

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report: November 10, 2022

Commission File Number: **001-40377**

Valneva SE

(Translation of registrant's name into English)

**6 rue Alain Bombard
44800 Saint-Herblain, France
(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

On November 10, 2022, the Registrant announced its results from the first nine months of 2022 and issued a press release and unaudited interim condensed consolidated financial statements, copies of which are attached hereto as Exhibits 99.1, and 99.2, respectively, and incorporated herein by reference. The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-266839).

Exhibit

[Exhibit 99.1](#)

[Press release dated November 10, 2022](#)

[Exhibit 99.2](#)

[Unaudited Interim Condensed Consolidated Financial Statements as at September 30, 2022 and for the nine months ended September 30, 2022](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 10,
2022

/s/ Thomas Lingelbach Thomas
Lingelbach Chief Executive
Officer and President

EXHIBIT 99.1

Valneva Reports Nine-Month 2022 Results and Provides Corporate Updates

Total nine-month revenues of €249.9 million, a ~ 3.5-fold increase compared to 2021

- Product sales of €74.4 million (vs €45.5 million in the first nine months of 2021) driven by a continued recovery of travel vaccine sales and by COVID-19 vaccine sales in Europe. Product sales outside of COVID-19 grew by double digits (11.2%) vs. prior period
- €175.5 million of other revenues (vs €24.4 million in the first nine months of 2021) mainly driven by revenue recognition related to previous COVID-19 vaccine supply agreements

Cash and cash equivalents of €261.0 million at the end of September 2022

- Excludes €102.9 million of gross proceeds received in October 2022 from an upsized global offering¹
- Includes drawing the final tranche (\$20 million) from Deerfield & Orbimed loan agreement²

Continued progression of late-stage clinical programs as guided

Lyme Disease Vaccine Candidate VLA15

- Phase 3 study recruitment ongoing; enrollment completion expected in the second quarter of 2023

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Ongoing rolling submission for Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA); submission completion expected by end of 2022

Progression of pre-clinical assets and focus on strengthening the Company's clinical pipeline

- VLA1554 (human metapneumovirus) and VLA2112 (Epstein-Barr virus) currently prioritized

Updated FY 2022 Financial Guidance

- Valneva reiterates expected total revenues of €340 million to €360 million, noting continued recovery of travel vaccine sales, further revenue recognition linked to payments received under the Advance Purchase Agreement (APA) with each of the European Commission (EC) and United Kingdom (UK) and the expected sales from the revised EC APA.
 - Product sales of the Company's travel vaccines are still expected to reach €70 million to €80 million despite supply challenges and COVID-19 product sales are expected to reach €30 million to €40 million.
 - Other Revenues are expected to reach approximately €240 million. They will be mainly related to COVID-19 revenue recognition in relation to the UK and EC APAs and will have no impact on cash. Other Revenues not related to COVID-19 will be negative in 2022 due to the increased refund liability resulting from the amendment of the VLA15 collaboration and license agreement with Pfizer.
- Given phasing of clinical trial expenses and accelerated wind-down of VLA2001 related activities, Valneva now expects lower R&D expenses of €95 million to €110 million compared to the €120 million to €135 million previously communicated. The Company remains committed to advancing its late-stage vaccine candidates and to further expanding its R&D pipeline, including, but not limited to, through the advancement of some of the Company's pre-clinical candidates towards clinical entry.
- As part of the communicated reshape strategy, Valneva is in the process of re-sizing its operations which is expected to result in a reduction of approximately 20% to 25% of its existing workforce. Post restructuring, the Company's total workforce is expected to be approximately 25% above pre-COVID levels enabling the Company to retain key talents and additional expertise to successfully execute on its strategy. This re-sizing and re-focusing is expected to result in annualized savings of approximately €12 million.

Financial Information

(unaudited results, consolidated per IFRS)

€ in million	Nine months ending September 30	
	2022	2021
Total revenues	249.9	69.8
Product sales	74.4	45.5
Net loss	(99.1)	(245.9)
Adjusted EBITDA loss	(38.0)	(227.6)
Cash (at end of period)	261.0	247.9

Saint-Herblain (France), November 10, 2022 – 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, 2022. 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 months financial results conference call beginning at 3 p.m. CET/9 a.m. EST today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/cay4shas>

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, "*Valneva is continuing to successfully execute on its key activities. Raising over €100 million in the current economic environment, attracting new investors, and maintaining support of our existing shareholders clearly underlines the value of the Company's fundamentals, its R&D pipeline and our strategic ambitions. We will continue to fully pursue the Company's strategic priorities, including advancing our chikungunya vaccine candidate towards marketing approval and launch, completing the Phase 3 trial of our Lyme disease vaccine candidate, progressing pre-clinical assets, and focusing on strengthening our clinical pipeline. The re-sizing of our operations will allow us to increase efficiency and focus on achieving our operational and strategic business objectives.*"

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15

Phase 3 study initiated

Valneva and Pfizer are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. The vaccine candidate covers the six OspA serotypes expressed by *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe.

Recruitment of approximately 6,000 participants five years of age and older for the Phase 3 clinical study "VALOR" (Vaccine Against Lyme for Outdoor Recreationists) is currently ongoing in highly endemic regions in the United States and Europe³. Enrollment for the study, which investigates the efficacy, safety, and immunogenicity of VLA15, is expected to be completed in the second quarter of 2023. As per the terms of the collaboration agreement between the two companies, Valneva received a \$25 million milestone payment from Pfizer in October following initiation of the Phase 3 study.

Pending successful Phase 3 completion, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2025.

Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15⁴. In June 2022, the terms of this collaboration were updated, and Pfizer invested €90.5 (\$95) million in Valneva as part of an Equity Subscription Agreement⁵. Valneva will continue to pay its 40% contribution to the Phase 3 activities over 2022 and 2023.

If approved, Pfizer will commercialize VLA15 and Valneva will be eligible to receive substantial milestone and royalty payments.

¹ Valneva Announces Closing of Upsized €102.9 Million Global Offering - Valneva

² Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed - Valneva

³ Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva

⁴ Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

⁵ Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553

BLA rolling submission with U.S. FDA initiated

VLA1553 is a live-attenuated, single-dose vaccine candidate against the chikungunya virus (CHIKV), a mosquito-borne virus that has spread to more than 120 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available, and VLA1553 is currently the only chikungunya vaccine candidate that successfully completed pivotal Phase 3 studies^{6,7} and the first chikungunya vaccine candidate for which a regulatory filing process has been initiated with the U.S. FDA.

Valneva initiated BLA rolling submission with the FDA for approval of VLA1553 in persons aged 18 years and above in August 2022⁸. This BLA submission is part of the accelerated approval pathway agreed with the FDA in 2020⁹ and follows final pivotal Phase 3 data in March 2022¹⁰ and final lot-to-lot consistency results in May 2022¹¹.

Valneva expects to complete its BLA submission by the end of 2022. Once completed, and if the FDA accepts the filing, the FDA will determine priority review eligibility along with the action due date upon which it will complete its evaluation. The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted PRiority MEDicine (PRIME) designation by the EMA in 2020. Valneva currently plans to make additional regulatory submissions for VLA1553 in the first half of 2023.

Valneva has presented and will continue to present clinical data for VLA1553 at high-profile medical and scientific congresses¹². Recently, the Company highlighted additional immunological results from an expanded panel of serological samples from adults over 65 years of age who received VLA1553 at the American Society for Tropical Medicine and Hygiene (ASTMH) Annual Meeting. Similar to the pivotal data presented previously, the results from the expanded cohort continue to show that older adults generated similarly high seroresponse rates compared to younger adults in the pivotal Phase 3 study¹³. The Company is also expecting to report twelve-month antibody persistence data in late 2022.

At the recent meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), Valneva presented an overview of VLA1553 safety and immunogenicity results and the chikungunya working group provided a preliminary review and timeline towards ACIP's recommendation decision. Ahead of the anticipated February 2024 ACIP vote, the working group plans to present further on CHIKV traveler epidemiology and disease burden, a more comprehensive review of immunogenicity and safety data as part of its Grading of Recommendations, Assessment, Development and Evaluation (GRADE) assessment, and longer-term additional data in younger age groups.

A clinical trial of VLA1553 in adolescents is also ongoing in Brazil¹⁴ for which topline results are expected in the first half of 2023. This trial may support future regulatory submissions and label extensions following a potential initial regulatory approval in adults in the U.S. This ongoing clinical trial conducted by Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI) is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

Pre-Clinical Vaccine Candidates

The Company continues to progress select pre-clinical assets and focus on strengthening its future clinical pipeline. The Company is currently focused on two pre-clinical assets, VLA1554 and VLA2112. The hMPV candidate, VLA1554, is a pre-fusion recombinant protein subunit vaccine targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection in children and is a common cause of morbidity and mortality in immunocompromised patients and in older adults. VLA1554 is currently in pre-clinical proof of concept studies. VLA2112 is a vaccine candidate targeting the Epstein-Barr virus (EBV), which is one of the most common human viruses and can cause infectious mononucleosis and other illnesses. VLA2112 is currently in a late-stage evaluation phase.

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

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

In the first nine months of 2022, IXIARO®/JESPECT® sales were €22.9 million compared to €33.7 million in the first nine months of 2021, as a result of the planned delivery schedule to the U.S. Department of Defense. This decrease was partly offset by the private travel markets, which showed significant recovery with IXIARO®/JESPECT® private sales reaching €19.4 million in the first nine months of 2022 compared to €4.6 million in the first nine months of 2021.

CHOLERA / ETEC¹⁵-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC¹⁶, 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 2022, DUKORAL® sales increased to €9.2 million compared to €0.5 million in the first nine months of 2021, also benefitting from the significant recovery in the private travel markets.

SARS-CoV-2 INACTIVATED WHOLE-VIRUS VACCINE

Valneva's COVID-19 vaccine, VLA2001, is the only inactivated whole-virus COVID-19 vaccine approved in Europe¹⁷ and was the first COVID-19 vaccine to receive a full marketing authorization from the European Medicines Agency (EMA). It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for the Company's commercial Japanese encephalitis vaccine, IXIARO®.

In addition to its marketing approval in Europe, Valneva's COVID-19 vaccine received conditional marketing authorization in the United Kingdom¹⁸ and emergency use authorization in the United Arab Emirates¹⁹ and Kingdom of Bahrain²⁰. During the third quarter of 2022, the World Health Organization (WHO) also issued recommendations for use of the vaccine, including for a booster dose of VLA2001 four to six months after completion of the primary series. The vaccine generated sales of €23.9 million during the first nine months of 2022.

Following a revised purchase agreement with the EC in July 2022, which included VLA2001 orders of 1.25 million²¹, Valneva has been delivering doses to participating EU Member States (Germany, Austria, Denmark, Finland, and Bulgaria). Valneva has retained inventory for potential additional supply to these EU Member States should demand increase and, in parallel, is continuing discussions on potential additional supply and financing agreements with various other governments around the world to deploy remaining inventory. VLA2001's shelf life is expected to be extended to up to 24 months, compared to 15 months currently.

⁶ *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva*

⁷ *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate - Valneva*

⁸ *Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate - Valneva*

⁹ *Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*

¹⁰ *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva*

¹¹ *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate - Valneva*

¹² *Valneva to Present on its Single-Shot Chikungunya Vaccine Candidate at Leading Scientific Conferences - Valneva*

¹³ *Presentation at ASTMH: Chikungunya: Phase 3 Clinical Development of a Single-shot Live-Attenuated Vaccine*

¹⁴ *Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*

¹⁵ 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.

¹⁶ 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.

¹⁷ *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*

¹⁸ *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*

¹⁹ *Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine*

²⁰ *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

²¹ *Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine - Valneva*

Valneva reported first positive heterologous booster results for VLA2001 in August 2022²² and expects additional heterologous booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection in the fourth quarter of 2022.

Subject to regulatory assessments, heterologous booster results may support label extensions for VLA2001, additional product approvals and/or additional scientific recommendations.

In light of the reduced order volume from EU Member States, Valneva suspended internal and terminated external manufacturing of VLA2001. Valneva is executing its “reshape” strategy including re-sizing which will allow the Company to increase efficiency and focus on its operational and strategic business objectives.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In June 2020, the Company entered into a distribution agreement with Bavarian Nordic, pursuant to which it agreed to commercialize Bavarian Nordic’s marketed vaccines for rabies (Rabipur[®]/RabAvert[®]) and tick-borne encephalitis, leveraging its commercial infrastructure in Canada, the United Kingdom, France and Austria. In September 2022, Valneva also announced a partnership with VBI Vaccines for the marketing and distribution of the only 3-antigen Hepatitis B vaccine, PreHevbri[®], in select European markets²³. Valneva and VBI expect PreHevbri to be available in these countries in early 2023.

In the first nine months of 2022, third party product sales increased by 64.6% to €18.4 million from €11.2 million in the first nine months of 2021.

Nine-Month 2022 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva’s total revenues were €249.9 million in the first nine months of 2022 compared to €69.8 million in the first nine months of 2021, an increase of 257.8%.

Product sales, including COVID-19 vaccine sales, increased by 63.7% to €74.4 million in the first nine months of 2022 compared to €45.5 million in the first nine months of 2021. Foreign currency fluctuations contributed positively to €4.9 million of the change in product sales. Product sales from commercial products amounted to €50.6 million in the first nine months of 2022, an increase of 11.2% compared to the first nine months of 2021. Product sales related to COVID-19 amounted to €23.9 million.

IXIARO[®]/JESPECT[®] sales decreased by 32.1% to €22.9 million in the first nine months of 2022 compared to €33.7 million in the first nine months of 2021, primarily as a result of the planned delivery schedule to the DoD during the period. This decrease was partly offset by the private travel markets, which showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €19.4 million in the first nine months of 2022 compared to €4.6 million in the first nine months of 2021. Foreign currency fluctuations also contributed positively for €4.6 million to the change in IXIARO[®] product sales. DUKORAL[®] also benefited from this recovery in the private travel market as sales increased significantly to €9.2 million in the first nine months of 2022 compared to €0.5 million in the first nine months of 2021. COVID-19 vaccine sales amounted to €23.9 million resulting from shipments to participating EU Member States and Bahrain. Third Party product sales increased by 64.6% to €18.4 million in the first nine months of 2022 from €11.2 million in the first nine months of 2021, driven by growth related to Valneva’s distribution agreement with Bavarian Nordic for the sale of Rabipur[®]/RabAvert[®] and Encepur[®].

Other Revenues, including revenues from collaborations, licensing and services, amounted to €175.5 million in the first nine months of 2022 compared to €24.4 million in the first nine months of 2021. This increase is attributable to €89.4 million of released refund liability as a result of the settlement with the UK government as well as a release of non-refundable advance payments from EU Member States amounting to €110.8 million. This was 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. Valneva’s future contribution to the VLA15 Phase 3 study will go against the refund liability included in the balance sheet.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €202.7 million in the first nine months of 2022. The gross margin on commercial product sales amounted to 55.4% compared to 37.8% in the first nine months of 2021. COGS of €6.4 million related to IXIARO[®] product sales, yielding a product gross margin of 72.0%. COGS of €3.7 million related to DUKORAL[®] product sales, yielding a product gross margin of 60.0%, which was positively impacted by provision releases resulting from reduced expiry risks on inventory. Of the remaining COGS in the first nine months of 2022, €12.4 million were related to the Third-Party products distribution business, €174.0 million to the COVID-19 vaccine business and €6.2 million to cost of services. COGS of the COVID-19 vaccine program included effects from the significant reduction of sales volumes to EU Member States. In the first nine months of 2021, overall COGS were €159.6 million, of which €142.4 million related to cost of goods and €17.2 million related to cost of services.

Research and development expenses amounted to €75.4 million in the first nine months of 2022, compared to €117.2 million in the first nine months of 2021. This decrease was mainly driven by lower clinical trials costs for Valneva’s chikungunya vaccine program advancing towards licensure as well as reduced spend on the COVID-19 program. Marketing and distribution expenses in the first nine months of 2022 amounted to €13.1 million compared to €15.0 million in the first nine months of 2021. Marketing and distribution expenses in the first nine months of 2022 notably included €4.3 million of expenses related to the launch preparation costs for Valneva’s chikungunya vaccine candidate, VLA1553, compared to €2.8 million in the first nine months of 2021. In the first nine months of 2022, general and administrative expenses declined to €23.3 million from €31.7 million in the first nine months of

2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a non-cash accrual adjustment of €30.6 million related to the positive effect of the Company's share price development on the employee share-based compensation programs. This income compares to a cost of €13.7 million in the first nine months of 2021.

Other income, net of other expenses, reduced to €7.5 million in the first nine months of 2022 from €16.0 million in the first nine months of 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending and an increase of other expenses related to the provision for the ongoing Vivalis / Intercell merger litigation proceedings.

Valneva recorded an operating loss of €57.1 million in the first nine months of 2022 compared to €237.6 million in the first nine months of 2021, of which the COVID-19 operating loss represented €14.2 million and €194.4 million in the first nine months of 2022 and 2021, respectively and the other segments represented €42.9 million in the first nine months of 2022 compared to €43.2 million in the first nine months of 2021. Adjusted EBITDA (as defined below) loss in the first nine months of 2022 was €38.0 million compared to an adjusted EBITDA loss of €227.6 million in the first nine months of 2021.

Net Result

In the first nine months of 2022, Valneva generated a net loss of €99.1 million compared to a net loss of €245.9 million in the first nine months of 2021.

Finance expense and foreign currency effects in the first nine months of 2022 resulted in a net finance expense of €39.8 million, compared to a net finance expense of €6.6 million in the first nine months of 2021. This was mainly a result of a foreign exchange loss amounting to €26.5 million in the first nine months of 2022, primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €5.3 million in the first nine months of 2021. Interest expenses net of interest income were €13.3 million in the first nine months of 2022 compared to €11.9 million in the first nine months of 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €189.5 million in the first nine months of 2022 compared to €36.5 million of cash generated by operating activities in the first nine months of 2021. Cash outflows in the first nine months of 2022 were mainly related to the operating loss generated in the period and non-cash revenues (cash received in previous periods), while during the first nine months of 2021 cash inflows mainly resulted from pre-payments received related to the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €22.5 million in the first nine months of 2022 compared to €69.9 million in the first nine months of 2021, both mainly a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

²² Valneva Reports Further Positive Phase 3 Immunogenicity and the First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001 - Valneva

²³ Valneva and VBI Vaccines Announce European Partnership for Marketing and Distribution of PreHevbr[®] - Valneva

Net cash generated from financing activities amounted to €121.6 million in the first nine months of 2022, which was mainly a result of proceeds from the equity subscription agreement with Pfizer as well as a draw-down in September on the credit facility provided by Deerfield & Orbimed²⁴. Cash inflows in the first nine months of 2021 amounted to €74.6 million which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement in May of 2021.

Cash and cash equivalents decreased to €261.0 million as of September 30, 2022, compared to €346.7 million as of December 31, 2021 and consisted of €258.1 million in cash and €3.0 million in restricted cash. The cash decrease mainly resulted from COVID-19-related investments into fixed assets, R&D and Manufacturing expenses. Net proceeds from the recent global offering were received in October and are not included in the cash position reported per September 30, 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.

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	Nine months ending September 30	
	2022	2021
(unaudited results, consolidated per IFRS)		
Loss for the period	(99.1)	(245.9)
Add:		
Income tax expense	2.2	1.6
Total Finance income	(0.1)	(0.2)
Total Finance expense	13.4	12.1
Foreign exchange gain/(loss) - net	26.5	(5.3)
Result from investments in associates	—	0.1
Amortization	5.3	4.9
Depreciation	10.6	5.1
Impairment	3.3	—
Adjusted EBITDA	(38.0)	(227.6)

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into the clinic, including candidates against Lyme disease and the chikungunya virus.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including but not limited to statements regarding expected total revenues and R&D spending for full fiscal year 2022, product sales, possible regulatory approvals of product candidates, the re-shaping of the Company's operations, initiation and progression of clinical trials, and development of pre-clinical vaccine candidates. 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, 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.

²⁴ *Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed - Valneva*



[Valneva SE 6-K](#) EXHIBIT 99.2

CONSOLIDATED FINANCIAL STATEMENTS 2022

VALNEVA

A European Company (*Societas Europaea*) with a Management and a Supervisory Board

Registered offices:

6 rue Alain Bombard, 44800 SAINT-HERBLAIN - France

Nantes Companies Register (RCS) No. 422 497 560

Unaudited Interim Condensed Consolidated financial statements
as at September 30, 2022 and for the nine months ended September 30, 2022



1. UNAUDITED INTERIM CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

1.1 Unaudited Interim Condensed Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	Nine months ended September 30,	
	2022	2021
Product sales	74,421	45,469
Other revenues	175,481	24,379
Revenues	249,902	69,847
Cost of goods and services	(202,726)	(159,586)
Research and development expenses	(75,385)	(117,234)
Marketing and distribution expenses	(13,089)	(15,000)
General and administrative expenses	(23,267)	(31,664)
Other income and expenses, net	7,472	16,034
OPERATING LOSS	(57,093)	(237,603)
Finance income	59	240
Finance expenses	(13,395)	(12,137)
Foreign exchange gain/(loss), net	(26,492)	5,334
Result from investments in associates	9	(120)
LOSS BEFORE INCOME TAX	(96,912)	(244,286)
Income tax income/(expense)	(2,163)	(1,647)
LOSS FOR THE PERIOD	(99,075)	(245,933)
Losses per share for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share		
basic	(0.92)	(2.51)
diluted	(0.92)	(2.51)

1.2 Unaudited Interim Condensed Consolidated Statement of Comprehensive Income (Loss)

€ in thousand	Nine months ended September 30,	
	2022	2021
Loss for the period	(99,075)	(245,933)
Other comprehensive income/(loss)		
Items that may be reclassified to profit or loss		
Currency translation differences	(1,488)	(143)
Items that will not be reclassified to profit or loss	-	-
Defined benefit plan actuarial gains/(losses)	168	—
Other comprehensive loss for the period, net of tax	(1,320)	(143)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY	(100,395)	(246,076)

**2 UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

€ in thousand	September 30, 2022	December 31, 2021
ASSETS		
Non-current assets	221,548	231,520
Intangible assets	29,652	32,700
Right of use assets	47,679	48,285
Property, plant and equipment	122,980	125,545
Investments in associates	—	2,124
Deferred tax assets	2,943	3,582
Other non-current assets	18,294	19,282
Current assets	476,535	585,832
Inventories	96,462	124,098
Trade receivables	57,732	44,013
Other current assets	59,165	71,036
Cash and cash equivalents	261,042	346,686
Assets classified as held for sale	2,134	—
TOTAL ASSETS	698,083	817,352
EQUITY		
Capital and reserves attributable to the Company's equity holders	164,983	170,581
Share capital	17,603	15,786
Share premium	501,638	409,258
Other reserves	51,791	52,512
Retained earnings/(Accumulated deficit)	(306,974)	(233,549)
Loss for the period	(99,075)	(73,425)
LIABILITIES		
Non-current liabilities	158,889	277,791
Borrowings	93,364	50,726
Lease liabilities	52,643	53,687
Contract liabilities	2,974	4,741
Refund liabilities	6,587	158,970
Provisions	1,357	8,308
Deferred tax liabilities	1,784	1,290
Other liabilities	181	69
Current liabilities	374,211	368,979
Borrowings	12,494	7,107
Trade payables and accruals	74,973	68,119
Income tax liability	137	83
Tax and Employee-related liabilities	16,036	17,249
Lease liabilities	3,118	3,135
Contract liabilities	6,906	124,017
Refund liabilities	225,712	95,611
Provisions	27,691	48,708
Other liabilities	7,145	4,950
TOTAL LIABILITIES	533,100	646,771
TOTAL EQUITY AND LIABILITIES	698,083	817,352

**3 UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

€ in thousand	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities		
Loss for the period	(99,075)	(245,933)
Adjustments for non-cash transactions	17,784	34,851
Changes in non-current operating assets and liabilities	(155,970)	4,210
Changes in working capital	48,830	244,948
Cash generated from/(used in) operations	(188,431)	38,076
Income tax paid	(1,082)	(1,624)
Net cash generated from/(used in) operating activities	(189,513)	36,452
Cash flows from investing activities		
Purchases of property, plant and equipment	(22,465)	(68,973)
Purchases of intangible assets	(76)	(938)
Interest received	59	45
Net cash used in investing activities	(22,483)	(69,866)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of costs of equity transactions	93,998	85,061
Disposal of treasury shares	—	209
Proceeds from borrowings, net of transaction costs	38,141	—
Repayment of borrowings	(1,793)	(1,956)
Payment of lease liabilities	(2,171)	(1,948)
Interest paid	(6,544)	(6,734)
Net cash generated from/(used in) financing activities	121,631	74,632
Net change in cash and cash equivalents	(90,365)	41,218
Cash and cash equivalents at beginning of the period	346,642	204,394
Exchange gains/(losses) on cash	1,814	2,324
Restricted cash	2,951	43
Cash and cash equivalents at end of the period	261,042	247,948

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4 UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand (except number of shares)	Number of shares issued	Share capital	Share premium	Other reserves	Retained earnings/ (Accumula- ted deficit)	Profit/ (loss) for the period	Total equity
Balance as at January 1, 2021	90,970,562	13,646	244,984	52,342	(169,156)	(64,393)	77,422
Total comprehensive loss	-	-	-	(143)	-	(245,933)	(246,076)
Income appropriation	-	-	-	-	(64,393)	64,393	-
Share-based compensation expense:							
- value of services	-	-	-	1,825	-	-	1,825
- exercises	799,450	120	2,105	-	-	-	2,225
Treasury shares	-	-	-	209	-	-	209
Issuance of ordinary shares, May 2021	8,145,176	1,222	88,375	-	-	-	89,597
Cost of equity transactions, net of tax	-	-	(6,761)	-	-	-	(6,761)
Balance as at September 30, 2021	99,915,188	14,987	328,703	54,234	(233,549)	(245,933)	(81,559)
Balance as at January 1, 2022	105,239,085	15,786	409,258	52,512	(233,549)	(73,425)	170,581
Total comprehensive loss	-	-	-	(1,320)	-	(99,075)	(100,395)
Income appropriation	-	-	-	-	(73,425)	73,425	-
Share-based compensation expense:							
- value of services	-	-	-	599	-	-	599
- exercises	2,563,011	384	3,333	-	-	-	3,718
Treasury shares	-	-	-	-	-	-	-
Issuance of ordinary shares, June 2022	9,549,761	1,432	89,195	-	-	-	90,627
Cost of equity transactions, net of tax	-	-	(148)	-	-	-	(148)
Balance as at September 30, 2022	117,351,857	17,603	501,638	51,791	(306,974)	(99,075)	164,983