of €126.1 million at year-end 2023 enhanced by €95 million from sale of Priority Review Voucher (PRV)[1]

- Extended the interest-only period of existing debt financing agreement to January 2026 significantly extending cash runway[2]
- Operational business considered sufficiently funded (excluding debt repayment) until commercial revenues from Lyme program enable sustained profitability

Excellent progress across R&D pipeline

- Approval of single-shot chikungunya vaccine IXCHIQ® in the United States (U.S.)
  - The world's first and only vaccine to address this significant unmet medical need
  - U.S. CDC recently adopted ACIP recommendations[3]
  - Regulatory reviews ongoing in Europe, Canada and Brazil
- Completion of recruitment for Lyme disease Phase 3 study conducted in collaboration with Pfizer
  - All execution milestones on track
- Advancing second-generation ZIKA vaccine candidate into Phase 1 clinical trial
  - Addressing a re-emerging medical need

Updated FY 2024 guidance

Valneva raises its 2024 product sales[4] guidance to between €160 million and €180 million due to an improved outlook regarding the IXIARO® supply constraints that were anticipated in February 2024. As such, 2024 total revenues are now expected to reach between €170 million and €190 million compared to €153.7 million in 2023, driven by continued sales growth of the Company's proprietary travel vaccines and the launch-year sales of IXCHIQ®.
Sales are expected to grow this year despite an estimated 20-30% reduction in third-party sales as a result of anticipated supply constraints.
In 2024, the Company anticipates lower R&D expenses than previously communicated, narrowing guidance to €60 million to €75 million, based on additional visibility for its chikungunya- and Zika-related expenses. Additionally, Valneva expects non-dilutive contributions from institutions for R&D costs in connection with its ongoing chikungunya activities and the product tech transfers to Valneva's brand-new state-of the art facility ("Almeida") in Scotland.
Other income is now expected between €100 million and €110 million in 2024, reflecting €95 million in proceeds from the PRV sale in early 2024.

[1] *Valneva Announces Sale of Priority Review Voucher for $103 Million - Valneva*
[2] *Valneva Announces Extension of the Interest-Only Period of Its Debt Facility with Deerfield and OrbiMed - Valneva*
[3] *ACIP Vaccine Recommendations and Schedules | CDC*
[4] *Valneva Reports Full Year 2023 Revenue and Cash, Provides First 2024 Guidance - Valneva*

Valneva anticipates a significantly lower cash burn this year than in 2023 and expects its commercial business to be cash-flow positive and contribute significantly to funding the Company's R&D from 2025.
Valneva's cost contributions for the Lyme disease Phase 3 study are expected to be completed in the first half of 2024. All remaining payments to Pfizer are reflected in current refund liability at December 31, 2023, and will not impact the Profit & Loss statement in 2024.
The Company has re-negotiated the terms of its loan agreement with Deerfield and OrbiMed[5] and will now start reimbursing the first $100 million tranche in January 2026 instead of July 2024. The loan interest rate remains unchanged and this portion of the loan will still mature in the first quarter of 2027.

Mid-term outlook

Product sales

In the mid-term, Valneva expects continued sales growth for its travel vaccines IXIARO® and DUKORAL®, and with the current launch of IXCHIQ®, the Company anticipates annual product sales to approximately double by the end of 2026. This will be driven by IXIARO®, for which continued double-digit annual growth is expected for at least the next three years, and by ramping IXCHIQ® sales, which are expected to exceed €100 million in year three after initial launch, subject to anticipated regulatory approvals and even assuming potential competitive product entry. There may also be upside from potential IXCHIQ® stockpiling opportunities. Regulatory reviews are ongoing in Europe, Canada and Brazil, and decisions for these submissions are expected in 2024. The Company currently estimates that the travel market opportunity for chikungunya vaccines could be valued between €300 million to €400 million based on the number of travelers to endemic regions and their anticipated adoption of the vaccine. Additionally, considering the high unmet medical need that chikungunya represents in Low- and Middle-Income Countries (LMICs), Valneva expects strong adoption of its chikungunya vaccine in these countries.
The third-party product business supported Valneva's revenues as a complement to its existing travel vaccine portfolio, especially during the COVID-19 pandemic. However, 2023 third-party sales of more than €35 million yielded only 36% gross margin, diluting Valneva's overall margins, and the Company has therefore decided to focus resources on direct sales of its proprietary products. Valneva expects that third-party sales will gradually wind down to less than 5% of product sales by 2026/2027, considering the anticipated end to its collaboration with Bavarian Nordic by the end of 2025. This is expected to bring the gross margin back to pre-COVID levels or better, with additional margin improvements expected from the cost-efficient manufacturing process of IXCHIQ® and scaling effects from leveraging the Company's new manufacturing facilities in Livingston (Scotland) and Solna (Sweden).

R&D

Valneva will continue leveraging its proven capabilities to develop differentiated first-, best- or only-in-class vaccine solutions in areas of high unmet medical need. As in previous years, the Company will focus on advancing a limited number of promising product candidates with the aim to have an additional clinical program entering Phase 3 upon completion of the Phase 3 program for Lyme. Valneva may reach its pipeline development objective organically and/or via strategic transactions.
Over the next three years, the Company expects approximately 40% of its R&D expenses to be linked to chikungunya development activities, including ongoing and anticipated clinical studies.

[5] *Valneva Announces Extension of the Interest-Only Period of Its Debt Facility with Deerfield and OrbiMed - Valneva*

These chikungunya expenses are expected to be supported at a sizable level by non-dilutive contributions from several institutions.

Cash management
In the mid-term, Valneva will continue focusing on stringent cost management with a particular focus on marketing and distribution as well as general and administrative costs. In parallel, IXCHIQ® sales ramp-up and anticipated gross margin improvements will further reduce the Company's cash burn. The Company reduced its loss by more than €40 million in 2023 and expects to further reduce it in the coming years, anticipating that Valneva may achieve sustained profitability with potential commercial revenues from a successful development, approval and launch of its Lyme disease vaccine candidate partnered with Pfizer.
With the eighteen-month extension of the interest-only period of its Deerfield and OrbiMed loan[6], and based on 2023 year-end cash as augmented by the proceeds from the PRV sale, Valneva believes that it is sufficiently financed for its operational business, excluding debt repayment, until potential commercial revenues from its Lyme program enable the Company to operate in a sustained profitable way.

Financial Information

(Audited 2023 results, consolidated per IFRS)

€ in million	**12 months ending December 31**	
	2023	**2022**
Total revenues	153.7	361.3
Product sales	144.6	114.8
Net profit/(loss)	(101.4)	(143.3)
Adjusted EBITDA (loss)	(65.2)	(69.2)
Cash	126.1	289.4

Saint-Herblain (France), March 20, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today reported its consolidated financial results for the year ending December 31, 2023 and provided several key corporate updates.

Valneva will provide a live webcast of its full-year 2023 results conference call beginning at 3 p.m. CET/10 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/hom3riyt

Peter Bühler, Valneva's Chief Financial Officer, commented, "In 2023, Valneva successfully executed on key strategic objectives despite a difficult economic environment. Our chikungunya vaccine IXCHIQ® became the world's first licensed chikungunya vaccine available to address this significant unmet medical need and we also managed to surpass our pre-pandemic product sales. Our objective for 2024 is to continue capitalizing on the travel industry recovery to generate further commercial growth and successfully launch our chikungunya vaccine IXCHIQ®. With the recent successful sale of our PRV, and extension of our loan repayment, we have entered 2024 in a solid financial position to support our near- and mid-term commercial and R&D objectives."

[6] *Valneva Announces Extension of the Interest-Only Period of Its Debt Facility with Deerfield and OrbiMed - Valneva*

Commercial Portfolio

Valneva's commercial portfolio is composed of three travel vaccines, IXIARO®/JESPECT®, DUKORAL® and IXCHIQ®. The Company also distributes certain third-party products in countries where it operates its own marketing and sales infrastructure.

JAPANESE ENCEPHALITIS VACCINE IXIARO®/JESPECT®

IXIARO®, or JESPECT® in Australia and New Zealand, is an inactivated Vero cell culture-derived Japanese encephalitis and is the only Japanese encephalitis vaccine currently approved for use in the United States, Canada and Europe. IXIARO® is 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, and is a required vaccine for U.S. military personnel who are deployed to areas of risk for Japanese encephalitis. The virus is spread by mosquitos and is the most important cause of viral encephalitis in Asia and the Western Pacific.

In 2023, IXIARO®/JESPECT® sales increased 78% to €73.5 million compared to €41.3 million in 2022, primarily benefiting from the continued travel market recovery after the COVID-19 pandemic, and price increases. At the end of September 2023, Valneva also signed a new one-year contract with the U.S. Department of Defense (DoD) worth a minimum of $32 million for the supply of IXIARO®.

CHOLERA / ETEC[7]-DIARRHEA VACCINE DUKORAL®

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC[8], 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.

In 2023, DUKORAL® sales increased 72% to €29.8 million compared to €17.3 million in 2022, of which Canada represented €17.5 million of global sales due to the strong overlap between Canadian travelers to regions of high ETEC prevalence and the vaccine's approved indication. Similar to IXIARO®, DUKORAL® benefitted from the significant recovery in the private travel markets.

CHIKUNGUNYA VACCINE IXCHIQ®

IXCHIQ® is a single-dose, live-attenuated vaccine against the chikungunya virus (CHIKV), which in November 2023 was approved in the U.S. by the Food and Drug Administration (FDA) for the prevention of disease caused by CHIKV in individuals 18 years of age and older who are at increased risk of exposure to the mosquito-borne CHIKV. With this approval, IXCHIQ® became the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need.

At the end of February 2024, the U.S. Advisory Committee on Immunization Practices (ACIP), which develops recommendations on how to use vaccines in the U.S., recommended IXCHIQ® for persons aged 18 years and above traveling to a country or territory where a chikungunya outbreak is occurring. Additionally, IXCHIQ® may be considered for persons traveling to a country or territory without an outbreak but with evidence of CHIKV transmission within the last five years, who are aged 65 years and above, and likely to have at least moderate exposure to mosquitos (at least two weeks,

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[7] 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.

[8] 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.

cumulatively) or who are traveling for a longer duration (six months or more, cumulatively). ACIP also recommended chikungunya vaccination for laboratory workers with potential for exposure to CHIKV. The ACIP recommendations were recently adopted by the Centers for Disease Control and Prevention[9].

Valneva's commercial team is currently launching the vaccine in the U.S. The single-shot vaccine is also under regulatory review in Canada, Brazil and Europe, where it was granted accelerated assessment by the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP). Decisions for these submissions are expected in 2024.

IXCHIQ®'s final pivotal Phase 3 data were published in The Lancet, the world's leading peer-reviewed medical journal, in June 2023[10]. The article 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 compared to the 70% threshold (for non-acceptance) agreed with the FDA. Valneva is working on the preparation of two Phase 4 post-marketing effectiveness studies, required as part of the FDA's approval under the accelerated pathway. The Company expects to launch these studies in 2025.

Earlier clinical data, published in the *Lancet Infectious Diseases*, showed a rapid onset of immune response with a single dose of VLA1553 between 7- and 14-days post-vaccination[11]. This was later confirmed in a further analysis of the Phase 1 data[12], which showed that 100% of vaccinated individuals reached the immune threshold[13] established with the FDA at day 14.

Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 and 24 months by 99% and 97% of participants, respectively, and was equally durable in younger and older adults[14][15]. This dedicated antibody persistence trial (VLA1553-303) will continue to evaluate persistence for a period of at least five years.

A clinical study in adolescents, VLA1553-321, is ongoing in Brazil, for which Valneva reported initial safety data in August 2023[16]. 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 to this age group following initial approvals 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 Company initiated a Phase 2 pediatric trial in children aged 1 to 11 years, VLA1553-221, in January 2024[17] to support a Phase 3 pivotal pediatric study and potentially extend the label to this age group following initial regulatory approvals in adults and possibly in adolescents.

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[9] *ACIP Vaccine Recommendations and Schedules | CDC*
[10] *Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva*
[11] *Wressnigg N, Hochreiter R, Zoihsl 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.*
[12] *McMahon R, Töpfer S, Schneider M, Hadl S, Hochreiter R, Kosulin K, Mader R, Zoihsl 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.*
[13] *Seroresponse*
[14] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[15] *Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[16] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*
[17] *Valneva Vaccinates First Participant in Pediatric Trial of Single-Shot Chikungunya Vaccine - Valneva*

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. The Company notably has distribution agreements with Bavarian Nordic[18] and VBI Vaccines[19].

In the year ended December 31, 2023, third-party product sales grew 34% to €35.7 million compared to €26.5 million in the year ended December 31, 2022.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 3 study ongoing

Valneva and Pfizer are developing VLA15, a Phase 3 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is the only Lyme disease program in late-stage 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[20,21,22]. 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[23].

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[24].

Recruitment completion for the study was announced in December 2023. 9,437 participants five years of age and older were enrolled in the trial and will receive, as part of the primary series, three doses of VLA15 or a saline placebo (1:1 ratio) within the first year, and one booster dose approximately one year after vaccination with the first three doses[25]. The VALOR study is currently ongoing and is designed to follow vaccinated participants over two consecutive tick seasons. In the second quarter of 2024, participants enrolled in the first cohort will receive their booster vaccination and participants of the second cohort will receive the last of their initial three doses ahead of the 2024 tick season.

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[18] *Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership - Valneva*
[19] *Valneva and VBI Vaccines Announce European Partnership for Marketing and Distribution of PreHevbri® - Valneva*
[20] *Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva*
[21] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*
[22] *Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva*
[23] *Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate - Valneva*
[24] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*
[25] *Pfizer and Valneva Complete Recruitment for Phase 3 VALOR Trial for Lyme Disease Vaccine Candidate, VLA15 - Valneva*

Topline data from the VALOR trial are expected by the end of 2025, with the aim for Pfizer to submit a Biologic License Application to the FDA and Marketing Authorization Application to the EMA in 2026, subject to positive data.

ZIKA VACCINE CANDIDATE – VLA1601
Entering Phase 1, 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[26]; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat and is included in the Food and Drug Administration's Tropical Disease Priority Review Voucher Program[27].

VLA1601 is being developed on the original manufacturing platform of Valneva's licensed Japanese Encephalitis vaccine IXIARO®, 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[28]. Valneva reported Phase 1 results from its first-generation Zika vaccine candidate in 2019 showing excellent immunogenicity and safety results in all tested doses and schedules[29]. The Company now expects to start the clinical evaluation of its second-generation vaccine in the coming weeks.

A vaccine against the Zika virus (ZIKV) would nicely complement Valneva's portfolio of travel vaccines against mosquito-borne diseases, which already includes IXCHIQ® and IXIARO®.

Pre-Clinical Vaccine Candidates

Valneva continues to progress select pre-clinical assets and focus on strengthening its future clinical pipeline.

The Company is currently focused on VLA2112, a vaccine candidate targeting the Epstein-Barr virus (EBV), which is one of the most common human viruses. EBV can cause infectious mononucleosis[30] and is strongly associated with the development of several types of cancer[31] and multiple sclerosis[32].

Valneva has also been working on a vaccine candidate targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection[33] and is exploring potential partnering opportunities.

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[26] *Zika virus disease (who.int)*
[27] *Tropical Disease Priority Review Voucher Program | FDA*
[28] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 - Valneva*
[29] *Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva*
[30] *https://www.cdc.gov/epstein-barr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults.*
[31] *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.*
[32] *https://www.nih.gov/news-events/nih-research-matters/study-suggests-epstein-barr-virus-may-cause-multiple-sclerosis#:~:text=Infection%20with%20Epstein%2DBarr%20virus,could%20help%20prevent%20multiple%20sclerosis*
[33] *https://www.cdc.gov/ncird/human-metapneumovirus.html*

Additionally, Valneva initiated pre-clinical work on vaccine candidates against different enteric diseases.

Full Year 2023 Financial Review

(Audited[34], consolidated under IFRS)

Revenues

Valneva's total revenues were €153.7 million in 2023 compared to €361.3 million in 2022. Total revenues in 2022 included €280.0 million of revenue recognition mainly related to the COVID-19 supply agreements in the prior year.

Valneva's total product sales reached €144.6 million in 2023 compared to €114.8 million in 2022. Currency fluctuations of €2.8 million adversely impacted product sales. COVID-19 vaccine sales in 2023 amounted to €5.7 million compared to €29.6 million in 2022. Excluding COVID-19, product sales reached €138.9 million in 2023 compared to €85.2 million in 2022, an increase of 63%.

IXIARO®/JESPECT® sales were €73.5 million in 2023 compared to €41.3 million in 2022. The 78% increase in sales is primarily the result of the continued travel market recovery, as well as price increases. The increase in IXIARO®/JESPECT® product sales included an adverse €1.5 million foreign currency impact.

DUKORAL® sales were €29.8 million in 2023 compared to €17.3 million in 2022. This 72% increase is also a result of the significant recovery in the private travel markets and price increases. Foreign currency fluctuations reduced DUKORAL® sales by €0.9 million.

Third Party product sales were €35.7 million in 2023 compared to €26.5 million in 2022, a 34% increase which was mainly driven by sales of Rabipur®/RabAvert® and Encepur® under the distribution agreement with Bavarian Nordic.

Other revenues, including revenues from collaborations, licensing and services amounted to €9.1 million in 2023 compared to €246.5 million in 2022. Other revenues in 2022 included COVID related one-time effects of €280.0 million consisting of released refund liability as a result of the settlement with the UK government, as well as released non-refundable advance payments from European Member States, partially offset by €45.9 million of negative revenue resulting from an increase in the refund liability linked to the amended VLA15 collaboration and license agreement with Pfizer.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €100.9 million in 2023. The gross margin on commercial product sales amounted to 46.0% compared to 45.5% in 2022. COGS of €35.1 million related to IXIARO® product sales, yielding a product gross margin of 52.3%. COGS of €17.1 million related to DUKORAL® product sales, yielding a product gross margin of 42.4%. Of the remaining COGS in 2023, €22.8 million related to the third-party products distribution business, €5.3 million to VLA2001 and €10.2 million to cost of services. In 2022, overall COGS were €324.4 million, of which €314.7 million related to cost of goods and €9.7 million related to cost of services. In 2022, COGS of the COVID-19 vaccine program amounted to €267.1 million and included effects from the significant reduction of sales volumes to the European Union Member States which resulted in impairment of fixed assets and inventories.

[34] *The audit procedures on the consolidated financial statements have been performed. The audit report will be issued upon finalization of procedures regarding the filing.*

Research and development expenses amounted to €59.9 million in 2023, compared to €104.9 million in 2022. This decrease was exclusively driven by the lower spend on Valneva's COVID-19 vaccine, VLA2001. At the same time, costs related to the Zika vaccine candidate increased as the Company has been working towards re-initiation of clinical development. Marketing and distribution expenses in 2023 amounted to €48.8 million compared to €23.5 million in 2022. The increase is mainly related to €20.7 million of expenses associated with launch preparations for IXCHIQ® (2022: €7.3 million). In 2023, general and administrative expenses increased to €47.8 million from €34.1 million in 2022. In the previous year 2022, COGS, research and development, marketing and distribution as well as general and administrative expenses all benefited from a non-cash accrual adjustment related to the positive effect of the Company's share price development on employee share-based compensation programs. This income compares to an expense in 2023.

Other income, net of other expenses, increased to €21.5 million in 2023 from €12.2 million in 2022. The increase was mainly driven by grant income received from Scottish Enterprise in the amount of €11.1 million and by a gain from a settlement with a supplier in connection with COVID-19 activities of €4.7 million.

Valneva recorded an operating loss of €82.1 million in 2023 compared to an operating loss of €113.4 million in 2022. The higher loss in 2022 was primarily driven by non-recurring expenses of goods and services related to valuation of inventory, and onerous agreement provisions for material in connection with our COVID-19 vaccine and its program suspension. Adjusted EBITDA (as defined below) loss in 2023 was €65.2 million, nearly unchanged to the Adjusted EBITDA loss of €69.2 million in 2022.

Net Result

In 2023, Valneva generated a net loss of €101.4 million compared to a net loss of €143.3 million in 2022.

Finance expense and currency effects in 2023 resulted in a net finance expense of €16.5 million, compared to a net finance expense of €31.4 million in 2022. This increase in finance income/expenses, net was mainly due to foreign exchange gains of €5.6 million in 2023 compared to a loss of €12.6 million in 2022, primarily related to the development of the USD and GBP exchange rates.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €202.7 million in 2023 compared to €245.3 million of cash used in operating activities in 2022. Cash outflows in 2023 were derived from the loss for the period amounting to €101.4 million and from working capital in the amount of €145.6 million, which largely were related to payments to Pfizer in conjunction with Valneva's contribution to the Phase 3 costs of the Lyme VLA15 R&D program, reducing the refund liability.

Cash outflows from investing activities amounted to €20.6 million in 2023 compared to €29.1 million in 2022, both mainly a result of construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities decreased to €63.1 million in 2023 from €215.1 million in 2022. Cash inflows in 2023 were primarily due to €81.1 million of net proceeds from the additional tranches from the loan agreement with Deerfield and OrbiMed drawn in the second half of the year. Cash inflows in 2022 were mainly a result of proceeds from the equity subscription agreement with Pfizer, proceeds from a global offering as well as a draw-down of the loan provided by Deerfield and OrbiMed.

Cash and cash equivalents were €126.1 million as at December 31, 2023, compared to €289.4 million as at December 31, 2022. Cash and Cash equivalents in 2023 included the drawing of a total of $100 million from the Deerfield and OrbiMed loan agreement as well as significant payments made to Pfizer related to the companies' Phase 3 Lyme disease study "VALOR". Cash at the end of 2023 does not include $103 million of proceeds from the PRV, which Valneva sold in February 2024.

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 common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. Adjusted EBITDA is defined as earnings (loss) for the period before income tax, finance income/expense, foreign exchange gain/(loss), results from investments in associates, amortization, depreciation, and impairment (excluding impairment loss of disposal).

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

€ in million	**Twelve months ending December 31**	
(consolidated per IFRS)	**2023**	**2022**
Loss for the period	(101.4)	(143.3)
Add:		
Income tax expense	2.8	(1.5)
Total Finance income	(1.2)	(0.3)
Total Finance expense	23.3	19.1
Foreign exchange gain/(loss) – net	(5.6)	12.6
Result from investments in associates	-	-
Amortization	5.8	7.0
Depreciation	11.8	14.0
Impairment	(0.7)	23.2
Adjusted EBITDA	**(65.2)**	**(69.2)**

About Valneva SE

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines, including the world's first and only chikungunya vaccine, as well as certain third-party vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

About IXCHIQ®

In the U.S., IXCHIQ® is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA's accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.

Please click here for full Prescribing Information for IXCHIQ®.

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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 guidance for certain financial results in fiscal year 2024 and mid-term outlook on financial results, cash position, and other business developments, including results of ongoing clinical trials, the timing and possible occurrence of further or initial regulatory approvals of its product candidates, the anticipated size of markets for its approved products and sales of those products, receipt of funding from external sources, supply of products sold by Valneva, and relationships with current business partners. 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. These risks and uncertainties include those developed or identified in any public documents filed with the French financial markets authority (*Autorité des marchés financiers*) and the U.S. Securities and Exchange Commission made or to be made by Valneva. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines (including in relation to organic or strategic expansion of Valneva's clinical pipeline), unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis and other global economic or political events, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, the impact of a pandemic, and changes in the regulatory environment in which Valneva operates. The occurrence of any of these risks and uncertainties 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.

Annex

1.1 Consolidated Statement of Profit or Loss and other Comprehensive Income

Consolidated Statement of Profit or Loss

		Year ended December 31,	
in € thousand	Note	2023	2022
Product sales	*5*	144,624	114,797
Other revenues	*5*	9,088	246,506
REVENUES		**153,713**	**361,303**
Cost of goods and services	*6*	(100,875)	(324,441)
Research and development expenses	*6*	(59,894)	(104,922)
Marketing and distribution expenses	*6*	(48,752)	(23,509)
General and administrative expenses	*6*	(47,799)	(34,073)
Other income and expenses, net	*8*	21,520	12,199
OPERATING PROFIT/(LOSS)		**(82,087)**	**(113,443)**
Finance income	*9*	1,210	260
Finance expenses	*9*	(23,325)	(19,054)
Foreign exchange gain/(loss), net	*9*	5,574	(12,587)
Result from investments in associates		—	9
PROFIT/(LOSS) BEFORE INCOME TAX		**(98,629)**	**(144,815)**
Income tax benefit/(expense)	*10*	(2,800)	1,536
PROFIT/(LOSS) FOR THE PERIOD		**(101,429)**	**(143,279)**
EARNINGS/(LOSSES) PER SHARE			
for profit/(loss) for the period attributable to the equity holders of the Company (expressed in € per share)			
Basic	*11*	(0.73)	(1.24)
Diluted	*11*	(0.73)	(1.24)

Consolidated Statement of Comprehensive Income

		Year ended December 31,	
	Note	2023	2022
PROFIT/(LOSS) FOR THE PERIOD		**(101,429)**	**(143,279)**
OTHER COMPREHENSIVE INCOME/(LOSS)			
Items that may be reclassified to profit or loss			
Currency translation differences	*22.2*	3,300	(73)
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)	*30.1*	(130)	178
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX		**3,170**	**105**
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD		**(98,258)**	**(143,174)**

1.2 Consolidated Statement of Financial Position

in € thousand	Note	Year ended December 31 2023	2022
ASSETS			
Non-current assets		**197,238**	**196,685**
Intangible assets	*12*	25,567	28,711
Right of use assets	*13*	20,392	41,603
Property, plant and equipment	*14*	136,198	112,435
Deferred tax assets	*10.2*	6,592	5,637
Other non-current assets	*19*	8,490	8,299
Current assets		**262,824**	**424,660**
Inventories	*17*	44,466	35,104
Trade receivables	*18*	41,645	23,912
Other current assets	*19*	50,633	74,079
Cash and cash equivalents	*20*	126,080	289,430
Assets classified as held for sale	*21*	—	2,134
TOTAL ASSETS		**460,062**	**621,344**
EQUITY			
Share capital	*22*	20,837	20,755
Share premium	*22*	594,003	594,043
Other reserves	*22.2*	65,088	55,252
Retained earnings/(Accumulated deficit)	*22*	(450,253)	(306,974)
Loss for the period		(101,429)	(143,279)
TOTAL EQUITY		**128,247**	**219,797**
LIABILITIES			
Non-current liabilities		**172,952**	**124,156**
Borrowings	*24*	132,768	87,227
Lease liabilities	*27*	29,090	28,163
Refund liabilities	*29*	6,303	6,635
Provisions	*30*	1,074	1,320
Deferred tax liabilities	*10.2*	3,638	694
Other liabilities	*31*	79	116
Current liabilities		**158,863**	**277,392**
Borrowings	*24*	44,079	11,580
Trade payables and accruals	*25*	44,303	41,491
Income tax liability		632	532
Tax and Employee-related liabilities	*26*	16,209	15,738
Lease liabilities	*27*	2,879	25,411
Contract liabilities	*28*	5,697	9,411
Refund liabilities	*29*	33,637	136,450
Provisions	*30*	10,835	31,257
Other liabilities	*31*	592	5,523
TOTAL LIABILITIES		**331,815**	**401,547**
TOTAL EQUITY AND LIABILITIES		**460,062**	**621,344**

1.3 Consolidated Statement of Cash Flows

in € thousand	Note	Year ended December 31, 2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss for the year		(101,429)	(143,279)
Adjustments for non-cash transactions	*5.32.1*	44,984	44,070
Changes in non-current operating assets and liabilities	*5.32.1*	514	(147,713)
Changes in working capital	*5.32.1*	(145,578)	1,732
Cash used in operations	*5.32.1*	**(201,509)**	**(245,189)**
Income tax paid		(1,236)	(154)
NET CASH GENERATED FROM/(USED IN) OPERATING ACTIVITIES		**(202,744)**	**(245,343)**
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisition of subsidiaries, net of cash acquired	*5.1.2*	(10,951)	—
Purchases of property, plant and equipment		(14,231)	(29,246)
Proceeds from sale of property, plant and equipment		111	8
Purchases of intangible assets		(81)	(76)
Proceeds from assets classified as held for sale		3,358	—
Interest received		1,210	260
NET CASH GENERATED FROM/(USED IN) INVESTING ACTIVITIES		**(20,585)**	**(29,054)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds/(payments) from issuance of common stock, net of costs of equity transactions	*5.22*	(240)	189,837
Proceeds from borrowings, net of transaction costs	*5.24*	81,111	39,331
Repayment of borrowings	*5.24*	(2,097)	(1,793)
Payment of lease liabilities	*5.27*	(3,127)	(3,048)
Interest paid		(12,567)	(9,211)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES		**63,081**	**215,116**
NET CHANGE IN CASH AND CASH EQUIVALENTS		**(160,248)**	**(59,282)**
Cash and cash equivalents at beginning of the year [(1)]	*5.20*	286,532	346,642
Exchange gains/(losses) on cash		(204)	(828)
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD [(1)]		**126,080**	**286,532**

(1) Cash and cash equivalents as at December 31, 2022 amounted to €289.4 million as it included restricted cash of €2.9 million.

1.4 Consolidated Statement of Changes in Equity

in € thousand	Note	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2023		**20,755**	**594,043**	**55,252**	**(306,974)**	**(143,279)**	**219,797**
Total comprehensive income/(loss)		—	—	3,170	—	(101,429)	(98,258)
Income appropriation		—	—	—	(143,279)	143,279	—
Share-based compensation expense:							
Value of services	*23*	—	—	6,666	—	—	6,666
Exercises	*23*	82	(39)	—	—	—	42
BALANCE AS AT DECEMBER 31, 2023		**20,837**	**594,003**	**65,088**	**(450,253)**	**(101,429)**	**128,247**

in € thousand	Note	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2022		**15,786**	**409,258**	**52,512**	**(233,549)**	**(73,425)**	**170,581**
Total comprehensive income/(loss)		—	—	105	—	(143,279)	(143,174)
Income appropriation		—	—	—	(73,425)	73,425	—
Share-based compensation expense:							
Value of services	*23*	—	—	2,636	—	—	2,636
Exercises	*23*	387	3,371	—	—	—	3,758
Capital Increase	*22*	4,582	181,413	—	—	—	185,996
BALANCE AS AT DECEMBER 31, 2022		**20,755**	**594,043**	**55,252**	**(306,974)**	**(143,279)**	**219,797**

Capital Increase includes the cost of transactions, net of tax.