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Valneva Reports Nine-Month 2023 Financial Results and Provides Corporate Updates

Product sales of €106.1 million, an increase of 42.6% compared to the first nine months of 2022

- IXIARO® and DUKORAL® sales benefited from a continued recovery of the travel industry
- Total revenues of €111.8 million in the first nine months of 2023

Cash position of €171.3 million as of September 30, 2023

- Includes $50 million of the $100 million available following upsize of credit facility with leading U.S. Healthcare Funds Deerfield and OrbiMed in August 2023[1]
- Includes a significant payment made to Pfizer in the third quarter of 2023 related to the companies' Phase 3 Lyme disease study "VALOR"

Chikungunya: progressing towards potential licensure of the world's first chikungunya vaccine

- Biologic License Application (BLA) currently under priority review by the U.S. Food and Drug Administration (FDA) with a PDUFA date at the end of November
- New Drug Submission (NDS) under review by Health Canada
- Marketing Authorization Application (MAA) submitted to the European Medicines Agency (EMA) in October 2023[2]; accelerated assessment granted by EMA's Committee for Medicinal Products for Human Use (CHMP).

Updated 2023 financial guidance reflects lower R&D expenditure

- 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 (assuming a sale of the Priority Review Voucher received upon a potential approval of VLA1553 before year-end)
- Expected R&D expenses now between €60 million and €70 million (previously between €70 million and €90 million); mainly driven by lower than anticipated costs related to the closeout of the COVID-19 activities

Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	Nine months ending September 30,	
	2023	2022
Total revenues	111.8	249.9
Product sales	106.1	74.4
Net loss	(69.3)	(99.1)
Adjusted EBITDA[3]	(46.0)	(38.0)
Cash	171.3	261.0

[1] *Valneva Announces Extension of Existing Loan Agreement - Valneva*
[2] Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment
[3] *For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR*

Saint-Herblain (France), November 9, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported consolidated financial results for the first nine months of the year, ended September 30, 2023. The condensed consolidated interim financial results are available on the Company's website (Financial Reports – Valneva).

Valneva will provide a live webcast of its nine-month 2023 results conference call beginning at 3 p.m. CET/9 a.m. ET today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/do4mozxx.

Peter Bühler, Valneva's Chief Financial Officer, commented, "In the third quarter, we continued growing our commercial sales and are confident that we will meet our revenue target for the year. We remain focused on advancing our key R&D programs with a strong emphasis on working with the FDA to obtaining the first regulatory approval worldwide for a chikungunya vaccine".

Clinical Stage Vaccine Candidates

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
BLA under priority review by the U.S. FDA; accelerated assessment confirmed by EMA

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[4] with the potential to rapidly expand further. The Pan American Health Organization issued an epidemiological alert in February 2023 as the number of cases and deaths due to chikungunya continues to rise in the Americas[5]. 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 BLA is currently under priority review by the U.S. FDA[6] with a Prescription Drug User Fee Act (PDUFA) action date planned for the end of November 2023[7].

Additionally, an MAA was submitted to EMA in October 2023[8], and EMA's CHMP confirmed accelerated assessment for the application based on the vaccine candidate's "major interest for public health and therapeutic innovation". A marketing application is also under review by Health Canada[9].

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

The regulatory submissions follow final pivotal Phase 3 data in March 2022[10], final lot-to-lot consistency results in May 2022[11], twelve-month persistence data in December 2022[12] and positive initial Phase 3 safety data in adolescents[13].

[4] https://www.who.int/news-room/fact-sheets/detail/chikungunya
[5] https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas
[6] FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva
[7] Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva
[8] Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment
[9] Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review - Valneva
[10] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
[11] Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate
[12] Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
[13] Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva

The pivotal Phase 3 data were published in *The Lancet*, the world's leading peer-reviewed medical journal, in June 2023[14]. 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.

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[15]. This was later confirmed in a further analysis of the Phase 1 data, which showed that 100% of vaccinated individuals reached the immune threshold[16] established with the FDA at day 14[17].

Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 months by 99% of participants and was equally durable in younger and older adults[18]. 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 initial safety data in August 2023[19]. 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.

Initial safety data generated from the study, Valneva's first clinical study in an endemic area and with individuals previously infected with CHIKV, showed 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 signed an agreement in January 2021 for the development, manufacturing, and marketing of VLA1553[20]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[21], 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 accelerated assessment in October 2023.

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[14] *Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva*
[15] *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.*
[16] *Seroresponse*
[17] *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.*
[18] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[19] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*
[20] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[21] *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[22].

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[23,24,25]. 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[26].

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[27].

The VALOR study is currently ongoing and is designed to follow vaccinated participants over two consecutive tick seasons. 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.

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

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[22] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[23] *Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva*
[24] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*
[25] *Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva*
[26] *Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate - Valneva*
[27] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*

countries and territories have reported evidence of mosquito-transmitted Zika virus infection[28]; 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®, 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[29].

Valneva plans to re-initiate clinical development in the first quarter of 2024.

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[30] and is strongly associated with the development of several types of cancer[31] and multiple sclerosis[32].

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[33].

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

IXIARO® 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® 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.

In the first nine months of 2023, IXIARO®/JESPECT® sales increased by 119.4% to €50.3 million compared to €22.9 million in the first nine months 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.

In September 2023, Valneva announced the signing of a one-year contract with the U.S. Department of Defense (DoD) for the supply of IXIARO®. Under this new contract, the DoD will buy a minimum of $32 million worth of IXIARO® vaccines and has the possibility to purchase additional doses during the twelve months of the contract. First doses were delivered in September.

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[28] *Zika virus disease (who.int)*
[29] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 - Valneva*
[30] *https://www.cdc.gov/epsteinbarr/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*

CHOLERA / ETEC[34]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC[35], 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 the first nine months of 2023, DUKORAL® sales increased by 128.5% to €21.1 million compared to €9.2 million in the first nine months of 2022, also benefiting from the significant recovery in the private travel markets and price increases. DUKORAL® sales for the first nine months of 2023 exceeded pre-COVID-19 sales levels during the first nine months of 2019.

SARS-CoV-2 INACTIVATED WHOLE-VIRUS VACCINE

Valneva's COVID-19 vaccine, VLA2001, is the only inactivated whole-virus COVID-19 vaccine approved in Europe[36] and was the first COVID-19 vaccine to receive a full marketing authorization from the EMA.

In light of reduced order volume linked to the decline of the COVID-19 pandemic, Valneva suspended manufacturing of the vaccine in August 2022 and inventories were fully written down as of December 31, 2022. In order to save additional costs linked to the vaccine including license fees, Valneva recently requested the withdrawal of VLA2001's marketing authorization in Europe. The withdrawal was accepted by EMA and will become effective on December 1, 2023.

In the first nine months of 2023, VLA2001 sales amounted to €5.7 million compared to €23.9 million in the first nine months of 2022.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In the first nine months of 2023, third party product sales increased by 58% to €29.1 million from €18.4 million in the first nine months of 2022.

[34] *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.*
[35] *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.*
[36] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*

Nine Months 2023 Financial Review[37]
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues were €111.8 million in the first nine months of 2023, compared to €249.9 million in the first nine months of 2022. The 55.3% decrease was related to non-recurring revenues recorded in the prior year linked to the Company's COVID-19 program.

Valneva's total product sales reached €106.1 million in the nine months ended September 30, 2023, compared to €74.4 million in the same period of 2022. This 42.6% increase was driven by the continued recovery of travel vaccine sales. Currency fluctuations of €1.6 million adversely impacted product sales. COVID-19 vaccine sales in the first nine months of 2023 amounted to €5.7 million compared to €23.9 million in the first nine months of 2022. Excluding COVID-19, product sales reached €100.4 million in the first nine months of 2023 compared to €50.6 million during the comparator period of 2022, an increase of 98.7%.

IXIARO®/JESPECT® product sales were €50.3 million in the first nine months of 2023 compared to €22.9 million in the first nine months of 2022. The 119.4% 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 €0.7 million foreign currency impact. DUKORAL® sales were €21.1 million in the first nine months of 2023 compared to €9.2 million in the first nine months of 2022. This 128.5% increase is also a result of the significant recovery in the private travel markets and price increases. Foreign currency fluctuations reduced DUKORAL® sales by €0.5 million. Third Party product sales were €29.1 million in the nine months ended September 30, 2023 compared to €18.4 million in the comparison period of 2022, a 58.0% 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 €5.7 million in the first nine months of 2023 compared to €175.5 million in the first nine months of 2022. The first nine months of 2022 included COVID-related one-time effects of €200.2 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 EU Member States, partially offset by €34.7 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 €74.8 million in the nine months ended September 30, 2023. The gross margin on commercial product sales, excluding COVID-19 vaccines sales, was 43.7% compared to 55.4% in the first nine months of 2022. COGS of €26.6 million were related to

[37] *While the financial figures included in this preliminary interim earnings announcement have been computed in accordance with International Financial Reporting Standards (IFRS Accounting Standards) applicable to interim periods, this announcement does not contain sufficient information to constitute an interim financial report as that term is defined in IFRS Accounting Standards.*

IXIARO® product sales, yielding a product gross margin of 47.2%. COGS of €12.7 million were related to DUKORAL® product sales, yielding a product gross margin of 39.8%. The IXIARO® gross margin was impacted by batch write-offs in the Scottish manufacturing site. Additionally, the gross margins of both IXIARO® and DUKORAL® were adversely impacted by high indirect sales in markets where Valneva sells through distributors. Of the remaining COGS for the first nine months of 2023, €17.3 million were related to the Third-Party product distribution business, €1.7 million to COVID-19 product sales and €9.3 million to initial COGS linked to the launch preparations for the Company's chikungunya vaccine candidate, as well as idle capacity costs. The remaining COGS related to services. In the nine months ended September 30, 2022, overall COGS were €202.7 million, of which €196.6 million related to cost of goods and €6.2 million related to cost of services. COGS in the first nine months 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 €42.2 million in the first nine months of 2023 compared to €75.4 million in the first nine months of 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 the first nine months of 2023 amounted to €33.9 million compared to €13.1 million in the first nine months of 2022. Marketing and distribution expenses in the first nine months of 2023 notably included €13.8 million of expenses related to launch preparations for the chikungunya vaccine candidate, VLA1553, compared to €4.3 million in the first nine months of 2022. In the first nine months of 2023, general and administrative expenses increased to €35.1 million from €23.3 million in the first nine months of 2022. In the first nine months of 2022, COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from an accrual adjustment income of €30.6 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 €17.0 million in the first nine months of 2023 versus €7.5 million in the first nine months of 2022. This increase was mainly driven by the recognition of grant income received from Scottish Enterprise during the first nine months of 2023.

Valneva recorded an operating loss of €57.2 million in the first nine months of 2023 compared to an operating loss of €57.1 million in the first nine months of 2022. Adjusted EBITDA loss in the first nine months of 2023 was €46.0 million compared to an adjusted EBITDA loss of €38.0 million in the first nine months of 2022 (as explained further below).

Net Result

In the nine months ended September 30, 2023, Valneva generated a net loss of €69.3 million compared to a net loss of €99.1 million in the nine months ended September 30, 2022.

Finance expense and foreign currency effects in the first nine months of 2023 resulted in a net finance expense of €13.2 million, compared to a net finance expense of €39.8 million in the first nine months of 2022. The difference is primarily driven by a decrease of €25.1 million in the revaluation results of non-Euro denominated balance sheet positions, to a €1.4 million net foreign exchange

loss in the first nine months of 2023 from €26.5 million in the first nine months of 2022. Interest expenses net of interest income were €11.8 million in the first nine months of 2023 compared to €13.3 million in the first nine months of 2022.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €136.8 million in the first nine months of 2023 compared to €189.5 million in the first nine months of 2022. Cash outflows in the first nine months of 2023 mainly resulted from the operating loss as well as payments of refund liabilities to Pfizer related to the Lyme VLA15 R&D collaboration agreement. Cash outflows in the first nine months of 2022 mainly resulted from the operating loss as well as releases from the refund liabilities following the signing of the COVID-19 settlement agreement with the UK government.

Cash outflows from investing activities amounted to €4.3 million in the first nine months of 2023 compared to €22.5 million in the first nine months of 2022. Cash outflows in the first nine months of 2023 mainly related to construction activities at the Scottish production site and purchases of equipment partly offset by proceeds from the divestment of the Clinical Trial Manufacturing unit in Sweden and from selling shares in BliNK Biomedical SAS. Cash outflows in the first nine months of 2022 mainly related to construction activities at the Scottish production site and purchases of equipment.

Net cash generated from financing activities amounted to €26.1 million in the first nine months of 2023, which mainly resulted from proceeds from the additional tranche added to the existing credit facility with U.S. healthcare investment firms Deerfield Management Company & OrbiMed, partly offset by interest payments as well as payments of lease liabilities. Cash inflows in the first nine months of 2022 amounted to €121.6 million and mainly related to proceeds from the equity subscription agreement with Pfizer as well as disbursements from the credit facility provided by Deerfield Management Company & OrbiMed.
Cash and cash equivalents amounted to €171.3 million as at September 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 common 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) 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 income, which is the most directly comparable IFRS measure, is set forth below:

€ in million	Nine months ended September 30,	
	2023	2022
Loss for the period	(69,271)	(99,075)
Add:		
Income tax (benefit)/expense	(1,103)	2,163
Total finance income	(724)	(59)
Total finance expense	12,477	13,395
Foreign currency (gain)/loss – net	1,441	26,493
Result from investments in associates	-	(9)
Amortization	4,680	5,259
Depreciation	8,396	10,581
Impairment excluding impairment loss of disposal	(1,881)	3,286
Adjusted EBITDA	**(45,985)**	**(37,967)**

Subsequent events:

Following the expiry of the lease agreement, on October 31, 2023 the Company's subsidiary "Valneva Austria GmbH" acquired the legal entity that owns the Vienna building it was previously leasing, leveraging the security deposit. The acquisition price, excluding the security deposit and the entity's cash, is approximately €10.9 million. The Company is evaluating the possibility of a sale and lease-back transaction.

As an update on Note 5.17 in the 2023 half-year financial statements[38], the litigation related to the Humalys acquisition has now finished, as no appeal was lodged prior to the statutory deadline."

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 two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

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, potentially the world's first vaccine against the chikungunya virus, as well as vaccine candidates against the Zika virus and other global public health threats.

[38] *H1 2023 Financial Report EN (valneva.com)*

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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.