

**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: May 4, 2023

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 May 4, 2023, the Registrant announced its results from the first three months of 2023 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 May 4, 2023 |
| Exhibit 99.2 | Unaudited Interim Condensed Consolidated Financial Statements as at and for the three months ended March 31, 2023 |

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: May 4, 2023

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



VALNEVA SE - CONSOLIDATED FINANCIAL STATEMENTS FIRST QUARTER 2023

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

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 March 31, 2023 and for the Three Months ended March 31, 2023



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) | Three months ended March 31, | |
|---|------------------------------|-----------------|
| | 2023 | 2022 |
| Product sales | 32,100 | 16,162 |
| Other revenues | 1,408 | 5,686 |
| Revenues | 33,508 | 21,847 |
| Cost of goods and services | (20,480) | (13,860) |
| Research and development expenses | (14,065) | (20,689) |
| Marketing and distribution expenses | (8,986) | (2,034) |
| General and administrative expenses | (10,038) | (5,770) |
| Other income and expenses, net | 3,488 | 2,084 |
| OPERATING LOSS | (16,574) | (18,422) |
| Finance income | 253 | 13 |
| Finance expenses | (5,096) | (4,718) |
| Foreign exchange gain/(loss), net | 3,170 | (2,412) |
| LOSS BEFORE INCOME TAX | (18,247) | (25,539) |
| Income tax income/(expense) | 120 | (502) |
| LOSS FOR THE PERIOD | (18,127) | (26,041) |
| Losses per share for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share | | |
| - basic | (0.13) | (0.24) |
| - diluted | (0.13) | (0.24) |

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

| € in thousand | Three months ended March 31, | |
|--|------------------------------|-----------------|
| | 2023 | 2022 |
| Loss for the period | (18,127) | (26,041) |
| Other comprehensive income/(loss) | | |
| Items that may be reclassified to profit or loss | | |
| Currency translation differences | 1,628 | (244) |
| Other comprehensive income/(loss) for the period, net of tax | 1,628 | (244) |
| TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY | (16,500) | (26,285) |

**2 UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

| € in thousand | March 31, 2023 | December 31, 2022 |
|--|---------------------------|------------------------------|
| ASSETS | | |
| Non-current assets | 200,671 | 196,685 |
| Intangible assets | 27,896 | 28,711 |
| Right of use assets | 43,640 | 41,603 |
| Property, plant and equipment | 114,399 | 112,435 |
| Deferred tax assets | 6,146 | 5,637 |
| Other non-current assets | 8,590 | 8,299 |
| Current assets | 389,329 | 424,660 |
| Inventories | 38,999 | 35,104 |
| Trade receivables | 27,018 | 23,912 |
| Other current assets | 66,693 | 74,079 |
| Cash and cash equivalents | 254,485 | 289,430 |
| Assets classified as held for sale | 2,134 | 2,134 |
| TOTAL ASSETS | 590,000 | 621,344 |
| EQUITY | | |
| Capital and reserves attributable to the Company's equity holders | 204,783 | 219,797 |
| Share capital | 20,752 | 20,755 |
| Share premium | 594,043 | 594,043 |
| Other reserves | 58,369 | 55,252 |
| Retained earnings/(Accumulated deficit) | (450,253) | (306,974) |
| Loss for the period | (18,127) | (143,279) |
| LIABILITIES | | |
| Non-current liabilities | 121,958 | 124,156 |
| Borrowings | 83,228 | 87,227 |
| Lease liabilities | 29,556 | 28,163 |
| Refund liabilities | 6,684 | 6,635 |
| Provisions | 1,326 | 1,320 |
| Deferred tax liabilities | 1,057 | 694 |
| Other liabilities | 107 | 116 |
| Current liabilities | 263,260 | 277,392 |
| Borrowings | 14,157 | 11,580 |
| Trade payables and accruals | 33,520 | 41,491 |
| Income tax liability | 420 | 532 |
| Tax and Employee-related liabilities | 15,875 | 15,738 |
| Lease liabilities | 25,787 | 25,411 |
| Contract liabilities | 9,159 | 9,411 |
| Refund liabilities | 135,294 | 136,450 |
| Provisions | 24,037 | 31,257 |
| Other liabilities | 5,010 | 5,523 |
| TOTAL LIABILITIES | 385,217 | 401,547 |
| TOTAL EQUITY AND LIABILITIES | 590,000 | 621,344 |



3 UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| € in thousand | Three months ended March 31, | |
|---|------------------------------|-----------------|
| | 2023 | 2022 |
| Cash flows from operating activities | | |
| Loss for the period | (18,127) | (26,041) |
| Adjustments for non-cash transactions | 8,438 | (6,922) |
| Changes in non-current operating assets and liabilities | (269) | (4,763) |
| Changes in working capital | (13,935) | 11,193 |
| Cash generated from/(used in) operations | (23,893) | (26,533) |
| Income tax paid | (433) | (318) |
| Net cash generated from/(used in) operating activities | (24,326) | (26,851) |
| Cash flows from investing activities | | |
| Purchases of property, plant and equipment, net of proceeds from sale | (3,814) | (9,385) |
| Purchases of intangible assets, net of proceeds from sale | — | (76) |
| Interest received | 253 | 13 |
| Net cash used in investing activities | (3,561) | (9,447) |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of costs of equity transactions | (194) | 3,726 |
| Payment of lease liabilities | (933) | (835) |
| Interest paid | (2,689) | (1,909) |
| Net cash generated from/(used in) financing activities | (3,816) | 982 |
| Net change in cash and cash equivalents | (31,703) | (35,316) |
| Cash and cash equivalents at beginning of the period | 286,532 | 346,642 |
| Exchange gains/(losses) on cash | (344) | (107) |
| Restricted cash | — | 45 |
| Cash and cash equivalents at end of the period | 254,485 | 311,264 |

Valneva Reports First Quarter 2023 Financial Results and Provides Corporate Updates

Product sales increased 98.6% to €32.1 million in the first quarter of 2023 compared to €16.2 million in the first quarter of 2022

- Driven by IXIARO® and DUKORAL® sales both of which more than quadrupled year-over-year
- Total revenues of €33.5 million in the first quarter of 2023 compared to €21.8 million in the first quarter of 2022

Strong cash position of €254.5 million at March 31, 2023

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

- Prescription Drug User Fee Act (PDUFA) review goal date confirmed for end of August 2023 by the U.S. Food and Drug Administration (FDA)
- Additional regulatory submission process to be initiated in the second quarter of 2023

2023 financial guidance confirmed

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

Financial Information

(Unaudited results, consolidated per IFRS)

| € in million | 3 months ending March 31, | |
|------------------------------|---------------------------|--------|
| | 2023 | 2022 |
| Total revenues | 33.5 | 21.8 |
| Product sales | 32.1 | 16.2 |
| Net loss | (18.1) | (26.0) |
| Adjusted EBITDA ¹ | (12.3) | (13.3) |
| Cash | 254.5 | 311.3 |

Saint-Herblain (France), May 4, 2023 – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its first quarter financial results ending March 31, 2023, and provided corporate updates.

Valneva will provide a live webcast of its first quarter 2023 results conference call beginning at 3 p.m. CEST/9 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/82fytb7o>

Peter Bühler, Valneva's Chief Financial Officer, commented, "We entered 2023 with good momentum as we managed to double our first quarter vaccine sales year-over-year, keeping us on track to deliver on our full year sales guidance of €130 million to 150 million. Our objective is to continue driving these sales in 2023 and, at the same time, continue to build a stronger vaccine portfolio and pipeline. As we approach our ten-year anniversary, we look forward to celebrating

¹ For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR

another major milestone with the potential approval of our chikungunya vaccine candidate in the U.S. later this year.”

Clinical Stage Vaccine Candidates

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553

FDA Mid-cycle review meeting for Biologics License Application (BLA) completed

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 countries² with the potential to rapidly expand further. The Pan American Health Organization (PAHO) issued an epidemiological alert in February 2023 as the number of cases and deaths due to chikungunya continues to rise in the Americas³. With no preventive vaccine or specific treatment yet available, chikungunya is considered a major public health threat.

In February 2023, the FDA accepted the filing of a BLA for approval of VLA1553 in persons aged 18 years and above⁴, and at a recent mid-cycle review meeting, indicated that no significant review or safety concerns were noted. The FDA confirmed the Prescription Drug User Fee Act (PDUFA) review goal date at the end of August 2023, on which an approval decision on the VLA1553 BLA is expected.

VLA1553 is currently the only chikungunya vaccine candidate worldwide for which a regulatory review process is underway⁵ and, if approved, it could become the first licensed chikungunya vaccine available to address this unmet medical need. It would also represent the third vaccine Valneva⁶ has brought from early R&D to approval. The sponsor of the first chikungunya vaccine approved in the U.S. is eligible to receive a Priority Review Voucher (PRV)⁷.

Valneva’s BLA application follows final pivotal Phase 3 data in March 2022⁸, final lot-to-lot consistency results in May 2022⁹ and positive twelve-month persistence data in December 2022¹⁰. A clinical study of VLA1553 in adolescents is ongoing in Brazil¹¹, for which Valneva reported enrollment and vaccination completion in February 2023¹². This trial, conducted by Valneva’s partner Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), may support future regulatory submissions in this age group, if VLA1553 is initially approved in adults, as well as licensure of the vaccine in Europe and Brazil, which would be the first potential approval for use in an endemic population. Topline results are expected mid-2023.

The program received FDA Fast Track, Breakthrough Therapy and Priority Review designations in 2018, 2021 and 2023, respectively. VLA1553 was also granted Priority Medicine (PRIME) designation by the European Medicines Agency (EMA) in 2020. Valneva currently plans to make additional regulatory submissions for VLA1553 in Canada, Europe and the United Kingdom in 2023.

LYME DISEASE VACCINE CANDIDATE – VLA15

Phase 3 study ongoing

² <https://www.who.int/news-room/fact-sheets/detail/chikungunya>

³ <https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas>

⁴ [FDA Accepts Valneva’s Chikungunya Vaccine License Application for Priority Review - Valneva](#)

⁵ [Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁶ [This statement refers to Valneva and its predecessor Intercell](#)

⁷ [Tropical Disease Priority Review Voucher Program | FDA](#)

⁸ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

⁹ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

¹⁰ [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

¹¹ [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

¹² [Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

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^{13,14,15}. 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 Europe¹⁶.

The VALOR study is currently ongoing and, as communicated in February 2023, Pfizer had to discontinue approximately half of the total recruited participants in the trial following violations of Good Clinical Practice (GCP) at certain trial sites in the U.S. run by a third-party trial site operator. The clinical trial remains ongoing with other sites not operated by the third party, and Pfizer continues to enroll new participants at those sites in addition to newly added sites in the U.S. and Canada. The original study design and endpoints previously agreed with regulators have not changed.

Currently enrolled participants will receive their booster vaccination as planned in the second quarter of 2024 in advance of the 2024 tick season. Additional enrollment for primary immunization will begin in the second quarter of 2023 with overall trial continuation to include the 2025 tick season.

As a result, Pfizer is aiming to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2026, subject to positive data. Current projected incremental study execution costs incurred due to the agreed amount of additional enrollment will be borne by Pfizer".

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 mononucleosis¹⁷ and is strongly associated with the development of several types of cancer¹⁸ and multiple sclerosis¹⁹. Valneva is also developing a vaccine candidate targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respi

¹³ [Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva](#)

¹⁴ [Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva](#)

¹⁵ [Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva](#)

¹⁶ [Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva](#)

¹⁷ <https://www.cdc.gov/epstein-barr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults>.

¹⁸ <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>.

¹⁹ <https://www.nih.gov/news-events/nih-research-matters/study-suggests-epstein-barr-virus-may-cause-multiple-sclerosis#:~:text=Infection%20with%20Epstein%20Bar%20virus,could%20help%20prevent%20multiple%20sclerosis>

ratory tract infection²⁰, and is currently exploring potential partnering opportunities. Additionally, Valneva initiated pre-clinical work on vaccine candidates targeting parvovirus B19, a virus, which can cause hydrops fetalis in pregnant women and aplastic crisis in persons with anemia²¹, as well as *Campylobacter*, a bacterium often associated with food poisoning²².

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

IXIARO® is an inactivated Vero cell culture-derived Japanese encephalitis that is the only Japanese encephalitis 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.

IXIARO®/JESPECT® sales were €17.4 million in the first quarter of 2023 compared to €4.2 million in the first quarter of 2022. This 315.2% sales increase was driven by the significant recovery of the private travel markets following the decline of the COVID-19 pandemic as well as price increases. Valneva has started discussions with the U.S. Department of Defense (DoD) and expects to sign a new contract with the DoD in the coming months.

Valneva is also exploring options for its Almeida manufacturing facility in Livingston (Scotland), initially built to produce its COVID-19 vaccine, including a possible sale or a repurposing to produce Ixiaro® and its chikungunya vaccine, if approved.

CHOLERA / ETEC²³-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC²⁴, 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.

DUKORAL® sales increased by 302.6% to €10.2 million in the first quarter of 2023 compared to €2.5 million in the first quarter of 2022, also benefitting from the significant recovery in the private travel markets as well as price increases.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In the first quarter of 2023, Valneva's third party product sales were €4.5 million compared to €5.6 million in the first quarter of 2022.

First Quarter 2023 Financial Review (Unaudited, consolidated under IFRS)

Revenues

²⁰ <https://www.cdc.gov/ncird/human-metapneumovirus.html>

²¹ Macri A, Crane JS. Parvoviruses. 2022 May 23. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. PMID: 29489222.

²² <https://www.cdc.gov/campylobacter/faq.html#:~:text=Campylobacter%20infection%2C%20or%20campylobacteriosis%2C%20is,year%20for%20every%20100%2C000%20people.>

²³ Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl.

dosage, safety and age groups in which this vaccine is licensed. ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

²⁴ 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.

Valneva's total revenues were €33.5 million in the first quarter of 2023 compared to €21.8 million in the first quarter of 2022, an increase of 53.4%.

Valneva's total product sales reached €32.1 million in the first quarter of 2023 compared to €16.2 million in the first quarter of 2022, an increase of 98.6%. This was driven by a continued recovery of travel vaccine sales. On a constant exchange rate (CER) basis, product sales increased by 101.0% in the first quarter of 2023 compared to the first quarter of 2022. No COVID-19 vaccine sales were recorded in the first quarter of 2023 while the previous year's quarter included €3.8 million.

IXIARO[®]/JESPECT[®] product sales were €17.4 million in the first quarter of 2023 compared to €4.2 million in the first quarter of 2022, an increase of 315.2% (314.5% at CER) with sales benefitting from the continuing recovery of travel markets and price increases. DUKORAL[®] sales were €10.2 million in the first quarter of 2023 compared to €2.5 million in the first quarter of 2022, an increase of 302.6% (317.3% at CER), also benefitting from the significant recovery in the private travel markets and price increases. Third Party product sales declined to €4.5 million in the first quarter of 2023 compared to €5.6 million in the first quarter of 2022, a decrease of 19.7%, which was mainly driven by supply constraints of products sold under the distribution agreement with Bavarian Nordic for the sales of Rabipur[®]/RabAvert[®] and Encepur[®].

Other revenues, including revenues from collaborations, licensing and services amounted to €1.4 million in the first quarter of 2023 compared to €5.7 million in the first quarter of 2022. The decline mainly resulted from declining customer services in the Clinical Trial Material (CTM) unit in Sweden and no further revenues recognized from the Pfizer Lyme VLA15 collaboration agreement.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €20.5 million in the first quarter of 2023. The gross margin on commercial product sales excluding COVID-19 sales was 48.4% compared to 68.5% in the first quarter of 2022. COGS of €7.2 million related to IXIARO[®] product sales yielded a product gross margin of 58.7%. COGS of €6.3 million related to DUKORAL[®] product sales yielded a product gross margin of 38.3%. Of the remaining COGS for the first quarter of 2023, €3.1 million were related to the Third-Party product distribution business. In the first quarter of 2022, overall COGS were €14.7 million, of which €9.6 million related to cost of goods and €5.1 million related to cost of services.

Research and development expenses amounted to €14.1 million in the first quarter of 2023 compared to €20.7 million in the first quarter of 2022. This decrease was mainly driven by lower spend on Valneva's COVID-19 vaccine VLA2001. Marketing and distribution expenses in the first quarter of 2023 amounted to €9.0 million compared to €2.0 million in the first quarter of 2022. Marketing and distribution expenses in the first quarter of 2023 notably included €3.4 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate, VLA1553, compared to €1.2 million in the first quarter of 2022. In the first quarter of 2023, general and administrative expenses increased to €10.0 million from €5.8 million in the first quarter of 2022. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited in the first quarter of 2022 from an accrual adjustment income of €11.7 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 €3.5 million in the first quarter of 2023 from €2.1 million in the first quarter of 2022. This increase was mainly driven by recognizing grant income received from Scottish Enterprise into the income statement in the first quarter of 2023.

Valneva recorded an operating loss of €16.6 million in the first quarter of 2023 compared to an operating loss of €18.4 million in the first quarter of 2022. Adjusted EBITDA loss in the first quarter of 2023 was €12.3 million compared to an Adjusted EBITDA loss of €13.3 million in the first quarter of 2022 (as explained further below).

Net Result

In the first quarter of 2023, Valneva generated a net loss of €18.1 million compared to a net loss of €26.0 million in the first quarter of 2022.

Finance expense and foreign currency effects in the first quarter of 2023 resulted in a net finance expense of €1.7 million, compared to a net finance expense of €7.1 million in the first quarter of 2022. This was mainly a result of a foreign exchange gain amounting to €3.2 million in the first quarter of 2023, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange loss of €2.4 million in the first quarter of 2022. Interest expenses net of interest income were €4.8 million in the first quarter of 2023 compared to €4.7 million in the first quarter of 2022.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €24.3 million in the first quarter of 2023 compared to €26.9 million of cash used in operating activities in the first quarter of 2022. Cash outflows in the first quarter of 2023 and 2022 mainly resulted from the operating loss generated in both periods.

Cash outflows from investing activities amounted to €3.6 million in the first quarter of 2023 compared to €9.4 million in the first quarter of 2022, both mainly related to construction activities at the Scottish production site and purchases of equipment.

Net cash used in financing activities amounted to €3.8 million in the first quarter of 2023, which was mainly due to interest payments as well as payments of lease liabilities. Cash inflows in the first quarter of 2022 amounted to €1.0 million and was a result of proceeds from the issuance of new shares in relation to employee stock option and free share programs.

Cash, cash equivalents and restricted cash amounted to €254.5 million as at March 31, 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 provide additional analytical tools. Adjusted EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

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

| € in million (unaudited results, consolidated per IFRS) | 3 months ending March 31 | |
|--|--------------------------|---------------|
| | 2023 | 2022 |
| Net Income | (18.1) | (26.0) |
| Add: | | |
| Income tax expense | (0.1) | 0.5 |
| Total Finance income | (0.3) | (0.0) |
| Total Finance expense | 5.1 | 4.7 |
| Foreign exchange gain/(loss) – net | (3.2) | 2.4 |
| Result from investments in associates | - | - |
| Amortization | 1.6 | 1.6 |
| Depreciation | 2.6 | 3.6 |
| Impairment of Tangible Assets | - | - |
| Adjusted EBITDA | (12.3) | (13.3) |

About Valneva SE

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

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to expected total revenues and product sales for full fiscal year 2023 and the expected timing for submissions to and responses by regulatory authorities. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future results. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance

or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results or delays, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.