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: September 21, 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 September 21, 2023, the Registrant announced its results from the first six months of 2023 and issued a press release and its half-year financial report, 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 September 21, 2023
Exhibit 99.2	Half-Year Financial Report, January 1 to June 30, 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.

Valneva SE (Registrant)

Date: September 21, 2023

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

VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Reports Half Year 2023 Financial Results and Provides Corporate Updates

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

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

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

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

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

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

2023 financial guidance confirmed

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

Financial Information

(Unaudited results, consolidated per IFRS)

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

Saint-Herblain (France), September 21, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its consolidated financial results for the first half of the year, ended June 30, 2023. The half year financial report, including the condensed consolidated interim financial report and the half year management report, is available on the Company's website (Financial Reports – Valneva).

[1] *Valneva Announces Extension of Existing Loan Agreement - Valneva*
[2] *For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR*

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

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

Clinical Stage Vaccine Candidates

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

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

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

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

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

---

[3] *https://www.who.int/news-room/fact-sheets/detail/chikungunya*
[4] *https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas*
[5] *FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva*
[6] *Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva*
[7] *Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva*
[8] *Valneva Files for Chikungunya Vaccine Authorization with Health Canada - Valneva*
[9] *Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review - Valneva*

The regulatory submissions with Health Canada and the FDA follow final pivotal Phase 3 data in March 2022[10], final lot-to-lot consistency results in May 2022[11] and positive twelve-month persistence data in December 2022[12]. The pivotal Phase 3 data were published in *The Lancet*, the world's leading peer-reviewed medical journal, in June 2023[13]. The article, titled, "Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicenter, randomized, placebo-controlled phase 3 trial," provides a detailed analysis of the Phase 3 results showing that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration. This immunogenicity profile was similar in both younger and older adults, and 96% of participants maintained seroresponse six months after vaccination. VLA1553 was equally well tolerated in younger and older adults. Earlier clinical data, published in the *Lancet Infectious Diseases*, showed that the onset of the immune response after a single dose of VLA1553 is between 7- and 14-days post-vaccination[14]. This potential for a rapid onset of seroresponse was later confirmed in a post-hoc analysis of the Phase 1 study which showed that 100% of vaccinated individuals reached the seroresponse threshold at day 14[15]. Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 months with a 99% seroresponse rate and was equally durable in younger and older adults[16]. This dedicated antibody persistence trial (VLA1553-303) will continue to evaluate persistence for a period of at least five years. VLA1553 uses the live-attenuated virus vaccine technology, known to induce long-lasting immunity after a single dose. Examples of live-attenuated vaccines include the combined measles, mumps and rubella (MMR), yellow fever, and chickenpox (varicella) vaccines.

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

Initial safety data generated from the study, Valneva's first clinical study in an endemic area and with individuals previously infected with CHIKV, show that VLA1553 was generally well tolerated in

---

[10] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
[11] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
[12] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[13] *Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva*
[14] *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.*
[15] *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.*
[16] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[17] *Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva*
[18] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*

754 adolescents aged 12 to 17 years, regardless of previous CHIKV infection. Immunogenicity data for the trial are expected in November 2023.

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

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

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[21].

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[22,23,24]. 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[25].

[19] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[20] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[21] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[22] *Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva*
[23] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*
[24] *Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva*
[25] *Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate - Valneva*

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[26].

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

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

Pfizer is aiming to submit a BLA to the FDA and a 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 countries and territories have reported evidence of mosquito-transmitted Zika virus infection; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat.

VLA1601 is being developed on the original manufacturing platform of Valneva's licensed Japanese Encephalitis vaccine IXIARO®, 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[27].

Valneva has decided to re-initiate clinical development with further program evaluation to be conducted subject to data, medical need and market prospects. This decision is based on the persistence of Zika transmission in several countries[28], the possibility to leverage the Company's existing

[26] *Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva*
[27] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 - Valneva*
[28] *Zika virus disease (who.int)*

inactivated viral platform and potentially its expertise in accelerated regulatory pathways, as well as VLA1601's compelling Target Product Profile (TPP).

Pre-Clinical Vaccine Candidates

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

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

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[32].

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

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

---

[29] *https://www.cdc.gov/epsteinbarr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults.*
[30] *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.*
[31] *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*
[32] *https://www.cdc.gov/ncird/human-metapneumovirus.html*

CHOLERA / ETEC[33]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC[34], 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 half of 2023, DUKORAL® sales increased by 197% to €17.1 million compared to €5.8 million in the first half of 2022, also benefiting from the significant recovery in the private travel markets and price increases.

THIRD-PARTY DISTRIBUTION

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

MANUFACTURING UPDATE

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

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

Valneva divests Swedish clinical trial manufacturing unit to NorthX Biologics

As part of its strategy to focus on core business activities, Valneva divested its clinical trial manufacturing, or CTM, unit in Solna, Sweden, to NorthX Biologics, an established Nordic contract development and manufacturing organization (CDMO) in July 2023. The deal comprised Valneva's CTM production facility and approximately 30 staff members in Sweden. Valneva Sweden retains 150 employees at its Swedish site, working in the Company's dedicated production unit for its cholera vaccine DUKORAL® and its center of excellence for fill and finish operations.

[33] 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.
[34] 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.

(Unaudited, consolidated under IFRS)

Revenues

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

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

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

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

Operating Result and Adjusted EBITDA

Costs of goods and services sold (COGS) were €53.8 million in the first half of 2023. The gross margin on commercial product sales excluding COVID-19 sales was 40.0% compared to 58.3% in the first half of 2022. COGS of €18.1 million related to IXIARO® product sales yielding a product gross margin of 40.2%. COGS of €10.1 million related to DUKORAL® product sales yielding a product gross margin of 40.9%. The gross margin of IXIARO® 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 half of 2023, €10.2 million were related to the Third-Party

product distribution business, €3.8 million to COVID-19 product sales and €6.1 million to initial COGS related to the launch preparations for the chikungunya vaccine candidate as well as to idle capacity costs. In the first half of 2022, overall COGS were €171.5 million, of which €167.2 million related to cost of goods and €4.3 million related to cost of services. COGS in the first half of 2022 included write-offs related to the significant reduction of COVID-19 sales volumes to EC Member States.

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

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

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

Net Result

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

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

Cash Flow and Liquidity

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

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

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

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

Non-IFRS Financial Measures

Management uses and presents IFRS results, as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Valneva's current performance, performance trends, and financial condition.

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

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

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

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.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
VP, Global Communications and European Investor Relations
M +33 (0)6 4516 7099
investors@valneva.com

Joshua Drumm, Ph.D.
VP, Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com

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.

H1 2023

HALF-YEAR FINANCIAL REPORT

JANUARY 1 TO JUNE 30, 2023

September 21, 2023

VALNEVA SE
Campus Bio-Ouest
6 rue Alain Bombard
44800 Saint-Herblain, France
www.valneva.com

valneva

TABLE OF CONTENTS

GENERAL INTRODUCTORY COMMENTS AND DISCLAIMER

In this interim financial report, unless stated otherwise, the terms “Company”, “Valneva” and “Group” refer to Valneva SE and its subsidiaries.

This interim financial report contains forward-looking statements about the Company’s targets and forecasts, especially in chapter 1.4 – “Operational and strategic outlook FY 2023”. Such statements are based on data, assumptions and estimates that the Company considers reasonable.

All forward-looking statements in this interim financial report are subject to change or adjustments as a result of uncertainties inherent in all research and development activities, as well as the economic, financial, competitive and regulatory environment. In addition, the Company’s business activities and its ability to meet its targets and forecasts may be affected if some of the risk factors described in chapter 1.5 – “Risk factors” of this interim financial report arise.

Investors are urged to pay careful attention to the risk factors set forth in chapter 1.5 – “Risk factors” of this interim report before making any investment decision. The risks presented in this interim report are those the Company considers to be the most significant for the second half of 2023 and are not all of the risks that the Company faces during this period or beyond. One or more of these risks may have an adverse effect on the Company’s activities, condition, the results of its operations or on its targets and forecasts. Furthermore, other risks not yet identified or considered as significant by the Company could have the same adverse effects, and investors may lose all or part of their investment.

Forward-looking statements, targets and forecasts shown in this interim financial report may be affected by risks, either known or unknown uncertainties and other factors that may lead to the Company’s future results of operations, performance and achievements differing significantly from the stated or implied targets and forecasts. These factors may include changes in economic or trading conditions and regulations, as well as the factors set forth in chapter 1.5 – “Risk factors” of this interim report as well as those risks and uncertainties discussed or identified in Valneva’s public filings with the “Autorité des Marchés Financiers" (AMF) in France, including those listed in the Company’s 2022 Universal Registration Document filed with the AMF on March 30, 2023, which is available on the websites of the Company and the AMF, and public filings and reports filed with the U.S. Securities and Exchange Commission (SEC), including the Company’s 2022 annual report on Form 20-F available on the SEC’s website.

References to Valneva’s website and social media accounts are included for information only and the content contained therein, or that can be accessed through, Valneva’s website and these social media accounts is not incorporated by reference into this report and does not constitute a part of this report.

I. MANAGEMENT REPORT

1 Overview

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

The Company has a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently markets two proprietary travel vaccines as well as certain third-party vaccines leveraging its established commercial infrastructure.

Revenues from this growing commercial business help fuel the continued advancement of the Company's 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.

Valneva has over 700 employees across its operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. For more information, visit www.valneva.com and follow the Company on LinkedIn.

2 Operational Review

2.1 Vaccine Research & Development (R&D)

Valneva's pipeline is composed of differentiated vaccine candidates at various stages of research and development. The Company aims to develop vaccine candidates that are either first-, best- or only-in-class and address unmet needs in infectious diseases.

Each of these assets are differentiated product candidates that either target diseases currently lacking a preventative or effective therapeutic treatment option or that the Company believes may have meaningful advantages relative to existing vaccine solutions or treatment options.

Valneva strives to develop products towards marketing approval and commercialization either in-house, as illustrated by its chikungunya vaccine candidate, which may be approved by the U.S. Food and Drug Administration (FDA) later this year, or through strategic licensing or partnering, as illustrated by its collaboration with Pfizer for its Lyme disease vaccine candidate VLA15.

Chikungunya Vaccine Candidate – VLA1553

Overview of the Chikungunya Virus

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes.

Infection leads to symptomatic disease in up to 97% of humans four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[1].

Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries[2].

As of July 2022, more than three million cases had been reported in the Americas[3] and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

VLA1553 Vaccine Candidate

Valneva has developed VLA1553, a live-attenuated single-dose vaccine candidate against the chikungunya virus (CHIKV). It has been designed by deleting specific segments of the virus, thereby weakening, or attenuating, the virus. Attenuation of the live virus is conducted by reverse genetics which leads to a reduced replication capability of the virus in vivo, making a reversion to wild-type impossible.

---

[1] VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

[2] https://www.who.int/news-room/fact-sheets/detail/chikungunya

[3] PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2022 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 25 Jul 2022.

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

Additionally, a regulatory application was filed with Health Canada at the end of May 2023[7] and accepted for review at the end of August 2023[8].

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

The regulatory submissions with Health Canada and the FDA follow final pivotal Phase 3 data in March 2022[9], final lot-to-lot consistency results in May 2022[10] and positive twelve-month persistence data in December 2022[11]. The pivotal Phase 3 data were published in The Lancet, the world's leading peer-reviewed medical journal, in June 2023[12]. The article, titled, "Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicenter, randomized, placebo-controlled phase 3 trial," provides a detailed analysis of the Phase 3 results showing that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration. This immunogenicity profile was similar in both younger and older adults, and 96% of participants maintained seroresponse six months after vaccination. VLA1553 was equally well tolerated in younger and older adults. Earlier clinical data, published in the Lancet Infectious Diseases, showed that the onset of the immune response after a single dose of VLA1553 is between 7- and 14-days post-vaccination[13]. This potential for a rapid onset of seroresponse was later confirmed in a post-hoc analysis of the Phase 1 study which showed that 100% of vaccinated individuals reached the seroresponse threshold at day 14[14]. Additionally, VLA1553 was able to demonstrate a robust immune response which was sustained for 12 months with a 99% seroresponse rate and was equally durable in younger and older adults[15]. This dedicated antibody persistence trial (VLA1553-303) will continue to evaluate persistence for a period of at least five years. VLA1553 uses the live-attenuated virus vaccine technology, known to induce long-lasting immunity after a single dose. Examples of live-attenuated vaccines include the combined measles, mumps and rubella (MMR), yellow fever, and chickenpox (varicella) vaccines.

A clinical study in adolescents, VLA1553-321, is ongoing in Brazil, for which Valneva reported enrollment and vaccination completion in February 2023[16] and initial safety data in August 2023[17]. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and conducted in collaboration with Instituto Butantan, the VLA1553-321 adolescent trial is intended to support the label extension in this age group following a potential initial FDA approval in adults. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. Additionally, the present safety analysis is expected to enable regulatory submission to the European Medicines Agency (EMA) later this year.

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

754 adolescents were vaccinated in the VLA1553-321 trial and the present analysis includes safety data up to Day 29. An independent Data and Safety Monitoring Board (DSMB) has continuously evaluated safety data during the trial and has not identified any safety concerns. Overall, the adverse event profile is consistent with the profile observed in Valneva's pivotal Phase 3 trial in adults. The majority of solicited adverse events observed following VLA1553 administration were of mild or moderate intensity and resolved within three days. Importantly, the initial data suggest a favorable safety profile in seropositive participants, confirming the observations following re-vaccination of individuals in Phase 1 trial VLA1553-101[18].

To make VLA1553 more accessible to Low- and Middle-Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing, and marketing of VLA1553[19]. The collabora

[4] FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva

[5] Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva

[6] Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva

[7] Valneva Files for Chikungunya Vaccine Authorization with Health Canada - Valneva

[8] Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review - Valneva

[9] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate

[10] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate

[11] Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva

[12] Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva

[13] 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.

[14] 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)

[15] Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva

[16] Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva

[17] Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva

[18] Chikungunya vaccine: a single shot for a long protection? - The Lancet Infectious Diseases

[19] Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

tion falls within the framework of the agreement signed between CEPI and Valneva in July 2019[20], 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 program was also granted PRIority MEdicine (PRIME) designation by the EMA in 2020, and Valneva plans to make regulatory submissions for VLA1553 in Europe in the second half of 2023.

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[21].

Lyme Disease Vaccine Candidate – VLA15

Overview of Lyme Disease

Lyme disease is a systemic infection caused by Borrelia burgdorferi bacteria transmitted to humans by infected Ixodes ticks[22]. It is considered the most common vector-borne illness in the Northern Hemisphere[23].

While the true incidence of Lyme disease is unknown, it is estimated to annually affect approximately 476,000 people in the United States and 130,000 people in Europe[24,25]. Research suggests that Lyme disease cases may rise 92% by 2100 in the U.S. due to climate change[26]. Although most patients recover from Lyme disease, 10-20% have persistent symptoms, which for some are chronic and disabling. Studies indicate that Lyme disease costs up to approximately $1.3 billion each year in direct medical costs in the U.S. alone[27].

The transmission of Lyme disease infection is well understood and documented. Borrelia bacteria colonize in the salivary glands of ticks. When a tick attaches for feeding, it injects its saliva into the human or animal host, bringing along antihistamines, cytokine blockers, anticoagulants and, in the case of an infected tick, Borrelia bacteria.

Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called erythema migrans or more nonspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia, or myalgia) can often be overlooked or misdiagnosed as they are often associated with other, often less severe, illnesses. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system[28]. The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens[29].

VLA15 Vaccine Candidate

Valneva and its partner, Pfizer, are developing a multivalent protein subunit vaccine candidate that targets the bacteria that cause Lyme disease. VLA15 is designed to prevent Lyme disease by generating antibodies against the outer surface protein A (OspA) on the surface of Borrelia, killing the bacteria before it can be transmitted from the infected tick to the human host. The program was granted Fast Track designation by the FDA in July 2017[30] and, in April 2020, Valneva announced a collaboration with Pfizer for late clinical development and commercialization of VLA15[31]. 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 Agreement. As per the updated[32] terms, Pfizer will fund 60% of the remaining shared development costs compared to 70% in the initial agreement. Valneva will receive tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement, which will be complemented by up to $100 million in milestones payable to us based on cumulative sales. Other development and early commercialization milestones were unchanged, of which $143 million remain to date.

Valneva and Pfizer reported results for the Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which high levels of antibodies against all six strains were observed[33,34,35]. 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 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). Depending on the primary schedule they received (month 0-2-6 or month 0-6), participants seroconv

[20] CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

[21] VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

[22] Stanek et al. 2012, The Lancet 379:461–473

[23] Gern L, Falco RC. Lyme disease. Rev Sci Tech. 2000 Apr;19(1):121-35

[24] Burn L, et al. Incidence of Lyme Borreliosis in Europe from National Surveillance Systems (2005–2020). April 2023. Vector Borne and Zoonotic Diseases. 23(4): 156–171.

[25] Kugeler KJ, et al. Estimating the frequency of Lyme disease diagnoses—United States, 2010-2018. February 2021. Emergency Infectious Disease. 27(2).

[26] Lyme disease cases may rise 92 per cent in US due to climate change

[27] Lyme Disease Costs Up to $1.3 Billion Per Year to Treat, Study Finds

[28] Sykes RA, et al. An estimate of Lyme borreliosis incidence in Western Europe. Journal of Public Health 2017; 39(1): 74-81

[29] Center for Disease Control and Prevention. Lyme Disease. Data and Surveillance. April 2021. Available at: https://www.cdc.gov/lyme/datasurveillance/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Flyme%2Fstats%2Findex.html Accessed July 2022.

[30] Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

[31] Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

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

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

[34] Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate

[35] Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

erted after the booster dose, yielding seroconversion rates (SCRs) of 95.3% and 94.6% for all outer surface protein A (OspA) serotypes in all age groups, respectively. Additionally, OspA antibody titers were significantly higher one month after the booster dose compared to one month after the primary schedule with 3.3- to 3.7-fold increases (Geometric Mean Fold Rises) in adults, 2.0- to 2.7- fold increases in adolescents and 2.3- to 2.5-fold increases in children for all serotypes. The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies as the vaccine candidate was well tolerated in all age groups regardless of the primary vaccination schedule. No vaccine-related serious adverse events (SAEs) and no safety concerns were observed by an independent Data Safety Monitoring Board (DSMB).

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[36].

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

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

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

Zika Vaccine Candidate – VLA1601

Overview of Zika Virus

Zika is a mosquito-borne viral disease caused by the Zika virus, a flavivirus transmitted by Aedes mosquitoes[37]. Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. According to the World Health Organization (WHO), there is scientific consensus that Zika is a cause of microcephaly and Guillain-Barré syndrome[38]. Between 2015 and January 2018, over 500,000 cases of suspected Zika infection, as well as many cases of the congenital syndrome associated with Zika, were reported by countries and territories in the Americas, according to the WHO. In addition, the first local mosquito-transmitted Zika virus disease cases were reported in Europe in 2019 and Zika virus outbreak activity was detected in India in 2021.

Zika virus transmission persists in several countries in the Americas and in other endemic regions. To date, a total of 89 countries and territories have reported evidence of mosquito-transmitted Zika virus infection; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat.

VLA1601 Vaccine Candidate

VLA1601 is a highly purified inactivated, adjuvanted vaccine candidate against the Zika virus (ZIKV). It 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[39].

Valneva reported positive topline results for VLA1601 from a first-in-human study in November 2018[40] but decided, at the time, to focus on its two leading vaccine candidates against chikungunya and Lyme disease.

Valneva has decided to re-initiate clinical development of a highly purified inactivated, adjuvanted vaccine candidate against ZIKV with further program evaluation to be conducted subject to data, medical need and market prospects. This decision is based on the persistence of Zika transmission in several countries[41], the possibility to leverage the Company's existing inactivated viral platform and potentially its expertise in accelerated regulatory pathways, as well as VLA1601's compelling Target Product Profile (TPP).

The Zika virus vaccine TPP issued by WHO/UNICEF[42] has called for an inactivated whole virus vaccine adjuvanted with alum for a target population of women of reproductive age, which may include pregnant women, and a secondary target population of adolescent and adult males.

---

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

[37] https://www.cdc.gov/zika/transmission/index.html

[38] http://www.who.int/mediacentre/factsheets/zika/en/

[39] Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 - Valneva

[40] Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva

[41] Zika virus disease (who.int)

[42] Target product profile - Zika vaccine.pdf (unicef.org)

Valneva plans to initiate a new Phase 1 study early next year. The Zika virus disease is on the list of tropical diseases that could qualify for a U.S. FDA Priority Review Voucher[43].

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[44] and is strongly associated with the development of several types of cancer[45] and multiple sclerosis[46].

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[47].

2.2 Marketed products

Valneva commercializes its two proprietary travel vaccines IXIARO®/JESPECT® and DUKORAL®. Sales from these products are complemented by sales from the distribution of third-party products in markets where Valneva operates its own marketing and sales infrastructure (United States, Canada, Nordic countries, United Kingdom, Austria and France). In addition, the Company has continued to receive marginal revenues from an existing supply agreement with the Kingdom of Bahrain for its COVID-19 vaccine VLA2001.

Valneva's product sales in the first half of 2023 increased by 109% to €69.7 million compared to €33.3 million in the first half of 2022, benefiting from a significant recovery of the travel market following the decline of the COVID-19 pandemic as well as from price increases for its travel vaccines.

Japanese encephalitis vaccine (IXIARO®/JESPECT®)

IXIARO®, or JESPECT® in Australia and New Zealand, is a Vero cell culture-derived inactivated Japanese encephalitis vaccine and is the only Japanese encephalitis vaccine currently approved for use in the United States, Canada and Europe. IXIARO® is indicated for active immunization against Japanese encephalitis in adults, adolescents, children and infants aged two months and older, and is a required vaccine for U.S. military personnel who are deployed to areas of risk for Japanese encephalitis. The pediatric indication of IXIARO® was granted Orphan Drug designation by the FDA. Japanese encephalitis virus, or JEV, is spread by mosquitos and is the most important cause of viral encephalitis in Asia and the Western Pacific.

Since the approval of IXIARO®/JESPECT® in 2009, the vaccine label has been extended by the EMA and the FDA for use in children from the age of two months. In addition, an accelerated, alternative vaccination schedule (seven days apart) for adult travelers (18-65 years) was approved by the EMA in 2015 as well as Health Canada and the FDA in 2018.

In March 2020, the FDA approved the extension of IXIARO®'s shelf life from 24 months to 36 months[48], an important achievement supporting supply management flexibility.

For the ten years prior to the COVID-19 pandemic, the Company, together with its marketing and distribution partners, successfully increased sales penetration for IXIARO®. With the lifting of travel restrictions and continued recovery of the private travel market, that historical growth is expected to resume.

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

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

Cholera / ETEC[49] vaccine (DUKORAL®)

Valneva's cholera vaccine DUKORAL® is an oral vaccine indicated for the prevention of diarrhea caused by Vibrio cholera and/or heat labile toxin producing ETEC, the leading cause of travelers' diarrhea. The vaccine contains four inactivated strains of the bacterium Vibrio cholerae serotype O1, and part of a toxin from one of these strains as active substances. It is authorized for use in the European Union and Australia to protect against cholera, and in Canada, Switzerland, New

[43] Tropical Disease Priority Review Voucher Program | FDA

[44] https://www.cdc.gov/epsteinbarr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults.

[45] 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.

[46] 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

[47] https://www.cdc.gov/ncird/human-metapneumovirus.html

[48] Valneva Announces FDA Approval of IXIARO® Shelf Life Extension to 36 Months; New US Military RFP Issued

[49] 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.

Zealand and Thailand to protect against cholera and ETEC. DUKORAL® is indicated for adults and children from two years of age who will be visiting endemic areas.

Originally licensed in Sweden by SBL Vaccines in 1991, and subsequently in the European Union in 2004 DUKORAL® was then prequalified by the WHO. Valneva acquired DUKORAL® in 2015 from Janssen Pharmaceuticals as part of the Company's strategic vision to extend its proprietary travel vaccine portfolio.

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

SARS-CoV-2 inactivated vaccine

Valneva's COVID-19 vaccine VLA2001 is the only inactivated whole-virus COVID-19 vaccine approved in Europe[50] and the first COVID-19 vaccine to receive a full marketing authorization from the EMA. It was produced using Valneva's established Vero cell platform, leveraging the manufacturing technology for Valneva commercial Japanese encephalitis vaccine, IXIARO®.

With the decline of the COVID-19 pandemic and reduced order volume from the European Commission[51], Valneva decided to suspend manufacturing of the vaccine in August 2022. Valneva fully wrote down its inventory as of December 31, 2022 and decided not to invest further in COVID-19 vaccine development activities.

In the first half of 2023, VLA2001 sales were €5.7 million compared to €3.8 million in the first half of 2022, as Valneva made a delivery to the Kingdom of Bahrain under the existing supply agreement.

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 Valneva's 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 three-antigen Hepatitis B vaccine, PreHevbri, in select European markets.

In the first half of 2023, third party product sales increased by 44% to €16.5 million from €11.5 million in the first half of 2022.

2.3 Other revenues

Valneva derives revenues from collaboration and partnership agreements. The Company's primary source of collaboration revenues is currently through its research collaboration and license agreement with Pfizer Inc., entered into in April 2020[52], to co-develop and commercialize the Company's Lyme vaccine candidate, VLA15. In June 2020, Pfizer paid Valneva a one-time non-refundable upfront payment of $130 million.

In June 2022, Valneva and Pfizer updated the terms of the collaboration and license agreement[53]. Valneva will now fund 40% of the remaining shared development costs compared to 30% in the initial agreement. Pfizer will pay Valneva tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement. In addition, Valneva is now eligible for up to $100 million in milestone payments based on cumulative sales. Other development and early commercialization milestones are unchanged, of which $143 million remain to date.

Other revenues, including revenues from collaborations, licensing and services, amounted to €4.1 million in the first half of 2023 compared to €60.0 million in the first half of 2022. This decrease is attributable to a one-time release of an €89.4 million refund liability in the first half of 2022 which did not recur in the first half of 2023. The release was related to the signing of a settlement agreement[54] with the UK government related to the COVID-19 supply contract.

2.4 Other Business Updates

Upsized Financing Arrangement with Leading U.S. Healthcare Funds Deerfield and OrbiMed

In August 2023, Valneva announced an agreement to increase the principal amount of its existing $100 million senior secured debt financing agreement with funds managed by leading U.S. healthcare investment firms Deerfield Management Company and OrbiMed. The add-on loan facility provides Valneva with immediate access to $50 million, with an additional $50 million available at the Company's discretion until December 31, 2023. The increased funding will be used to further invest in R&D, as well as continued market access preparations and potential commercialization of Valneva's chikungunya vaccine candidate. The add-on facility has a three-year interest-only period and will mature in the third quarter of 2028. The loan interest rate remains unchanged. The original loan agreement was signed in February 2020.

[50] Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001

[51] Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine - Valneva

[52] Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15 – Valneva

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

[54] Valneva Announces Settlement Agreement with the UK Government - Valneva

Appointment and Reappointment of Supervisory Board Members and Statutory Auditors

During Valneva's Annual General Meeting in June 2023, Dr. Kathrin U. Jansen, Ph.D., was appointed to Valneva's Supervisory Board for a three-year term[55]. She notably served as Senior Vice President and Head of Vaccine Research and Development at Pfizer Inc., and was a member of Pfizer's Worldwide Research, Development and Medical leadership team. The term of office of Supervisory Board members Dr. Johanna W. Pattenier and Ms. Sharon E. Tetlow was renewed until June 2026. The term of office of PricewaterhouseCoopers Audit as Statutory Auditor was renewed for a period of six years.

Valneva's Supervisory Board Recommended Transition from a Two-Tier Governance Model to a Board of Directors

In June 2023, Valneva's Supervisory Board recommended a change of governance model and voted in favor of transitioning from the Company's current two-tier governance model, which includes a Supervisory Board and a Management Board, to a one-tier model led by a Board of Directors, with CEO Thomas Lingelbach included as an executive member. The Supervisory Board's proposal also recommended the establishment of an Executive Committee to be comprised of, among others, the members of the current Management Board.

This proposed change in Valneva's governance structure will be submitted to the vote of the Company's shareholders at an Extraordinary General Meeting later this year.

Valneva's Management Board Decides on Strategic Direction for New Scottish Manufacturing Facility Almeida

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

Valneva divests Swedish clinical trial Manufacturing unit to NorthX Biologics

As part of its strategy to focus on core business activities, Valneva divested its clinical trial manufacturing, or CTM, unit in Solna, Sweden, to NorthX Biologics, an established Nordic contract development and manufacturing organization (CDMO) in July 2023. The deal comprised Valneva's CTM production facility and approximately 30 staff members in Sweden. Valneva Sweden retains 150 employees at its Swedish site working in the Company's dedicated production unit for its cholera vaccine DUKORAL® and its center of excellence for fill and finish operations.

3 Financial Review

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

Revenues

Valneva's total revenues were €73.7 million in the six months ended June 30, 2023 compared to €93.2 million in the six months ended June 30, 2022, a decrease of 20.9%. The decrease was related to non-recurring revenues recorded in the prior year related to the Company's COVID-19 program.

Valneva's total product sales reached €69.7 million in the six months ended June 30, 2023 compared to €33.3 million in the same period of 2022, an increase of 109.0%. This was driven by a continued recovery of travel vaccine sales. Foreign currency fluctuations contributed to a €0.7 million decline in product sales. COVID-19 vaccine sales in the first half of 2023 amounted to €5.7 million compared to €3.8 million in the first half of 2022. Excluding COVID-19, product sales reached €64.0 million in the first half of 2023 compared to €29.5 million in the comparator period of 2022, an increase of 116.6%.

IXIARO®/JESPECT® product sales were €30.3 million in the first half of 2023 compared to €12.3 million in the first half of 2022, an increase of 146.8% with sales benefiting from the continuing recovery of travel markets as well as price increases. Foreign currency fluctuations contributed to a €0.2 million decline in product sales. DUKORAL® sales were €17.1 million in the first half of 2023 compared to €5.8 million in the first half of 2022, an increase of 197.4%, also benefiting from the significant recovery in the private travel markets and price increases. Foreign currency fluctuations contributed to a €0.3 million decline in product sales. Third Party product sales were €16.5 million in the six months ended June 30, 2023 compared to €11.5 million in the comparison period of 2022, an increase of 43.8%, which was mainly driven by products sold under the distribution agreement with Bavarian Nordic for Rabipur®/RabAvert® and Encepur®.

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

[55] Valneva Announces Successful Outcome of its AGM and the Appointment of Pfizer's Former Vaccine R&D Head to its Supervisory Board - Valneva

Operating Result and Adjusted EBITDA

Costs of goods and services sold (COGS) were €53.8 million in the six months ended June 30, 2023. The gross margin on commercial product sales excluding COVID-19 sales was 40.0% compared to 58.3% in the first half of 2022. COGS of €18.1 million related to IXIARO® product sales yielding a product gross margin of 40.2%. COGS of €10.1 million related to DUKORAL® product sales yielding a product gross margin of 40.9%. The gross margin of IXIARO® was impacted by batch write offs in the Scottish manufacturing site. Additionally, the gross margins of both IXIARO® and DUKORAL®'s were adversely impacted by high indirect sales in markets where Valneva sells through distributors. Of the remaining COGS for the first half of 2023, €10.2 million were related to the Third-Party product distribution business, €3.8 million to COVID-19 product sales and €6.1 million to initial COGS related to the launch of the chikungunya vaccine candidate as well as to idle capacity costs. In the six months ended June 30, 2022, overall COGS were €171.5 million, of which €167.2 million related to cost of goods and €4.3 million related to cost of services. COGS in the first half of 2022 included write-offs related to the significant reduction of COVID-19 sales volumes to EC Member States.

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

Other income, net of other expenses, increased to €14.0 million in the first half of 2023 from €3.6 million in the first half of 2022. This increase was mainly driven by recognizing grant income received from Scottish Enterprise into the income statement in the first half of 2023.

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

Net Result

In the six months ended June 30, 2023, Valneva generated a net loss of €35.0 million compared to a net loss of €171.5 million in the six months ended June 30, 2022.

Finance expense and foreign currency effects in the first half of 2023 resulted in a net finance expense of €3.9 million, compared to a net finance expense of €18.8 million in the first half of 2022. This was mainly a result of a foreign exchange gain amounting to €4.5 million in the first half of 2023, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange loss of €10.7 million in the first half of 2022. Interest expenses net of interest income were €8.9 million in the first half of 2023 compared to €8.2 million in the first half of 2022.

Cash Flow and Liquidity

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

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

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

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

Non-IFRS Financial Measures

Management uses and presents IFRS results, as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Valneva's current performance, performance trends, and financial condition.

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

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

	Six months ended June 30,	
(In € million)	**2023**	**2022**
Loss for the period	**(35,046)**	**(171,493)**
Add:		
Income tax expense	(3,778)	2,271
Total finance income	(504)	(35)
Total finance expense	8,879	8,199
Foreign currency gain/(loss) - net	(4,517)	10,657
Result from investments in associates	—	(9)
Amortization	3,192	3,477
Depreciation	5,365	7,677
Impairment excluding impairment loss of disposal	(1,888)	3,286
ADJUSTED EBITDA	**(28,297)**	**(135,970)**

4 Operational and Strategic Outlook 2023

Valneva's strategy supports its vision to contribute to a world in which no one dies or suffers from a vaccine-preventable disease. This strategy is based on an integrated business model that has allowed the Company to build a portfolio of differentiated clinical and pre-clinical assets as well as a growing commercial business. Valneva is focused on utilizing its proven and validated product development capabilities to rapidly advance solutions addressing unmet needs in infectious diseases towards regulatory approval, with the goal of becoming first-, best- or only-in-class, and commercialization. The Company has strategically entered into partnerships with other well-established pharmaceutical companies to leverage clinical and commercial capabilities and optimize the potential value of select assets. As Valneva advances its late-stage portfolio, it also remains focused on investing in its research and development pipeline in order to develop its earlier stage assets as well as identify new targets and indications where the Company believes it can make a significant difference.

In the second half of 2023, Valneva will focus on the following goals:

- Receive BLA approval for its chikungunya vaccine candidate VLA1553 from the U.S. FDA.
- Work closely with Health Canada to progress its review of the VLA1553 marketing application and make a regulatory submission for VLA1553 to the EMA.
- Monetize the PRV the Company could receive upon potential BLA approval of VLA1553 in order to help finance its R&D programs.
- Continue to progress, together with Pfizer, the VALOR Phase 3 study of its Lyme disease vaccine candidate VLA15.
- Continue to grow product sales using its established commercial infrastructure.
- Expand the Company's pipeline of pre-clinical and clinical programs by initiating a new Phase 1 study for its Zika vaccine candidate VLA1601 and continuing to progress pre-clinical candidates, while continuing to opportunistically pursue strategic partnerships and / or in-licensing opportunities.
- Strengthening Valneva's ESG (environmental, social, and governance) strategy and initiatives following the recent creation of ESG committees at the Supervisory Board and operational levels.

Noting the above, the Company confirms its financial goals for the full year 2023 of total revenues and other income reaching €220 to €260 million, including €130 million to €150 million of product sales and between €90 million and €110 million of other income. R&D expenses are expected between €70 million and €90 million.

5 Risk Factors

Valneva considers that the risk factors discussed below are the main risks and uncertainties that the Group may face in the remaining six months of 2023. These risk factors track those in section 1.5 of the Company's 2022 universal registration document (document d'enregistrement universel, "URD") submitted to the French Financial Markets Authority (Autorité des Marchés Financiers or AMF), on March 30, 2023 (AMF number D.23-0199) and in the Company's 2022 annual report on its form 20-F ("20-F") filed with the SEC on March 30, 2023). These are not the only risks and uncertainties facing the Group and may also occur in future years. The Company invites investors to review its URD, 20-F and other public disclosure for additional information, including additional risks not discussed below.

The development of innovative products includes the inherent risk of failure and the Group is therefore exposed to significant industry-specific risks. Valneva is subject to additional risks because most of its product sales arise from two commercialized vaccines only, namely DUKORAL® and IXIARO®/JESPECT®, and these belong to the market segment of travel vaccines which is now in the process of recovering. Management has established a risk management system in order to monitor and mitigate the risks associated with its business. However, the Group remains exposed to significant risks, including the following:

Risks relating to sales of core products. Valneva's revenues continue to be substantially dependent upon sales of its existing products, IXIARO® and DUKORAL®. Sales of these products will continue to be impacted by the rate of recovery of the travel industry and other factors, such as rising oil prices and market volatility relating to the conflict in Ukraine. Sales of IXIARO® and DUKORAL® will also depend on Valneva's ability to adjust manufacturing in response to demand, and there is no guarantee that Valneva will be able to supply quantities of these vaccines to meet any greater than expected demand. Valneva has not been able to increase its manufacturing of DUKORAL® to match demand following the reduced pace of manufacturing during the pandemic and expects that its supply will not meet demand in the remainder of 2023. Sales of DUKORAL® may also be negatively impacted by the launch of the Vaxchora cholera vaccine in Europe and Canada. Additionally, although the Group's sales of IXIARO® and DUKORAL® increased significantly in the first half of 2023 compared to the first half of 2022, there is no guarantee that such recovery will be sustained. Further factors may also affect the level of product sales in the future, including recommendations by global and local health organizations, a potential review of approved indications by health authorities (notably for DUKORAL®), the ability of customers to pay for treatment costs, and stronger competition. While the Company makes every effort to support review processes in the best interest of travelers, it cannot be ruled out that existing vaccination recommendations or indications may change in the future.

Risks relating to financing. Valneva will need to raise additional capital to complete the development and commercialization of its product candidates and fund certain of its existing manufacturing and other commitments. Such additional financing may be very difficult to obtain, on acceptable terms or at all, under existing or future circumstances of the Company and the financial markets. Additionally, the Company may be unable to meet the minimum revenue and liquidity requirements of its financing agreement with Deerfield and OrbiMed, which would constitute an event of default and could result in additional costs, as further described in the Company's annual reports referenced above.

Manufacturing and procurement risks. The Group's manufacturing facilities in Livingston, Scotland, and Solna, Sweden, are, and will continue to be, significant factors in growing revenues from product sales and maintaining control over production costs. The manufacturing of biological materials is a complex undertaking and technical problems may occur. Valneva may experience delays, be unsuccessful in manufacturing or face difficulties in the ability to manufacture and distribute its products according to market demands or regulatory requirements, including in response to greater than expected growth of the travel industry. Valneva may also experience delays or unforeseen challenges in transferring production to its new Almeida facility in Livingston and will likely continue to face an increase in costs of manufacturing as a result of inflation. Biological manufacturing is subject to government regulation and regular inspection. It is not possible to predict the changes that regulatory authorities may require during the life cycle of a novel vaccine, including any of Valneva's vaccine candidates. Such changes may be costly and may affect the Group's sales and marketing and product revenue expectations. The failure to comply with regulatory requirements, including current Good Manufacturing Practices, or a deficiency in quality control could give rise to regulatory actions or suspensions, revocations of manufacturing licenses, supply failures, product recalls or fines. The risk of suspension or revocation of a license also applies to third parties with whom Valneva has entered into manufacturing, supply, distribution or services agreements. The Group is currently dependent upon its key manufacturing facilities in Livingston, Scotland and Solna, Sweden for the production of IXIARO®, DUKORAL®, and the drug substance of the chikungunya vaccine candidate. The destruction by fire or other catastrophic events of any of the Group's key manufacturing facilities or the facilities of a key manufacturer, such as IDT, would prevent Valneva from manufacturing the relevant products and supplying its customers or its clinical trial centers, any of which would cause considerable losses. In addition, the Group's business requires the use of hazardous materials, which increases the Group's exposure to dangerous and costly accidents that may result in accidental contamination or injury to people or the environment. Further, the business is subject to stringent environmental health and safety and other laws, regulations and standards, which result in costs related to compliance and remediation efforts that may adversely affect the Group's performance and financial condition. Finally, the Group depends upon third-party manufacturers and contractors for the manufacture and supply of its commercial vaccines and product candidates. If such a third party could no longer provide services or failed to meet requirements, Valneva may not be able to supply one or more of its vaccines for several months, and the development and commercialization of the Company's product and product candidates may be limited or delayed, either of which would have a material adverse effect on the Group's business, financial condition, and results of operations.

Product development and approval risks. The Group's R&D activities, and in particular the development of its clinical-stage vaccine candidates, are expensive and time-consuming. The result of these R&D activities is inherently uncertain and delays or failures are possible. In order to continue to develop and commercialize its product candidates, the Group will require regulatory approvals from regulatory agencies, which may be delayed or denied if Valneva cannot establish the safety and efficacy of its product candidates, primarily through clinical trial data. Failure to demonstrate efficacy or safety in clinical trials, delays or failures in development (including clinical trials) or regulatory filings, changes in regulatory requirements, or other adverse events may force the Group to stop development of its product candidates, prevent or delay regulatory approval of its product candidates, or impact its existing products, any of which could materially harm the Group's business. In particular, the Phase 3 clinical trial of VLA15, Valneva's Lyme disease vaccine candidate, is currently ongoing, and the success of the trial will depend in part on obtaining the case count necessary to demonstrate effectiveness of VLA15 as well as the ability to manage, fund and receive regulatory approval for any further adjustments to the clinical trial that may be required, such as recruiting additional patients or extending the timeline.

Risk relating to Pfizer partnership. The Company's strategic partnership with Pfizer to develop and commercialize Valneva's Lyme disease vaccine candidate is of critical importance to the Company. If this partnership fails or is terminated for any reason, the Company may be unable to find another partner. In such a case, Valneva would not have sufficient financial resources to complete Phase 3 development of the Lyme disease vaccine candidate alone.

Listed company requirements. As a company listed in France and the United States, Valneva must comply with regulations applicable to listed companies in these jurisdictions, notably including the EU Corporate Sustainability Reporting Directive ("CSRD"), which imposes significant new reporting obligations for Valneva beginning in 2025, and the Sarbanes-Oxley Act ("SOX") on financial record-keeping and reporting. Compliance with existing and anticipated disclosure and other requirements is complex, requires significant time and expense, and may divert the attention of management from other matters, which could negatively impact the Group's business. The Group will be particularly focused on its compliance efforts for SOX and CSRD during the second half of 2023. Additionally, there is a higher risk of shareholder litigation associated with companies listed in the U.S. Such litigation could also divert time, attention, and resources away from the Group's business. Failing to comply with applicable U.S. regulations or involvement in lawsuits with U.S. investors could have significant consequences for Valneva and could materially impact the Group's business and results of operations.

Cybersecurity risks. The internal computer and information technology systems of Valneva and its collaborators, service providers and other contractors or consultants are potentially vulnerable to cyber-based attacks and data security breaches that may result in damage to or the interruption or impairment of key business processes, or the loss, exposure or corruption of confidential information, including intellectual property, proprietary business information and personal information, and other similar threats. Valneva has in the past experienced and may in the future experience security breaches of its information technology systems and phishing attacks, and it may be a target of such attacks in the future.

Litigation. Risks associated with litigation are set out in Note 5.17 to the H1 financial statements (Section III of this report).

6 Related Parties' Transactions

In the first six months of 2023, there was no transaction or change in transactions between related parties which materially affected Valneva's financial position or performance. In the first six months of 2022, Valneva transferred certain assets (patent and cell lines) to Vital Meat SAS (part of Groupe Grimaud La Corbière) for a consideration of €1.0 million.

II. UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS AT JUNE 30, 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)	Note	Six months ended June 30, 2023	2022
Product sales	5.3	69,665	33,335
Other revenues	5.3	4,078	59,889
REVENUES		**73,743**	**93,224**
Cost of goods and services	5.4	(53,838)	(171,479)
Research and development expenses	5.4	(25,978)	(51,883)
Marketing and distribution expenses	5.4	(20,009)	(7,837)
General and administrative expenses	5.4	(22,899)	(16,031)
Other income and expenses, net	5.5	14,015	3,597
OPERATING LOSS		**(34,966)**	**(150,410)**
Finance income	5.6	504	35
Finance expenses	5.6	(8,879)	(8,199)
Foreign exchange gain/(loss), net	5.6	4,517	(10,657)
Result from investments in associates		—	9
LOSS BEFORE INCOME TAX		**(38,824)**	**(169,222)**
Income tax benefit/(expense)		3,778	(2,271)
LOSS FOR THE PERIOD		**(35,046)**	**(171,493)**
Losses per share for loss for the period attributable to the equity holders of the Company (expressed in € per share)			
Basic		**(0.25)**	**(1.58)**
Diluted		**(0.25)**	**(1.58)**

The accompanying Notes form an integral part of these financial statements.

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

in € thousand	Note	Six months ended June 30, 2023	2022
Loss for the period		**(35,046)**	**(171,493)**
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences		2,735	(567)
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)		(8)	168
Other comprehensive income/(loss) for the year, net of tax		**2,727**	**(399)**
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		**(32,318)**	**(171,892)**

The accompanying Notes form an integral part of these financial statements.

2 Unaudited Interim Condensed Consolidated Balance Sheets

in € thousand	Note	June 30, 2023	December 31, 2022
ASSETS			
Non-current assets		**201,091**	**196,685**
Intangible assets		27,125	28,711
Right of use assets		42,595	41,603
Property, plant and equipment		113,505	112,435
Deferred tax assets		9,934	5,637
Other non-current assets	5.9	7,933	8,299
Current assets		**341,480**	**424,660**
Inventories		33,353	35,104
Trade receivables	5.8	33,669	23,912
Other current assets	5.9	65,082	74,079
Cash and cash equivalents		204,411	289,430
Assets classified as held for sale	5.10	4,966	2,134
TOTAL ASSETS		**542,571**	**621,344**
EQUITY			
Share capital		20,834	20,755
Share premium		593,960	594,043
Other reserves		61,211	55,252
Retained earnings/(Accumulated deficit)		(450,253)	(306,974)
Loss for the period		(35,046)	(143,279)
TOTAL EQUITY		**190,707**	**219,797**
LIABILITIES			
Non-current liabilities		**110,821**	**124,156**
Borrowings		74,216	87,227
Lease liabilities		27,882	28,163
Refund liabilities	5.13	6,211	6,635
Provisions	5.14	1,442	1,320
Deferred tax liabilities		971	694
Other liabilities	5.15	98	116
Current liabilities		**241,043**	**277,392**
Borrowings		21,195	11,580
Trade payables and accruals	5.11	69,152	41,491
Income tax liability		503	532
Tax and Employee-related liabilities		16,508	15,738
Lease liabilities		25,939	25,411
Contract liabilities	5.12	11,580	9,411
Refund liabilities	5.13	82,017	136,450
Provisions	5.14	12,650	31,257
Other liabilities	5.15	75	5,523
Liabilities classified as held for sale	5.10	1,423	—
TOTAL LIABILITIES		**351,865**	**401,547**
TOTAL EQUITY AND LIABILITIES		**542,571**	**621,344**

The accompanying Notes form an integral part of these financial statements.

3 Unaudited Interim Condensed Consolidated Statements of Cash Flows

in € thousand	Note	Six months ended June 30, 2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss for the year		(35,046)	(171,493)
Adjustments for non-cash transactions	5.16	12,764	5,673
Changes in non-current operating assets and liabilities	5.16	279	(92,844)
Changes in working capital	5.16	(42,787)	159,254
Cash used in operations	5.16	**(64,789)**	**(99,410)**
Income tax paid		(643)	(818)
NET CASH GENERATED FROM/(USED IN) OPERATING ACTIVITIES		**(65,432)**	**(100,228)**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(7,164)	(15,952)
Proceeds from sale of property, plant and equipment	5.16	42	—
Purchases of intangible assets		(12)	(76)
Interest received	5.6	504	35
NET CASH GENERATED FROM/(USED IN) INVESTING ACTIVITIES		**(6,631)**	**(15,994)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions		(285)	94,308
Proceeds from borrowings, net of transaction costs		—	18,074
Repayment of borrowings		(2,097)	(1,793)
Payment of lease liabilities		(1,740)	(1,529)
Interest paid	5.6	(5,353)	(4,054)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES		**(9,476)**	**105,006**
NET CHANGE IN CASH AND CASH EQUIVALENTS		**(81,539)**	**(11,216)**
Cash and cash equivalents at beginning of the year[1]		286,532	346,642
Exchange gains/(losses) on cash	5.6	(582)	751
Restricted cash		—	48
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD		**204,411**	**336,225**

[1] Cash and cash equivalents as at December 31, 2022 amounted to €289.4 million (of which restricted cash: of €2.9 million).

The accompanying Notes form an integral part of these financial statements.

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/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2022	**105,239,085**	**15,786**	**409,258**	**52,512**	**(233,549)**	**(73,425)**	**170,581**
Total comprehensive income/(loss)	—	—	—	(399)	—	(171,493)	(171,892)
Income appropriation	—	—	—	—	(73,425)	73,425	—
Share-based compensation expense:							
Value of services	—	—	—	369	—	—	369
Exercises	2,563,011	384	3,333	—	—	—	3,718
Capital Increase	9,549,761	1,432	89,047	—	—	—	90,479
Treasury shares	—	—	—	—	—	—	—
BALANCE AS AT JUNE 30, 2022	**117,351,857**	**17,603**	**501,638**	**52,482**	**(306,974)**	**(171,493)**	**93,255**
BALANCE AS AT JANUARY 1, 2023	**138,367,482**	**20,755**	**594,043**	**55,252**	**(306,974)**	**(143,279)**	**219,797**
Total comprehensive income/(loss)	—	—	—	2,727	—	(35,046)	(32,318)
Income appropriation	—	—	—	—	(143,279)	143,279	—
Share-based compensation expense:							
Value of services	—	—	—	3,232	—	—	3,232
Exercises	529,118	79	(82)	—	—	—	(3)
Treasury shares	—	—	—	—	—	—	—
BALANCE AS AT JUNE 30, 2023	**138,896,600**	**20,834**	**593,960**	**61,211**	**(450,253)**	**(35,046)**	**190,707**

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

The accompanying Notes form an integral part of these financial statements.

5 Selected Notes to the Condensed Consolidated Financial Statements

Valneva SE ("the Company") is domiciled in Saint-Herblain, France. The unaudited interim condensed consolidated financial statements as at and for the six months ended June 30, 2023 comprise the Company together with its subsidiaries (the "Group" or "Valneva"). The Group is focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical needs.

5.1 Basis of preparation

The unaudited interim condensed consolidated financial statements as at June 30, 2023 and for the six months ended June 30, 2023 and June 30, 2022, have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union (EU) and issued by the IASB authorizing the presentation of selected explanatory notes. In consequence, these consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2022.

The unaudited interim condensed consolidated financial statements of the Company were approved by the Supervisory Board on September 20, 2023.

The accounting policies adopted in the preparation of the unaudited interim consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2022.

Although it is difficult to predict future liquidity requirements, the Group considers that the existing cash and cash equivalents as at June 30, 2023 will be sufficient to fund the operations for at least the 12 months from the date of authorization for issuance of these consolidated financial statements.

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

In general, revenues have fluctuated in the past and the Company expects that they will continue to do so over different reporting periods in the future.

Standards, amendments to existing standards and interpretations issued by IASB and adopted by the European Union whose application has been mandatory since January 1, 2023

A few amended standards became applicable for the current reporting period:

- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to IAS 12
- IFRS 17 Insurance Contracts
- Disclosure of Accounting Policies – Amendments to IAS 1 and IFRS Practice Statement 2
- Definition of Accounting Estimates – Amendments to IAS 8

The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these standards.

Standards, amendments to existing standards and interpretations whose application is not yet mandatory

No standards or interpretations were early adopted unless their application is mandatory in 2023. These standards and amendments are not expected to have a material impact on the entity in the current reporting periods and on foreseeable future transactions.

Group Structure

There have been no changes to the group structure as of June 30, 2023.

Significant events of the period and significant agreements

Divestment of CTM Unit in Solna, Sweden

Valneva decided to divest its Clinical Trial Manufacturing (CTM) unit in Solna. The Company completed a business transfer agreement with NorthX Biologics, an established contract development and manufacturing organization (CDMO), with over 30 years of Good Manufacturing Practices (GMP) production experience. Their ownership of the unit took effect on July 1, 2023. The deal comprised Valneva's CTM production equipment and approximately 30 staff members in Sweden, including current Valneva Sweden Site Head. The business will continue utilizing the existing premises in Solna. Valneva Sweden will sub-lease the premises to NorthX Biologics and provide services in Facility Management, Engineering and Warehousing. The CTM unit is presented as of June 30, 2023 as a disposal group held for sale (see Note 5.10).

Key sources of estimation uncertainty

No additional key sources of estimation uncertainty that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year have been added to those reported as of December 31, 2022.

5.2 Segment information

The Company's Management Board, as its chief operating decision maker ("CDM"), considers Valneva's operating business in its entirety to allocate resources and assess performance. The CDM evaluates all vaccine candidates and vaccine products together as a single operating segment "development and commercialization of prophylactic vaccines". Therefore, the split used to allocate resources and assess performance is based on a functional view, thus correlating to the income statement format.

As a consequence, the Group has changed its internal reporting process as at January 1, 2023 to present a single operating segment instead of the previously disclosed product-based segments.

Segment reporting information for earlier periods has been restated to conform to these changes.

5.3 Revenues

Revenues include both revenues from contracts with customers and other revenues (mainly subleases), which are out of scope from IFRS 15:

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Product sales	69,665	33,335
Revenues from contracts with customers	3,710	59,524
Other non-IFRS 15 revenue	368	365
REVENUES	**73,743**	**93,224**

The product sales increased in the six months ended June 30, 2023 by €36.3 million compared to the same period last year. This is a result of higher demand for IXIARO® following the globally increased travel activities. Further DUKORAL® sales went up substantially after supply shortages in 2022.

In the six months ended June 30, 2023 the other revenues from contracts with customers decreased by €55.8 million. In the comparative period €89.4 million of revenues (COVID VLA2001) were recognized from the re-assessment of the likelihood of the royalty obligation towards the UK Authority following the settlement agreement in connection the the UK Supply Agreement. This was offset by €36.1 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer.

5.3.1 Disaggregated revenue information

The Group's revenues are disaggregated as follows:

Type of goods or service

	Six months ended June 30,	
in € thousand	**2023**	**2022**
IXIARO®	30,288	12,270
DUKORAL®	17,140	5,764
Third party products	16,545	11,503
COVID VLA2001	5,691	3,798
PRODUCT SALES	**69,665**	**33,335**
Chikungunya VLA1553	1,628	956
COVID VLA2001	—	89,383
Lyme VLA15	—	(36,107)
Services related to clinical trial material	1,396	2,447
Others	686	2,844
OTHER REVENUES FROM CONTRACTS WITH CUSTOMERS	**3,710**	**59,524**
Other non-IFRS 15 revenue	368	365
REVENUES	**73,743**	**93,224**

In the six months ended June 30, 2022, Lyme VLA15 revenues include €36.1 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer. Further COVID VLA2001 revenue include

€89.4 million revenues from the re-assessment of the likelihood of the royalty obligation towards the UK Authority following the settlement agreement.

Sales channels for product sales

Products are sold via the following sales channels:

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Direct product sales	50,879	26,526
Indirect product sales (Sales through distributors)	18,786	6,809
TOTAL PRODUCT SALES	**69,665**	**33,335**

Geographical markets

In presenting information on the basis of geographical markets, revenue is based on the final location where Valneva's distribution partner sells the product or where the customer/partner is located.

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Canada	15,374	6,683
Germany	9,977	2,197
United Kingdom	9,536	95,931
United States	8,299	(31,442)
Nordics	6,176	2,535
Other Europe	6,111	3,176
Austria	5,645	6,482
France	2,753	2,338
Rest of World	9,872	5,325
REVENUE TOTAL	**73,743**	**93,224**

Nordics includes Finland, Denmark, Norway and Sweden.

In the six months ended June 30, 2022, revenues from the Unites States include €36.1 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer. Further revenues from the United Kingdom in the first six months of 2022 includes non-product revenue of €89.4 million revenues from the re-assessment of the likelihood of the royalty obligation towards the UK Authority following the COVID VLA2001 settlement agreement.

5.4 Expenses by nature

The consolidated income statement line items cost of goods and services, research and development expenses, marketing and distribution expenses and general and administrative expenses include the following items by nature of cost:

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Consulting and other purchased services	35,442	87,171
Cost of services and change in inventory	7,843	102,476
Employee benefit expense other than share-based compensation	39,028	23,089
Share-based compensation expense	3,028	(5,480)
Raw materials and consumables used	8,611	5,536
Depreciation and amortization and impairment	6,669	14,440
Building and energy costs	6,210	7,050
Supply, office and IT costs	4,892	6,134
License fees and royalties	1,971	1,650
Advertising costs	4,159	2,740
Warehousing and distribution costs	1,826	686
Travel and transportation costs	1,128	849
Other expenses	1,915	889
OPERATING EXPENSES	**122,723**	**247,230**

The decrease in operating expenses of €124.5 million in the six months ended June 30, 2023 compared to June 30, 2022 primarily resulted from cost of services and change in inventory. In the six months ended June 30, 2022, cost of services and change in inventory included effects from the significant changes to the ordered volumes and the expected future

demand for COVID VLA2001, in particular a write-down of inventory of €83.5 million as well as a €26.9 million provision related to expected settlement costs in connection with judicial or contractual claims and €14.1 million of write-downs of advanced payments.

The position depreciation and amortization and impairment contains a reversal of a fixed asset impairment in the amount of €1.9 million related to the COVID production equipment.

Further consulting and other purchased services reduced substantially as in the comparison period of 2022 considerable expenses for COVID VLA2001 related to research and development and external manufacturing costs had been booked.

The employee benefit expenses and cash-settled share-based compensation expense from the six months ended June 30, 2022 have been positively impacted by non-cash income from the revaluation of share-based compensation programs resulting from a reduction of Valneva's share price between December 31, 2021 and June 30, 2022.

5.5 Other income/(expenses), net

Other income and expenses, net include the following:

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Research and development tax credit	4,955	6,770
Grant income	9,946	89
Profit/(loss) on disposal of fixed assets and intangible assets, net	(73)	(46)
Profit/(loss) from revaluation of lease agreements	64	—
Taxes, duties, fees, charges, other than income tax	(353)	(227)
Miscellaneous income/(expenses), net	(525)	(2,989)
OTHER INCOME AND EXPENSES, NET	**14,015**	**3,597**

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and the Group will comply with all conditions. In the six months ended June 30, 2023, the Group recorded income from grants and tax credits for research and development totaling €14.9 million, of which €8.7 million were awarded by Scottish Enterprise (SE), Scotland's national economic development agency for developing non-COVID-19 vaccines (Chikungunya VLA1553 and IXIARO®). A loss of €1.4 million from the divestment of the CTM Unit in Solna is included in the Miscellaneous income/(expenses), net.

In the six months ended June 30, 2022 the position miscellaneous income/expenses was negatively impacted by an increase of litigation provision of €3.1 million.

5.6 Finance income/(expenses), net

Interest income is recognized on a time-proportion basis using the effective interest method.

	Six months ended June 30,	
in € thousand	**2023**	**2022**
Interest income from other parties	504	35
TOTAL FINANCE INCOME	**504**	**35**
Interest expense on loans	(5,623)	(2,695)
Interest expense on refund liabilities	(2,615)	(4,812)
Interest expenses on lease liabilities	(619)	(457)
Other interest expense	(22)	(235)
TOTAL FINANCE EXPENSES	**(8,879)**	**(8,199)**
FOREIGN EXCHANGE GAIN/(LOSSES), NET	**4,517**	**(10,657)**
FINANCE INCOME/(EXPENSES), NET	**(3,858)**	**(18,821)**

The foreign exchange gain/(losses), net are primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions, especially caused by USD denominated liabilities.

5.7 Impairment testing

At the end of each reporting period Valneva assesses whether there is any indication that an asset may be impaired. Indicators for the necessity of an impairment test are, among others, actual or expected declines in sales or margins and significant changes in the economic environment with an adverse effect on Valneva's business. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). The cash-generating units (CGU's) correspond with the specific vaccine products and vaccine candidates. Non-financial assets, other than goodwill, that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

As at June 30, 2023, a triggering event was identified resulting from a significant change in the utilization of the manufacturing capacity installed for DUKORAL® driven by increased market demand. An impairment test for the DUKORAL® CGU was performed as at June 30, 2023. Impairment testing performed in December 2022 for DUKORAL® resulted in a carrying value exceeding the value in use by €8.3 million. An impairment charge for the same amount was posted in December 2022 and resulted in an impairment loss amounting to €2.5 million for leasehold improvements, €2.7 million for manufacturing equipment and €3.2 million for right of use assets.

The impairment test performed by June 30, 2023 was conducted by calculating the value in use for 3 different sales scenarios, which were then weighted to calculate an average value in use for the CGU. The discount rate of 9.0% for DUKORAL® was based on the following factors: 2.3% risk-free rate, 7.6% market risk premium, minus 0.7% country risk premium, 0.1% currency risk, levered beta of 1.30 and peer group related equity-capital ratio. The results of the impairment test performed as at June 30, 2023 are not materially different from the position as at December 31, 2022. No adjustments were made to the previously recorded impairment of €8.3 million.

Sensitivity to changes in assumptions

The net present value calculations are most sensitive to the following assumptions:

- discount rate
- reduction of expected revenues

The net present value calculation as at June 30, 2023 uses a discount rate of 9.0% (December 31, 2022: 8.3%) for DUKORAL®. The recoverable amounts of the CGU would equal its carrying amount if the key assumptions were to change as follows: increase in the discount rate by 100 basis points from 9.0% to 10.0% would trigger an additional impairment loss for DUKORAL® of €4.2 million (December 31, 2022: €5.1 million).

The net present value calculations are based upon assumptions regarding market size, expected sales volumes resulting in sales value expectations, expected royalty income or expected milestone payments. A reduction in DUKORAL® revenues of 10% would result in an additional impairment loss of €7.9 million (December 31, 2022: €4.0 million).

As at December 31, 2022 impairment charges amounted to €23.1 million, of which €8.3 million related to DUKORAL® assets (of which €3.2 million right of use assets, €2.5 million of leasehold improvements and €2.7 million of manufacturing equipment), further €14.8 million related to COVID assets (of which €1.0 million right of use assets, €1.9 million leasehold improvements and €11.9 million manufacturing equipment).

5.8 Trade receivables

Trade receivables and other assets are initially recognized at fair value.

The carrying amount of trade receivables is reduced through an allowance for doubtful account. When a trade receivable is considered uncollectible, it is written off against this allowance account. Subsequent recoveries of amounts previously written off are credited against the allowance account. Changes in the carrying amount of the allowance account are recognized in the profit or loss.

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise when the Group provides money, goods, or services directly to a debtor with no intention of trading the receivable.

They are included in current assets, except those with maturities beyond 12 months after the balance sheet date. These are classified as non-current assets. Loans and receivables are classified as “trade receivables and other assets” in the balance sheet.

Trade receivables include the following:

in € thousand	June 30, 2023	December 31, 2022
Trade receivables	33,795	23,997
Less: loss allowance of receivables	(127)	(84)
TRADE RECEIVABLES, NET	**33,669**	**23,912**

In 2023 and 2022, no material impairment losses were recognized. As at June 30, 2023, the amount of trade receivables past due amounted to €4.8 million (December 31, 2022: €4.4 million) of which €3.4 million come from a governmental authority with a credit rating of B+.

Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

As at June 30, 2023, trade receivables included €33.7 million (December 31, 2022: €23.9 million) of receivables from contracts with customers.

5.9 Other assets

Other assets include the following:

in € thousand	June 30, 2023	December 31, 2022
R&D tax credit receivables	42,183	49,174
Advance payments	1,452	1,672
Tax receivables	2,915	9,066
Prepaid expenses	3,463	4,939
Contract costs	3,710	3,710
Consumables and supplies on stock	81	1,380
Miscellaneous current assets	7,032	451
OTHER NON-FINANCIAL ASSETS	**60,836**	**70,391**
Deposits	12,009	11,822
Miscellaneous financial assets	170	165
OTHER FINANCIAL ASSETS	**12,179**	**11,988**
OTHER ASSETS	**73,015**	**82,378**
Less non-current portion	7,933	8,299
CURRENT PORTION	**65,082**	**74,079**

Due to the short term nature of the financial instruments included in other assets, their carrying amount is considered to be the same as their fair value.

The decrease in R&D tax credit receivables is mainly related to the received research and development tax credit primarily in connection with the COVID-19, chikungunya and Lyme vaccine candidates. The reduction in tax receivables goes back to receipt of VAT claims. The increase in the miscellaneous current assets is mainly related to the deferred income from a partnering agreement with the Coalition for Epidemic Preparedness Innovations (CEPI) and with Scottish Enterprise. The deposits mainly relate to a deposit associated with a lease agreement.

5.10 Assets classified as held for sale

	Assets held for sale		Liabilities held for sale	
in € thousand	**June 30, 2023**	**December 31, 2022**	**June 30, 2023**	**December 31, 2022**
BliNK Biomedical SAS	2,134	2,134	—	—
CTM Unit Solna	2,832	—	1,423	—
TOTAL	**4,966**	**2,134**	**1,423**	**—**

BliNK Biomedical SAS

As at June 30, 2023, Valneva held a 48.9% equity interest in BliNK Biomedical SAS, Marseille (BliNK), a private company not listed on a stock exchange. BliNK is run as an independent business by its own management team. Valneva does not have control or joint-control over BliNK.

Management's intent to sell the equity interest triggered the change in the classification by June 30, 2022. The BliNK equity interest continues to be classified as an asset held for sale in accordance with IFRS 5. The sale transaction was closed in the third quarter 2023 (see Note 5.19).

The book value of the investment amounted to €2.1 million as at June 30, 2023. There was no impact on the consolidated statement of income (loss) for the six months ended June 30, 2023.

Divestment of CTM Unit in Solna, Sweden

Valneva decided to divest its Clinical Trial Manufacturing (CTM) unit in Solna; see respective explanation in Note 5.1. The transfer of ownership of the unit took effect on July 1, 2023.

The CTM unit is presented as of June 30, 2023 as a disposal group held for sale. The carrying amount of this disposal group amounts to €2.8 million whereas the transaction price less cost to sell amounts to €1.4 million. A loss of

€1.4 million writing down the carrying amount of the disposal group to its fair value less cost to sell has been included in "other expenses" in the condensed consolidated statement of profit or loss and OCI.

in € thousand	June 30, 2023
Property, plant and equipment	3,628
Inventories	386
Trade and other receivables	181
TOTAL ASSETS	**4,194**
Contract liabilities	(1,020)
Tax and Employee-related liabilities	(404)
CARRYING AMOUNT OF THE DISPOSAL GROUP	**2,771**
Disposal Loss	(1,362)
FAIR VALUE LESS COST TO SELL	**1,408**

5.11 Trade payables and accruals

Trade payables and accruals include the following:

in € thousand	June 30, 2023	December 31, 2022
Trade payables	44,136	14,505
Accrued expenses	25,016	26,986
TOTAL	**69,152**	**41,491**
Less non-current portion	—	—
CURRENT PORTION	**69,152**	**41,491**

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

The increase in trade payables stems from a liability in connection with the Collaboration and License Agreement with Pfizer.

5.12 Contract liabilities

A contract liability has to be recognized, when the customer already provided the consideration or part of the consideration, before an entity has fulfilled its performance obligation (agreed goods or services which should be delivered or provided), resulting from the “contract”.

Development of contract liabilities is presented in the table below:

in € thousand	June 30, 2023	December 31, 2022
BALANCE AS AT JANUARY 1	**9,411**	**128,758**
Revenue recognition	(2,779)	(130,678)
Addition	6,074	10,833
Other releases	(1,032)	—
Exchange rate differences	(94)	498
BALANCE AS AT CLOSING DATE	**11,580**	**9,411**
Less non-current portion	—	—
CURRENT PORTION	**11,580**	**9,411**

In the six months ended June 30, 2023, revenue recognition in the amount of €2.3 million came from the Advanced Purchase Agreement (APA) with the Kingdom of Bahrain. An addition of €4.8 million derived from the Collaboration and License Agreement with Pfizer. The other releases affect a reclassification of contract liabilities to liabilities held for sale in the amount of €1.0 million.

In 2022, revenue recognized in the amount of €116.8 million related to the APA with the European Commission, €2.3 million related to the APA with the Kingdom of Bahrain, €2.0 million related to the agreement with Instituto Butantan and €5.9 million related to the Collaboration and License Agreement with Pfizer. Additions (amounts received for future performance obligations) in 2022 amounting to €4.2 million related to the Collaboration and License Agreement with Pfizer, €2.0 million related to Instituto Butantan, and €3.8 million related to the APA with the Kingdom of Bahrain.

5.13 Refund liabilities

A refund liability has to be recognized when the customer already provided a consideration which is expected to be refunded partially or totally. It is measured at the amount the Company has an obligation to repay or amounts which did not meet the criteria for revenue recognition in the past, but there are no remaining goods and services to be provided in future. Development of refund liabilities:

in € thousand	June 30, 2023	December 31, 2022
BALANCE AS AT JANUARY 1	**143,085**	**254,582**
Additions	612	52,012
Payments	(54,755)	(2,626)
Other releases	—	(879)
Revenue recognition	(78)	(169,242)
Interest expense capitalized	3,134	9,597
Exchange rate difference	(3,770)	(357)
BALANCE AS AT CLOSING DATE	**88,229**	**143,085**
Less non-current portion	(6,211)	(6,635)
CURRENT PORTION	**82,017**	**136,450**

As at June 30, 2023, from the total of €88.2 million, an amount of €80.9 million is connected to the Collaboration and License Agreement with Pfizer whereas €6.5 million relates to the expected payment to GlaxoSmithKline (GSK) related to the termination of the strategic alliance agreements (SAA) in 2019. The payments in the six months ended June 30, 2023 relate largely to scheduled payments in connection with the above-mentioned Pfizer agreement.

As at December 31, 2022, €135.5 million (of which €135.5 million is current) stems from the collaboration with Pfizer and €6.6 million (of which €6.6 million is non-current) related to the expected payment to GSK from the termination of the SAA in 2019. Revenue recognized in 2022 related primarily to the de-recognition of the previously included royalty obligation towards the UK Authority in the amount of €89.2 million and the de-recognition of the previously included CAPEX obligation towards the UK Authority in the amount of €80.0 million. Additions included the milestone of $25 million (€24.5 million) related to the Collaboration and License Agreement with Pfizer as well as other payments received where Valneva has a repayment obligation.

5.14 Provisions

5.14.1 Provisions for employee commitments

in € thousand	June 30, 2023	December 31, 2022
Employer contribution costs on share-based compensation plans	2,857	3,330
Phantom shares	1,936	2,976
Retirement termination benefits	380	330
Leaving indemnities	54	267
TOTAL	**5,227**	**6,903**
Less non-current portion	511	360
CURRENT PORTION	**4,717**	**6,543**

Share-based provisions

Employer contribution costs on share-based compensation plans and phantom shares are calculated at the balance sheet date using the share price of Valneva as at June 30, 2023: €6.68 (December 31, 2022: €6.22).

5.14.2 Other provisions

in € thousand	June 30, 2023	December 31, 2022
Non-current	932	960
Current	7,933	24,714
PROVISIONS	**8,865**	**25,674**

As at June 30, 2023, €1.8 million of the provision related mainly to onerous purchase agreements related to the wind-down of COVID activities (December 31, 2022 : €18.8 million). The position also comprises €5.2 million from a provision for expected legal and settlement costs under a court proceeding related to the Intercell AG/Vivalis SA merger (December 31, 2022 : €5.2 million).

5.15 Other liabilities

in € thousand	June 30, 2023	December 31, 2022
Deferred income	94	5,519
Other financial liabilities	7	32
Miscellaneous liabilities	71	88
OTHER LIABILITIES	**172**	**5,639**
Less non-current portion	(98)	(116)
CURRENT PORTION	**75**	**5,523**

As at December 31, 2022 deferred income mainly included conditional advances from government enterprise grants in Scotland.

5.16 Cash flow information

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

	Six months ended June 30,	
in € thousand	**2023**	**2022**
LOSS FOR THE YEAR	**(35,046)**	**(171,493)**
Adjustments for:		
Depreciation and amortization	8,557	11,153
Write-off / impairment fixed assets/intangibles	(1,888)	3,286
Share-based compensation expense	2,192	(8,921)
Income tax expense/(income)	(3,778)	2,271
(Profit)/loss from disposal of property, plant, equipment and intangible assets	41	46
Share of (profit)/loss from associates	—	(9)
Provision for employer contribution costs on share-based compensation plans [1]	(440)	(19,290)
Other non-cash (income)/expense	(294)	8,972
Interest income	(504)	(35)
Interest expense	8,879	8,199
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and consolidation):		
Other non-current assets	365	1,335
Long term refund liabilities [2]	(16)	(94,780)
Other non-current liabilities and provisions	(70)	601
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
Inventory	1,724	26,041
Trade and other receivables	2,872	44,960
Contract liabilities	2,346	(4,304)
Refund liabilities	(57,448)	44,654
Trade and other payables and provisions	7,720	47,904
CASH USED IN OPERATIONS	**(64,789)**	**(99,410)**

1 In the six months ended June 30, 2022, the position “employee benefit other than share-based compensation” includes an income of €19.5 million, which resulted from release of the employer contribution provision, which was accounted for as of December 31, 2021 for the payable at the exercise of the IFRS 2 programs.

2 As at June 30, 2022, the terms of the royalty obligation towards the UK Authority were redefined under the 2022 settlement agreement. Management assessed the likelihood for this future obligation as remote. This resulted in a value of € nil, which led to a reduction of refund liabilities and recognition of other revenues recognized of €89.4 million.

5.17 Contingencies and litigations

Following the merger between the companies Vivalis SA and Intercell AG in 2013, certain former Intercell shareholders initiated legal proceedings before the Commercial Court of Vienna to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used in the merger. In October 2021, a court-appointed expert recommended an increase in the cash compensation as well as further valuation work on the exchange ratio. In April 2022, this expert presented the result of its work on the exchange ratio; in April 2023 the courts expert committee has provided their view; however, the final outcome will depend on the court’s position on a couple of legal points. The Company therefore assessed the probability of several scenarios and decided to hold a provision of €5.2 million to cover the reassessed risk and potential legal costs (December 31, 2022: €5.2 million).

In July 2016, a claim for additional payment was raised and litigation was filed in December 2016, in connection with the 2009 acquisition of Humalys SAS, from which the Company had acquired a technology, which was later combined with other antibody discovery technologies and spun off to BliNK Biomedical SAS in early 2015. Former shareholders of Humalys claimed additional consideration as a result of the spin-off transaction. A first instance decision in the Humalys case was rendered on September 6, 2023. The court has rejected the plaintiff's claims. An appeal is possible. Detailed information on the potential specific financial consequences, which might result from a successful claim could adversely affect the Company's ability to defend its interests in this case and therefore is not provided, in accordance with IAS 37.92.

5.18 Related-party transactions

In the six months ended June 30, 2023, there have been no changes to related parties.

Rendering of services

Transactions with related parties are carried out on arm's length terms. During the six months ended June 30, 2023, there were no material additional compensations paid to the Supervisory Board members or material services rendered to the related parties Groupe Grimaud La Corbière SAS and Bpifrance.

Services provided by Valneva to Groupe Grimaud La Corbière SAS, a significant shareholder of Valneva, are considered related party transactions and consist of services within a collaboration and research license agreement and of the provision of premises and equipment and sale of patents and cells, according to which Valneva transferred in the six months ended June 30, 2022 certain assets (patent and cell lines) to Vital Meat SAS for a consideration of €1.0 million.

From June 2022 onward, French sovereign fund Bpifrance qualifies as a related party, as Bpifrance is a shareholder of Valneva with significant influence through membership on the Company's Supervisory Board. A financing of receivables from the French Tax Authorities relating to the Research Tax Credit 2021, previously domiciled and assigned to Bpifrance, amounting to 80% of the amount of the assigned receivables, was granted in November 2022 until July 31, 2023. The amount borrowed is €1.4 million.

Key management compensation

In the six months ended June 30,2023, the aggregate compensation of the members of the Company's Management Board amounted to €1.5 million (June 30, 2022: €1.2 million) and represents mostly salaries and other short-term benefits.

5.19 Events after the reporting period

Sale of CTM unit

On July 3, 2023 Valneva sold its multi-purpose clinical trial manufacturing operations and bulk drug manufacturing operations (CTM) in Solna, Sweden for a transaction price less cost to sell of €1.4 million. The assets and liabilities of these operations were disclosed as a disposal group according to IFRS 5 as of June 30, 2023 with a net carrying amount of €1.4 million (see Note 5.10).

Extension of existing loan agreement by $100 million

On August 16, 2023 Valneva entered into an agreement to increase the principal amount of its existing $100 million senior secured debt financing facility with funds managed by leading U.S. healthcare investment firms Deerfield Management Company and OrbiMed. The add-on loan facility has a three-year interest-only period and will mature in the third quarter of 2028. The loan interest rate remains unchanged.

The additional facility provides Valneva with immediate access to $50 million, with an additional $50 million available at the Company's discretion until December 31, 2023. The increased funding will be used to further invest in R&D, as well as continued market access preparations and potential commercialization of Valneva's chikungunya vaccine candidate.

BliNK equity interest

On September 8, 2023, the Company sold its 48% equity interest in BliNK Biomedical SAS, Marseille. which has been classified as a held for sale asset as at June 30, 2023 (please refer to the Note 5.10).

III. RESPONSIBILITY STATEMENT

We, hereby, declare that, to the best of our knowledge, the condensed consolidated financial statements for the half year ended June 30, 2023 have been prepared in accordance with applicable accounting standards and present a fair view of the assets, financial position and results of the Company and all companies included in the scope of consolidation, and that the management report fairly presents all major events during the first six months of the year, their impact on the accounts and the main transactions between related parties and provides a description of the main risks and uncertainties the company faces in the remaining six months of the year.

Thomas Lingelbach

President and Chief Executive Officer

Franck Grimaud

“Directeur Général” and Chief Business Officer