
**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: August 11, 2022

Commission File Number: **001-40377**

Valneva SE

(Translation of registrant's name into English)

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

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

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

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

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

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

EXPLANATORY NOTE

Half-Year 2022 Financial Statements

Valneva SE (the “Company”) announced financial results for the first half of 2022 on August 11, 2022. The Company’s press release and H1 2022 Half-Year Financial Report are attached hereto as Exhibits 99.1 and 99.2, respectively.

Exhibit

99.1	Press release dated August 11, 2022
99.2	H1 2022 Half-Year Financial Report, January 1 to June 30, 2022
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

Date: August 11, 2022

Valneva SE
(Registrant)
/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 H1 2022 Results and Provides Corporate Updates

Excellent progress on late-stage clinical programs

Lyme Disease Vaccine Candidate VLA15

- Phase 3 study initiated in August 2022¹
- Further positive Phase 2 results reported, including first pediatric data²

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Initiation of rolling submission for Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) imminent
- Final positive pivotal Phase 3 results reported³
- Final positive lot-to-lot consistency Phase 3 results reported⁴

Four marketing authorizations granted for inactivated COVID-19 vaccine

- First Standard Marketing Authorization granted in Europe by the European Medicines Agency (EMA)⁵
- Conditional Marketing Authorization granted in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA)⁶ and Emergency Use Authorizations granted in the Kingdom of Bahrain⁷ and the United Arab Emirates (UAE)⁸

H1 revenue and cash

- Total revenue of €93.2 million in the first half of 2022 compared to €47.5 million in the first half of 2021
 - Includes product sales of €33.3 million (vs €31.8 million in the first half of 2021) with first COVID-19 vaccine sales of €3.8 million
 - €59.9 million of other revenues (vs €15.7 million in the first half of 2021)
- Cash position of €336.2 million as of June 30, 2022
 - Includes €90.5 (\$95) million of proceeds from Pfizer's investment in Valneva via an equity subscription agreement⁹

Updated FY 2022 Financial Guidance

- Valneva expects total revenues to reach €340 million to €360 million in 2022 noting the continued recovery of travel vaccine sales, the revenue recognition linked to the EC and UK supply contracts and the recently revised Advance Purchase Agreement (APA) with the European Commission for the Company's COVID-19 vaccine.

¹ [Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15](#)

² [Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate - Valneva](#)

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

⁴ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁵ [Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001](#)

⁶ [Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine - Valneva](#)

⁷ [Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 - Valneva](#)

⁸ [Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine](#)

⁹ [Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15](#)

August 11, 2022

VALNEVA SE



- Product sales of the Company’s travel vaccine franchise are expected to reach €70 million to €80 million while COVID-19 product sales are expected to reach €30 million to €40 million.
- Other Revenues are expected to reach approximately €240 million and will be mainly COVID-19 related. Other non-COVID-19 related revenues will be negative in 2022 due to the increased refund liability linked to the amendment of the VLA15 collaboration and license agreement with Pfizer. COVID-19 related Other Revenues will have no cash impact in 2022 and relate to revenues recognized in relation to the UK and EC Advance Purchase Agreements.
- Valneva expects R&D expenses of €120 million to €135 million in 2022. The Company will continue investing in progressing its two leading, late-stage investigational vaccines against Lyme disease and chikungunya in the second half of 2022. Valneva will invest in further development of its current or any potential second-generation COVID-19 vaccine only if it receives the necessary funding or commitments to such funding during the third quarter of 2022. The Company also remains committed to further expanding its R&D pipeline, including through the advancement of some of the Company’s pre-clinical candidates towards clinical entry.

Financial Information

(unaudited results, consolidated per IFRS)

€ in million	6 months ending June 30	
	2022	2021
Total revenues	93.2	47.5
Product sales	33.3	31.8
Net loss	(171.5)	(86.4)
Adjusted EBITDA loss	(136.0)	(80.1)
Cash (at end of period)	336.2	346.7

Saint-Herblain (France), August 11, 2022 – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported consolidated financial results for the first half of the year, ended June 30, 2022. 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](#)).

Valneva will provide a live webcast of its half year financial results conference call beginning at 3 p.m. CEST or 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/gpxqaiqr>

Thomas Lingelbach, Valneva’s Chief Executive Officer, commented, “Valneva continued to achieve significant R&D milestones in the first half of the year. Our updated Lyme disease collaboration agreement with Pfizer included a substantial equity investment which we see as a strong sign of confidence and recognition of our vaccine expertise, and the recent Phase 3 initiation brings us a step closer to a potential vaccine solution against Lyme disease. Our chikungunya vaccine program successfully met all Phase 3 clinical endpoints, readying us for BLA submission. Our COVID-19 vaccine became the first to receive full marketing authorization in Europe, and we look forward to delivering the first doses in Europe in the coming weeks. However, given the revised volume of orders from the EU Member States, we are evaluating how to re-shape our operations. Looking at our other commercial products, we are seeing a faster recovery than expected in the travel vaccine market and demand may even exceed our current supply capacity in the later part of the year. I would like to take this opportunity to thank our shareholders, partners and employees for their ongoing support and contribution.”



LYME DISEASE VACCINE CANDIDATE – VLA15

Phase 3 study initiated

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

In August 2022, Valneva and Pfizer announced the initiation of a Phase 3 clinical study, “Vaccine Against Lyme for Outdoor Recreationists (VALOR)” (NCT NCT05477524), to investigate the efficacy, safety and immunogenicity of VLA15 in approximately 6,000 participants five years of age and older in highly endemic regions in the United States and Europe. As per the terms of the collaboration agreement between the two companies, Valneva will receive a \$25 million milestone payment from Pfizer within 60 days following initiation of the Phase 3 study.

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

Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15¹⁰. 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 Agreement¹¹. If approved, Pfizer will commercialize VLA15 and Valneva will be eligible to receive substantial milestone and royalty payments.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553

Initiation of BLA rolling submission with U.S. FDA imminent

VLA1553 is a live-attenuated, single-dose vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available and VLA1553 is currently the only chikungunya vaccine candidate that successfully completed primary analysis in a pivotal Phase 3 study.

Valneva reported final pivotal Phase 3 data in March 2022¹² and final lot-to-lot consistency results in May 2022¹³, enabling BLA submission with the FDA. Valneva expects initiation of the rolling submission for approval of VLA1553 in persons aged 18 years and above imminently. This rolling BLA submission will be part of the accelerated approval pathway agreed upon with the FDA in 2020¹⁴.

¹⁰ [Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15](#)

¹¹ [Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15](#)

¹² [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

¹³ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

¹⁴ [Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study](#)



Valneva is currently targeting the end of 2022 for completion of the BLA submission. Once all portions of the application have been submitted and if the FDA has accepted the filing, the FDA will determine priority review eligibility and the action date upon which the FDA will complete its evaluation. The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted PRiority Medicine (PRIME) designation by the European Medicines Agency (EMA) in 2020, and Valneva currently plans to make regulatory submissions for VLA1553 in Europe in the first half of 2023.

A clinical trial of VLA1553 in adolescents is currently ongoing in Brazil¹⁵, which may support future regulatory submissions and label extensions following a potential initial regulatory approval in adults in the US. Conducted by Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

Pre-Clinical Vaccine Candidates

The Company plans to advance research and development activities relating to two of its pre-clinical assets, VLA1554 and VLA2112. VLA1554 is a vaccine candidate targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection in children and is also a common cause of morbidity and mortality in immunocompromised patients and older adults. VLA1554 is currently in pre-clinical proof of concept studies. VLA2112 is a vaccine candidate targeting the Epstein-Barr virus, which is one of the most common human viruses and can cause infectious mononucleosis and other illnesses. VLA2112 is currently in a late-stage evaluation phase.

Marketed Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO[®]/JESPECT[®])

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

In the first half of 2022, IXIARO[®]/JESPECT[®] sales were €12.3 million compared to €25.4 million in the first half of 2021, as a result of the planned delivery schedule to the U.S. Department of Defense. This decrease was partly offset by the private travel markets, which showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €11.3 million in the first half of 2022 compared to €3.1 million in the first half of 2021.

CHOLERA / ETEC¹⁶-DIARRHEA VACCINE (DUKORAL[®])

DUKORAL[®] is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC¹⁷, 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.

¹⁵ [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

¹⁶ [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.](#)

¹⁷ [Enterotoxigenic Escherichia coli \(ETEC\) is a type of Escherichia coli and one of the leading bacterial causes of diarrhea in the developing world,^{\[1\]} as well as the most common cause of travelers' diarrhea.](#)



In the first half of 2022, DUKORAL[®] sales increased to €5.8 million compared to €0.4 million in the first half of 2021, also benefitting from the significant recovery in the private travel markets.

SARS-CoV-2 INACTIVATED WHOLE-VIRUS VACCINE

Valneva's COVID-19 vaccine is the only inactivated whole-virus COVID-19 vaccine to receive marketing authorization in Europe¹⁸ and the only COVID-19 vaccine to receive a full marketing authorization in Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for the Company's commercial Japanese encephalitis vaccine, IXIARO[®].

During the first half of the year, Valneva's COVID-19 vaccine was also granted conditional marketing authorization in the United Kingdom¹⁹ and emergency use authorization in the United Arab Emirates²⁰ and Kingdom of Bahrain²¹. The vaccine generated sales of €3.8 million during the first six months of 2022.

In July 2022, Valneva announced an amendment to the APA it signed with the EC in November 2021²². The amended APA includes orders of 1.25 million doses of the vaccine, with the option to purchase an equivalent quantity later this year for delivery in 2022. This amendment followed remediation discussions based on the EC's notice of intent²³ to terminate the initial APA for doses in 2022 and optional doses for 2023.

First vaccine doses are currently expected to be delivered to participating EU Member States (Germany, Austria, Denmark, Finland, and Bulgaria) in August 2022. Valneva will retain inventory for potential additional supply to these EU Member States should demand increase and, in parallel, Valneva will continue discussions on potential additional supply and financing agreements with various other governments around the world. Valneva will aim to deploy approximately eight to ten million doses of remaining inventory into international markets. Given that the vaccine's shelf life is expected to be gradually extended from the current 15 months to at least 24 months over time, the Company will seek to deploy its inventory doses in the next six to twelve months.

In light of the reduced order volume from EU Member States, Valneva has suspended manufacturing of the vaccine and recognized write-downs of €100.6 million as of June 30, 2022 relating to existing inventory acquired to produce and supply volumes under the original EC APA. Valneva is also evaluating its COVID-19 program and associated activities and will re-shape its operations accordingly. In addition, Valneva and IDT Biologika (IDT) are discussing potential ways of terminating their drug substance manufacturing agreement in light of the suspended manufacturing of Valneva's COVID-19 vaccine. Valneva will continue certain ongoing clinical trials, in particular on the potential use of the vaccine as a booster. Valneva will invest in further development of the vaccine or second-generation COVID-19 vaccine candidate only if it receives the necessary funding or commitments to such funding during the third quarter of 2022.

¹⁸ [Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001](#)

¹⁹ [Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva](#)

²⁰ [Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine](#)

²¹ [Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva](#)

²² [Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001](#)

²³ [Valneva Receives Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement – Valneva](#)



THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In June 2020, the Company entered into a distribution agreement with Bavarian Nordic, pursuant to which it agreed to commercialize Bavarian Nordic's marketed vaccines for rabies (Rabipur[®]/RabAvert[®]) and tick-borne encephalitis, leveraging its commercial infrastructure in Canada, the United Kingdom, France and Austria.

In the first half of 2022, third party product sales increased by 93.5% to €11.5 million from €5.9 million in the first half of 2021.

First Half 2022 Financial Review²⁴ (Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €93.2 million in the first half of 2022 compared to €47.5 million in the first half of 2021, an increase of 96.3%.

Product sales, including COVID-19 vaccine sales, increased by 5.0% to €33.3 million in the first half of 2022 compared to €31.8 million in the first half of 2021. Foreign currency fluctuations contributed positively to €2.6 million of the change in product sales. Product sales from our commercial products amounted to €29.5 million in the first half of 2022, a decrease of 7.0% compared to the first half of 2021. Product sales related to COVID-19 amounted to €3.8 million.

IXIARO[®]/JESPECT[®] sales decreased by 51.7% to €12.3 million in the first half of 2022 compared to €25.4 million in the first half of 2021, primarily as a result of the planned delivery schedule to the DoD during the period. Foreign currency fluctuations contributed positively to €2.4 million of the change in IXIARO[®] product sales. This was partly offset by the private travel markets, which showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €11.3 million in the first half of 2022 compared to €3.1 million in the first half of 2021. DUKORAL[®] also benefited from this recovery as sales increased significantly to €5.8 million in the first half of 2022 compared to €0.4 million in the first half of 2021. COVID-19 vaccine sales amounted to €3.8 million resulting from shipments of the vaccine to Bahrain. Third Party product sales increased by 93.5% to €11.5 million in the first half of 2022 from €5.9 million in the first half of 2021, driven by growth related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur[®]/RabAvert[®] and Encepur[®].

Other revenues, including revenues from collaborations, licensing and services, amounted to €59.9 million in the first half of 2022 compared to €15.7 million in the first half of 2021. This increase is attributable to €89.4 million released from the refund liability as a result of the settlement with the UK government achieved in the second quarter of 2022, 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 €171.5 million in the first half of 2022. The gross margin on commercial product sales amounted to 58.3% compared to 39.2% in the first half of 2021. COGS of €3.6 million were related to IXIARO[®] product sales, yielding a product gross margin of 70.4%. COGS of €1.3 million were related to DUKORAL[®] product sales, yielding a product gross margin of 77.8%, which was positively impacted by provision releases resulting from reduced expiry risks on inventory. Of the remaining COGS in the first half of 2022, €7.4 million were related to the Third Party products distribution business, €154.9 million to the COVID-19 vaccine business and €4.3 million to cost of services. COGS of the COVID-19 vaccine program included effects from the significant reduction of sales volumes to EC Member States. In the first half of 2021, overall COGS were €34.8 million, of which €23.5 million related to cost of goods and €11.3 million related to cost of services.

²⁴ *Further details about the results presented below are available in the Company's half year report*



Research and development expenses amounted to €51.9 million in the first half of 2022, compared to €78.7 million in the first half of 2021. This decrease was mainly driven by lower clinical trials costs for Valneva's chikungunya and COVID-19 vaccine program as those advanced towards licensure. Marketing and distribution expenses in the first half of 2022 amounted to €7.8 million compared to €9.6 million in the first half of 2021. Marketing and distribution expenses in the first half of 2022 notably included €2.2 million of expenses related to the launch preparation costs for Valneva's chikungunya vaccine candidate, VLA1553, compared to €2.0 million in the first half of 2021. In the first half of 2022, general and administrative expenses declined to €16.0 million from €20.9 million in the first half of 2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a non-cash accrual adjustment to income of €17.8 million related to the positive effect of the Company's share price development on the employee share-based compensation programs. This income compares to a cost of €7.3 million in the first half of 2021.

Other income, net of other expenses, reduced to €3.6 million in the first half of 2022 from €10.4 million in the first half of 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending and an increase of expenses related to the provision for the ongoing merger litigation proceedings.

Valneva recorded an operating loss of €150.4 million in the first half of 2022 compared to €86.2 million in the first half of 2021, of which the COVID-19 operating loss represented €110.7 million and €55.5 million as of June 30, 2022 and 2021 respectively and the other segments represented €39.7 million in the first half of 2022 compared to €30.7 million in the first half of 2021. Adjusted EBITDA (as defined below) loss in the first half of 2022 was €136.0 million compared to an adjusted EBITDA loss of €80.1 million in the first half of 2021.

Net Result

In the first half of 2022, Valneva generated a net loss of €171.5 million compared to a net loss of €86.4 million in the first half of 2021.

Finance expense and currency effects in the first half of 2022 resulted in a net finance expense of €18.8 million, compared to a net finance income of €0.5 million in the first half of 2021. This was mainly a result of a foreign exchange loss amounting to €10.7 million in the first half of 2022, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €8.7 million in the first half of 2021. Interest expenses net of interest income were €8.2 million in the first half of 2022 compared to €8.2 million in the first half of 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €100.2 million in the first half of 2022 compared to €84.2 million of cash generated by operating activities in the first half of 2021. Cash outflows in the first half of 2022 were mainly related to the operating loss generated in the period, while during the first half of 2021 cash inflows mainly resulted from pre-payments received related to the vaccine supply agreement signed with the UK government.



Cash outflows from investing activities amounted to €16.0 million in the first half of 2022 compared to €39.9 million in the first half of 2021, both mainly a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €105.0 million in the first half of 2022, which was mainly a result of proceeds from the equity subscription agreement with Pfizer as well as disbursements from the credit facility provided by Deerfield & Orbimed. Cash inflows in the first half of 2021 amounted to €78.7 million which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement (Global Offering).

Cash and cash equivalents decreased to €336.2 million as of June 30, 2022, compared to €346.7 million as of December 31, 2021. The cash decrease mainly resulted from ongoing COVID-19-related investments into fixed assets and R&D expenses.

Non-IFRS Financial Measures

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

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

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

€ in million (unaudited results, consolidated per IFRS)	6 months ending June 30	
	2022	2021
Loss for the period	(171.5)	(86.4)
Add:		
Income tax expense	2.3	0.7
Total Finance income	(0.0)	(0.2)
Total Finance expense	8.2	8.4
Foreign exchange gain/(loss) – net	10.7	(8.7)
Result from investments in associates	(0.0)	0.1
Amortization	3.5	3.1
Depreciation	7.7	3.0
Impairment	3.3	-
Adjusted EBITDA	(136.0)	(80.1)





About Valneva SE

Valneva is a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19, which was approved by the EMA and MHRA during the second quarter of 2022.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including but not limited to statements regarding expected total revenues and R&D spending for full fiscal year 2022, product sales, possible regulatory approvals of product candidates, the re-shaping of the Company's operations, and initiation of clinical trials. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future results. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.



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AUGUST 11, 2022

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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 Group’s targets and forecasts, especially in chapter 1.4 – “Operational and strategic outlook FY 2022”. 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 Group’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 Group considers to be the most significant for the second half of 2022 and are not all of the risks that the Group faces during this period or beyond. One or more of these risks may have an adverse effect on the Group’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 Group 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 Group’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 and reports filed with the U.S. Securities and Exchange Commission (SEC), including the Company’s 2021 annual report on Form 20-F available on the SEC’s website.

1. MANAGEMENT REPORT

1.1 Overview

Valneva is a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need.

The Company takes a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly or debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases.

Valneva has leveraged its expertise and capabilities to successfully commercialize two wholly owned vaccines and rapidly advance multiple vaccine candidates into late-stage clinical development, including candidates against Lyme disease (partnered with Pfizer), the chikungunya virus, and COVID-19 which was notably approved in Europe and the United Kingdom (UK) during the second quarter of 2022.

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](#).

1.2 Operational Review

1.2.1 Vaccine Research & Development (R&D)

Valneva's portfolio is composed of highly differentiated vaccine candidates designed to prevent infectious diseases with high unmet needs.

The Company has a broad portfolio that consists of late-stage clinical vaccine candidates and commercial products, as well as preclinical assets. Each of the assets in its portfolio are differentiated products or 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 other vaccine solutions or treatment options.

Valneva strives to develop products towards marketing approval and commercialization either through strategic licensing or partnering, as illustrated by its collaboration for its Lyme disease vaccine candidate VLA15 or in-house, leveraging existing industrial and commercial infrastructures.

Lyme Disease Vaccine Candidate – VLA15

Overview of Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks¹. It is considered the most common vector-borne illness in the Northern Hemisphere².

While the true incidence of Lyme disease is unknown, according to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 people are diagnosed with Lyme disease in the United States³ each year with at least a further 200,000 cases occurring annually in Europe⁴. Research suggests that Lyme disease cases may rise 92% by 2100 in the U.S. due to climate change⁵. 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. alone⁶.

¹ Stanek et al. 2012, *The Lancet* 379:461–473

² Gern L, Falco RC. Lyme disease. *Rev Sci Tech*. 2000 Apr;19(1):121-35

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 with it antihistamines, cytokine blockers, anticoagulants and, in the case of an infected tick, *Borrelia* bacteria as well.

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 system⁷. The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens⁸.

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 U.S. Food and Drug Administration (FDA) in July 2017⁹ and, in April 2020, Valneva announced a collaboration with Pfizer for late clinical development and commercialization of VLA15¹⁰. In June 2022, the terms of this collaboration were updated¹¹ and Pfizer invested €90.5 (\$95) million in Valneva as part of an Equity Subscription Agreement. If approved, Pfizer will commercialize VLA15 and Valneva will be eligible to receive substantial milestone and royalty payments¹².

Valneva and Pfizer reported results for three Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which VLA15 generated high levels of antibodies against all six *Borrelia* strains. The two companies announced the initiation of a Phase 3 clinical study, “Vaccine Against Lyme for Outdoor Recreationists (VALOR)” (NCT05477524), in August 2022 to investigate the efficacy, safety and immunogenicity of VLA15¹³ in approximately 6,000 participants five years of age and older in highly endemic regions in the United States and Europe. As per the terms of the collaboration agreement between the two companies, Pfizer will make a \$25 million milestone payment to Valneva within 60 days following initiation of the Phase 3 study.

³ As estimated by the CDC : How many people get Lyme disease? | Lyme Disease | CDC

⁴ As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed: Comparison of Lyme Disease in the United States and Europe - PMC (nih.gov)

⁵ [Lyme disease cases may rise 92 per cent in US due to climate change](#)

⁶ [Lyme Disease Costs Up to \\$1.3 Billion Per Year to Treat, Study Finds](#)

⁷ Sykes RA, et al. An estimate of Lyme borreliosis incidence in Western Europe. *Journal of Public Health* 2017; 39(1): 74-81

⁸ 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.

⁹ [Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15](#)

¹⁰ [Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15](#)

¹¹ [Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15](#)

¹² [Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15](#)

¹³ [Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15](#)

Pending successful Phase 3 completion, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorisation Application (MAA) to the European Medicines Agency by 2025.

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. 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. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat. As of September 2022, there were more than 3 million reported cases in the Americas¹⁴ 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. Current high risk infection areas include the Americas, parts of Africa, and Southeast Asia.

Chikungunya infection is characterized by an acute onset of fever, rash, myalgia and sometimes debilitating arthritic pain in multiple joints. Mortality of chikungunya is low (<1%), but the potentially long-term debilitating impact of its joint pain (arthralgia) and inflammatory symptoms represents a significant disease burden. In addition to having a significant impact on people who become infected, chikungunya is highly transmissible and prior outbreaks have led to significant spread of the virus. No vaccine to prevent chikungunya infection has been approved to date. Preventive measures rely on avoiding mosquito bites as effective mosquito control has proven challenging, even in higher income countries.

VLA1553 Vaccine Candidate

Valneva has developed VLA1553, a live-attenuated single-dose vaccine candidate against the chikungunya virus. It has been designed by deleting specific segments of the virus, thereby weakening, or attenuating, the virus. Attenuation for live virus has been conducted by reverse genetics which leads to a reduced replication capability of the virus in vivo, making a reversion to wild-type impossible. VLA1553 is currently the only chikungunya vaccine candidate that successfully completed primary analysis in a pivotal Phase 3 study. 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 2032¹⁵.

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 VLA1553¹⁶. The collaboration falls within the framework of the agreement signed between the Coalition for Epidemic Preparedness Innovations (CEPI) and Valneva in July 2019¹⁷, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

¹⁴ 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.

¹⁵ VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

¹⁶ [Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries](#)

Valneva reported final pivotal Phase 3 data in March 2022¹⁸ and final lot-to-lot consistency results in May 2022¹⁹, enabling BLA submission with the FDA. Valneva expects initiation of the rolling submission for approval of VLA1553 in persons aged 18 years and above imminently. The rolling BLA submission is part of the accelerated approval pathway agreed upon with the FDA in 2020²⁰.

Valneva is currently targeting the end of 2022 for completion of the BLA submission. Once all portions of the application have been submitted and if the FDA has accepted the filing, the FDA will determine priority review eligibility and the action date upon which the FDA will complete its evaluation. The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted PRiority MEDicine (PRIME) designation by the European Medicines Agency (EMA) in 2020, and Valneva plans to make regulatory submissions for VLA1553 in Europe in the first half of 2023.

A clinical trial of VLA1553 in adolescents is currently ongoing in Brazil²¹, which may support future regulatory submissions and label extensions following a potential initial regulatory approval in adults in the US. Conducted by Instituto Butantan and funded by CEPI, the trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

Pre-clinical Vaccine Candidates

The Company plans to advance research and development activities relating to two of its pre-clinical assets, VLA1554 and VLA2112. VLA1554 is a vaccine candidate targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection in children and is also a common cause of morbidity and mortality in immunocompromised patients and older adults. VLA1554 is currently in pre-clinical proof of concept studies. VLA2112 is a vaccine candidate targeting the Epstein-Barr virus, which is one of the most common human viruses and can cause infectious mononucleosis and other illnesses. VLA2112 is currently in a late-stage evaluation phase.

1.2.2 Marketed products

Valneva commercializes three fully owned vaccines, its travel vaccines IXIARO[®]/JESPECT[®] and DUKORAL[®], and its inactivated COVID-19 vaccine. 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).

Valneva's product sales in the first half of 2022 increased by 5.0% to €33.3 million compared to €31.8 million in the first half of 2021, benefiting from the inclusion of its COVID-19 vaccine sales and a significant recovery in the private travel markets, offset by the planned delivery schedule of IXIARO[®] to the U.S. Government's Department of Defense (DoD) in the second half of 2022.

Japanese encephalitis vaccine (IXIARO[®]/JESPECT[®])

Valneva's Japanese encephalitis vaccine is the only approved vaccine for European and American travelers visiting endemic areas and for U.S. military personnel being deployed to those areas. It is licensed in more than thirty-five countries and marketed under the trade names IXIARO[®] in North America, Europe, Hong Kong, Singapore and Israel, and under the trade name JESPECT[®] in Australia and New Zealand.

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.

¹⁷ [CEPI awards up to \\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine](#)

¹⁸ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

¹⁹ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

²⁰ [Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study](#)

²¹ [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

In March 2020, the FDA approved the extension of IXIARO[®]'s shelf life from 24 months to 36 months²², an important achievement supporting supply management flexibility.

For the past ten years, the Company, together with its marketing and distribution partners, has successfully increased sales penetration until the COVID-19 pandemic significantly impacted sales beginning in 2019 due to the decline in travel.

Valneva distributes IXIARO[®] directly to the DoD. In September 2020, the Defense Logistics Agency (DLA) awarded Valneva a new contract for the supply of IXIARO[®]. The terms of the agreement contemplate an initial base year followed by two option years, each with a range of minimum and maximum potential dose orders. In September 2021, Valneva announced that DLA exercised the first option year of this agreement. Due to the impact of the COVID-19 pandemic on DoD operations, the option terms were amended such that the minimum number of doses for the first option year is now 200,000 with an approximate value of \$28.8 million. This brings the total minimum value of the agreement to approximately \$118 million, assuming the exercise of the second-year option of 250,000 doses, which remains unchanged.

In the first half of 2022, IXIARO[®]/JESPECT[®] sales were €12.3 million compared to €25.4 million in the first half of 2021, as a result of the planned delivery schedule to the DoD. This decrease was partly offset by the private travel markets which showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €11.3 million in the first half of 2022 compared to €3.1 million in the first half of 2021.

Cholera / ETEC²³ vaccine (DUKORAL[®])

Valneva's cholera vaccine DUKORAL[®] is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholera* and/or heat labile toxin producing ETEC, the leading cause of travelers' diarrhea. It is authorized for use in the EU and Australia to protect against cholera, and in Canada, Switzerland, New 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.

DUKORAL[®] was first granted authorization for use in Sweden in 1991. In 2004, DUKORAL[®] was granted a marketing authorization by the European Commission for European Union members (including Norway and Iceland) and was prequalified by the World Health Organization (WHO).

In the first half of 2022, DUKORAL[®] sales increased to €5.8 million compared to €0.4 million in the first half of 2021, also benefiting from the significant recovery in the private travel markets.

SARS-CoV-2 Inactivated Vaccine

Valneva's COVID-19 vaccine is the only inactivated, whole-virus, COVID-19 vaccine to receive marketing authorization in Europe²⁴ and is the first and only COVID-19 vaccine to receive a standard marketing authorization in Europe to date. The vaccine is approved in Europe for use as primary vaccination in people from 18 to 50 years of age. The vaccine was also granted conditional marketing authorization in the United Kingdom²⁵ and emergency use authorization in the United Arab Emirates²⁶ and Kingdom of Bahrain²⁷.

²² [Valneva Announces FDA Approval of IXIARO[®] Shelf Life Extension to 36 Months; New US Military RFP Issued](#)

²³ 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.

In July 2022, Valneva announced that the European Commission (EC) adopted an amendment to the Advance Purchase Agreement (APA) which was originally signed in November 2021²⁸. The EC APA originally included an order of up to 60 million doses in 2022 and 2023, with approximately 24 million doses expected to be delivered in 2022. The amended APA includes orders of 1.25 million doses of the vaccine with the option to purchase an equivalent quantity later this year for delivery in 2022. This amendment followed remediation discussions based on the EC's notice of intent²⁹ to terminate the initial APA for vaccine doses in 2022 and optional doses for 2023.

The first vaccine doses are currently expected to be delivered to participating EU Member States (Germany, Austria, Denmark, Finland, and Bulgaria) in August 2022. Valneva will retain inventory for potential additional supply to these EU Member States should demand increase and, in parallel, Valneva will continue discussions on potential additional supply and financing agreements with various other governments around the world. The Company will aim to deploy approximately eight to ten million doses of remaining inventory into international markets. Given that the vaccine's shelf life is expected to be gradually extended from currently 15 months to at least 24 months over time, the Company will seek to deploy its inventory doses in the next six to twelve months.

In light of the reduced order volume from EU Member States, the Company has suspended manufacturing of its vaccine and, as at June 30, 2022, recognized write-downs of €100.6 million of inventory acquired to produce and supply products under the original EC APA. The Company is evaluating its COVID-19 program and associated operations. In addition, Valneva and IDT Biologika (IDT) are discussing potential ways of terminating their COVID-19 vaccine drug substance manufacturing agreement in light of the suspended manufacturing of the vaccine. The Company will continue certain ongoing clinical trials, in particular on the potential use of its COVID-19 vaccine as a booster. The Company will invest in further development of its current or second-generation COVID-19 vaccine only if it reaches an agreement with potential customers and receives the necessary funding during the third quarter of 2022.

Third-party distribution

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In June 2020, the Company entered into a distribution agreement with Bavarian Nordic, pursuant to which it agreed to commercialize Bavarian Nordic's marketed vaccines for rabies (Rabipur[®]/RabAvert[®]) and tick-borne encephalitis, leveraging its commercial infrastructure in Canada, the United Kingdom, France and Austria.

In the first half of 2022, third party product sales increased by 93.3% to €11.5 million from €5.9 million in the first half of 2021.

²⁴ [*Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*](#)

²⁵ [*Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*](#)

²⁶ [*Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine*](#)

²⁷ [*Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*](#)

²⁸ [*Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001*](#)

²⁹ [*Valneva Receives Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement – Valneva*](#)

1.2.3 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 2020³⁰, to co-develop and commercialize the Company's Lyme vaccine candidate, VLA15. As partial consideration for the license grant under the agreement, 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 their collaboration and license agreement³¹. 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 eligible for up to \$100 million in milestone payments based on cumulative sales. Other development and early commercialization milestones are unchanged, of which \$168 million remain, including a \$25 million payment to Valneva upon Pfizer's initiation of the Phase 3 study.

Valneva also derives revenues from its technologies and services. Services revenues consist of research and development services Valneva provides to third parties, including process and assay development, production and testing of clinical trial material. Revenues from technologies consist of license revenues from its EB66[®] cell line, which is derived from duck embryonic stem cells and provides an alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines, and its IC31[®] vaccine adjuvant, which is a synthetic adjuvant targeting antigens to improve immune response and has been licensed to several pharmaceutical companies.

Other revenues, including revenues from collaborations, licensing and services, amounted to €59.9 million in the first half of 2022 compared to €15.7 million in the first half of 2021. This increase is attributable to €89.4 million released from the refund liability on the COVID-19 program as a result of the settlement with the UK government achieved in the second quarter of 2022, as mentioned further below. Furthermore, other revenues included €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.

1.2.4 Other Business Updates

Valneva Awarded Up to £20 Million by Scottish Enterprise to Advance Vaccine Development

In February 2022, Valneva's subsidiary Valneva Scotland was awarded research and development funding of up to £20 million by Scottish Enterprise. The investment from Scotland's national economic development agency is comprised of two grants, which build upon the agency's longstanding engagement with Valneva and will benefit the Company's manufacturing site in Livingston. The grants are expected to be received over the next three years. The first grant of up to £12.5 million is expected to support research and development related to the manufacture of its inactivated, whole virus COVID-19 vaccine. The second grant of up to £7.5 million is expected to support research and development connected to Valneva's manufacturing processes for other vaccines, including VLA1553, the Company's single-shot vaccine candidate against the chikungunya virus, which is also expected to be manufactured in Livingston.

³⁰ [Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15 – Valneva](#)

³¹ [Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15](#)

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

In April 2022, Valneva announced an agreement to increase the principal amount of its existing \$60 million debt financing agreement with funds managed by leading U.S.-based healthcare investment firms Deerfield Management Company and OrbiMed. This extension provided Valneva immediate access to \$20 million, with an additional \$20 million made available upon approval of its inactivated COVID-19 vaccine by the EMA. The increased funding will be used to further invest in R&D, including market access preparations for Valneva's chikungunya vaccine candidate, VLA1553. The loan interest rate remains unchanged from that disclosed in the Company's annual reports for 2021. The interest-only period has been extended to the third quarter of 2024, and the loan will now mature in the first quarter of 2027.

Settlement Agreement with the UK Government

In June 2022, Valneva entered into a settlement agreement with the Government of the United Kingdom ("HMG")³² in relation to the termination of the supply agreement for Valneva's COVID-19 vaccine. The settlement agreement resolved certain matters relating to Valneva's obligations and HMG following termination and in relation to the separate agreement relating to clinical trials of its COVID-19 vaccine in the United Kingdom, which remains in place.

Renewal of the Term of Office of Valneva's Management Board Members

In March 2022, Valneva's Supervisory Board renewed the term of office of the Company's current Management Board members for an additional three years starting at the end of the Company's June 2022 Annual General Meeting (AGM), when the previous terms were set to expire.

Dr. Thomas Decker and Dr. Michael Pflleiderer appointed to Valneva's Scientific Advisory Board

In May 2022, Valneva announced the appointment of leading vaccine experts Dr. Thomas Decker and Dr. Michael Pflleiderer to its Scientific Advisory Board (SAB). Dr. Thomas Decker is a professor of Immunobiology at the Max Perutz Labs of the University of Vienna with over 30 years of research and teaching in Germany, Sweden, Austria and the U.S., and a focus on the molecular aspects of immunity to infection. Dr. Michael Pflleiderer is an internationally renowned expert in regulatory affairs and development of vaccines who significantly contributed to numerous EMA and WHO guidelines on scientific and regulatory issues related to vaccines.

Bpifrance Participations and Mr. James Connolly appointed to Valneva's Supervisory Board

During its Annual General Meeting in June 2022, Valneva's shareholders appointed two new Supervisory Board members, Bpifrance Participations (Bpifrance) and Mr. James Connolly, for a three-year term. Bpifrance Participations will be represented by Mailys Ferrère, a French national who is Director of Large Venture Investments at Bpifrance, France's state-owned investment bank. Mr. Connolly, an American national, is a seasoned business executive with more than three decades of experience in the life sciences industry, including 24 years at Wyeth (now Pfizer).

Additionally, the term of office of Supervisory Board members Frédéric Grimaud, James Sulat, and Anne-Marie Graffin was renewed until June 2025. In a separate meeting, Frédéric Grimaud was re-elected as Chairman of Valneva's Supervisory Board.

Valneva Joined Euronext's Tech Leaders Index

In June 2022, Valneva announced its inclusion in the Euronext Tech Leaders Index. The Euronext Tech Leaders Index is composed of 100+ European Tech companies, which were identified by Euronext either to be leaders in their field or to have a particularly strong growth profile. It aims to strengthen the European Tech sector and be a catalyst for the next generation of Tech leaders. The initiative is supported by a powerful network of partners including global investment banks as well as French state-owned investment arm Groupe Caisse des Dépôts.

³² [Valneva Announces Settlement Agreement with the UK Government - Valneva](#)

1.3 Financial Review

FIRST HALF 2022 FINANCIAL REVIEW (unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €93.2 million in the first half of 2022 compared to €47.5 million in the first half of 2021, an increase of 96.3%.

Product sales, including COVID-19 vaccine sales, increased by 5.0% to €33.3 million in the first half of 2022 compared to €31.8 million in the first half of 2021. Foreign currency fluctuations contributed positively to €2.6 million of the change in product sales. Product sales from our commercial products amounted to €29.5 million in the first half of 2022, a decrease of 7.0% compared to the first half of 2021. Product sales related to COVID-19 amounted to €3.8 million.

IXIARO[®]/JESPECT[®] sales decreased by 51.7% to €12.3 million in the first half of 2022 compared to €25.4 million in the first half of 2021, primarily as a result of the planned delivery schedule to the DoD during the period. Foreign currency fluctuations contributed positively to €2.4 million of the change in IXIARO[®] product sales. This was partly offset by the private travel markets, which showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €11.3 million in the first half of 2022 compared to €3.1 million in the first half of 2021. DUKORAL[®] also benefited from this recovery as sales increased significantly to €5.8 million in the first half of 2022 compared to €0.4 million in the first half of 2021. COVID-19 vaccine sales amounted to €3.8 million resulting from shipments of the vaccine to Bahrain. Third Party product sales increased by 93.5% to €11.5 million in the first half of 2022 from €5.9 million in the first half of 2021, driven by growth related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur[®]/RabAvert[®] and Encepur[®].

Other revenues, including revenues from collaborations, licensing and services, amounted to €59.9 million in the first half of 2022 compared to €15.7 million in the first half of 2021. This increase is attributable to €89.4 million released from the refund liability as a result of the settlement with the UK government achieved in the second quarter of 2022, 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 €171.5 million in the first half of 2022. The gross margin on commercial product sales amounted to 58.3% compared to 39.2% in the first half of 2021. COGS of €3.6 million were related to IXIARO[®] product sales, yielding a product gross margin of 70.4%. COGS of €1.3 million were related to DUKORAL[®] product sales, yielding a product gross margin of 77.8%, which was positively impacted by provision releases resulting from reduced expiry risks on inventory. Of the remaining COGS in the first half of 2022, €7.4 million were related to the Third Party products distribution business, €154.9 million to the COVID-19 vaccine business and €4.3 million to cost of services. COGS of the COVID-19 vaccine program included effects from the significant reduction of sales volumes to EC Member States. In the first half of 2021, overall COGS were €34.8 million, of which €23.5 million related to cost of goods and €11.3 million related to cost of services.

Research and development expenses amounted to €51.9 million in the first half of 2022, compared to €78.7 million in the first half of 2021. This decrease was mainly driven by lower clinical trials costs for Valneva's chikungunya and COVID-19 vaccine program as those advanced towards licensure. Marketing and distribution expenses in the first half of 2022 amounted to €7.8 million compared to €9.6 million in the first half of 2021. Marketing and distribution expenses in the first half of 2022 notably included €2.2 million of expenses related to the launch preparation costs for Valneva's chikungunya vaccine candidate, VLA1553, compared to €2.0 million in the first half of 2021. In the first half of 2022, general and administrative expenses declined to €16.0 million from €20.9 million in the first half of 2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a non-cash accrual adjustment to income of €17.8 million related to the positive effect of the Company's share price development on the employee share-based compensation programs. This income compares to a cost of €7.3 million in the first half of 2021.

Other income, net of other expenses, reduced to €3.6 million in the first half of 2022 from €10.4 million in the first half of 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending and an increase of expenses related to the provision held for the ongoing merger litigation proceedings.

Valneva recorded an operating loss of €150.4 million in the first half of 2022 compared to €86.2 million in the first half of 2021, of which the COVID-19 operating loss represented €110.7 million and €55.5 million as of June 30, 2022 and 2021 respectively. and the other segments represented €39.7 million in the first half of 2022 compared to €30.7 million in the first half of 2021. Adjusted EBITDA (as defined below) loss in the first half of 2022 was €136.0 million compared to an adjusted EBITDA loss of €80.1 million in the first half of 2021.

Net Result

In the first half of 2022, Valneva generated a net loss of €171.5 million compared to a net loss of €86.4 million in the first half of 2021.

Finance expense and currency effects in the first half of 2022 resulted in a net finance expense of €18.8 million, compared to a net finance income of €0.5 million in the first half of 2021. This was mainly a result of a foreign exchange loss amounting to €10.7 million in the first half of 2022, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €8.7 million in the first half of 2021. Interest expenses net of interest income were €8.2 million in the first half of 2022 compared to €8.2 million in the first half of 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €100.2 million in the first half of 2022 compared to €84.2 million of cash generated by operating activities in the first half of 2021. Cash outflows in the first half of 2022 were mainly related to the operating loss generated in the period, while during the first half of 2021 cash inflows mainly resulted from pre-payments received related to the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €16.0 million in the first half of 2022 compared to €39.9 million in the first half of 2021, both mainly a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €105.0 million in the first half of 2022, which was mainly a result of proceeds from the equity subscription agreement with Pfizer as well as disbursements from the credit facility provided by Deerfield & Orbimed. Cash inflows in the first half of 2021 amounted to €78.7 million which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement (Global Offering).

Cash and cash equivalents decreased to €336.2 million as of June 30, 2022, compared to €346.7 million as of December 31, 2021. The cash decrease mainly resulted from ongoing COVID-19-related investments into fixed assets and R&D expenses.

Non-IFRS Financial Measures

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

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

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

€ in million (unaudited results, consolidated per IFRS)	6 months ending June 30	
	2022	2021
Loss for the period	(171.5)	(86.4)
Add:		
Income tax expense	2.3	0.7
Total Finance income	-	(0.2)
Total Finance expense	8.2	8.4
Foreign exchange gain/(loss) – net	10.7	(8.7)
Result from investments in associates	-	0.1
Amortization	3.5	3.1
Depreciation	7.7	3.0
Impairment	3.3	-
Adjusted EBITDA	(136.0)	(80.1)

1.4 Operational and Strategic Outlook 2022

Noting the revised EC APA for Valneva's COVID-19 vaccine, the current recovery of travel vaccine sales and the revenue recognition linked to the EC and UK supply contracts, Valneva expects total revenues to reach €340 to €360 million in 2022.

Product sales of the Company's travel vaccine franchise are expected to reach €70 to €80 million while COVID-19 product sales are expected to reach €30 to €40 million. Other Revenues are expected to reach approximately €240 million and will be mainly COVID-related while non-COVID related Other Revenues will be negative in 2022 due to the increased refund liability linked to the amendment to the VLA15 collaboration and license agreement with Pfizer.

COVID-19 related Other Revenues will have no cash impact in 2022 and relate to revenues recognized in relation to the UK and the EC Advance Purchase Agreements.

Valneva will continue investing in progressing its two leading late-stage investigational vaccines: its Lyme disease vaccine candidate VLA15, whose Phase 3 study was recently initiated, and its single-shot chikungunya vaccine candidate VLA1553, for which the Company expects initiation of the BLA rolling submission with the FDA in the third quarter of 2022.

As previously announced, Valneva will invest in further development of its current or any potential second-generation COVID-19 vaccine only if it reaches an agreement with potential customers and receives the necessary funding in the third quarter of 2022.

As the Company advances its late-stage portfolio, it also remains committed to further expanding its R&D pipeline, including through the advancement of some of the Company's preclinical candidates towards clinical entry. Noting the above, the Company expects R&D expenses of €120 million to €135 million in 2022.

In the second half of 2022, Valneva will focus on the following goals:

- Further progress its late-stage development program against Lyme disease and chikungunya as well as its preclinical R&D portfolio
- Maximize product sales through its established commercial infrastructure including driving sales for available inventory of the Company's COVID-19 vaccine
- Opportunistically explore potential future business for COVID-19, subject to firm commitments only
- Re-shape the Company's operations to reflect the evolution of the COVID-19 program

1.5 Risk Factors

The Company considers that the risk factors discussed below are the main risks and uncertainties that the Company may face in the remaining six months of 2022. These risk factors track those in the Company's 2021 annual report on its form 20-F filed with the SEC on March 24, 2022. These are not the only risks and uncertainties facing the Company and may also occur in future years. The Company invites investors to review its other public disclosure for additional information.

The development of innovative products includes the inherent risk of failure and the Company is therefore exposed to significant industry-specific risks. Valneva is subject to additional risks because of its COVID-19 vaccine program and because most of its other revenues, excluding grants, arise from two commercialized vaccines only, namely DUKORAL[®] and IXIARO[®]/JESPECT[®], and these belong to the market segment of travel vaccines which has been severely affected by the COVID-19 pandemic and 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 Company remains exposed to significant risks, including the following:

Failure to further commercialize and develop Valneva's COVID-19 vaccine. Valneva's COVID-19 vaccine has received a standard marketing authorization from the European Commission, a conditional marketing authorization from the MHRA in the United Kingdom, and emergency use authorizations from the local authorities in Bahrain and the United Arab Emirates. Additional clinical trials, including to evaluate the vaccine in the elderly and for use as a booster, remain ongoing.

As of the date of this report, the Company has entered into two agreements for the supply of its COVID-19 vaccine: one with the Kingdom of Bahrain to supply one million doses in 2022 and 2023, and one with the European Commission (the "EC APA"). The EC APA originally included an order of up to 60 million doses in 2022 and 2023, with approximately 24 million doses expected to be delivered in 2022. Following the Company's receipt of a notice of the EC's intent to terminate the EC APA due to a failure to obtain a marketing authorization prior to April 30, 2022, the Company and the EC announced an amendment to the EC APA on July 20, 2022, and the amended EC APA reduced the order volume to 1.25 million doses for delivery in 2022, with the possibility of placing a later order for an additional amount to be delivered later in 2022. As a result of this significant reduction in the order volume, the Company announced on July 20, 2022 that it: a) is evaluating its COVID-19 program and associated operations, b) has suspended manufacturing of the vaccine and was assessing its related assets with regard to a potential write-down, and c) will invest in the further development of its COVID-19 vaccine or a second-generation COVID-19 vaccine only if it reaches an agreement with potential customers and receives the necessary funding over the summer of 2022. The Company is continuing to discuss supply agreements with other countries around the world, but there can be no assurance that it will be able to secure the orders and other funding required to continue the program.

A failure to secure additional orders and financing for this vaccine will result in financial losses mostly due to additional write-downs, as well as subsequent restructuring costs and the lack of return on development expenses. The Company had already purchased most of the materials needed to fulfill the original order volume of the EC APA and had manufactured a substantial number of doses prior to suspending manufacturing. The Company has now taken the decision to write down €100.6 million of inventory to produce and supply products under the original EC APA, and if it is not successful in selling the already manufactured doses, it may have to recognize further write-downs of this inventory. Additionally, the Company may not be able to fulfill all of its ongoing obligations with respect to certain of the regulatory approvals it has received for its COVID-19 vaccine, which could lead to a loss of licensure in one or more jurisdictions. The Company could also have to repay the up to £12.5 million in grant funding that it may receive for the COVID-19 program from Scottish Enterprise if it discontinues the program or fails to comply with the terms of the grant, or the amount and conditions of the grant for the COVID-19 program could change depending on the evolution of the program. The Company received an initial payment of £4.3 million pursuant to the COVID-19 grant in July 2022. Further, Valneva's stock price and market capitalization have varied significantly since Valneva announced its COVID-19 program and further developments regarding the program. The trading price of Valneva's shares listed on Euronext Paris and its American Depositary Shares listed on Nasdaq as well as Valneva's overall market capitalization and ability to raise financing in the future may be severely affected if Valneva significantly curtails the program or stops development altogether.

Many factors could cause further challenges in commercialization of the vaccine or, if the Company continues with the COVID-19 program, further development efforts. These include but are not limited to delays in conducting clinical trials (for example due to difficulties recruiting participants) and obtaining data, clinical trial data that does not support further label expansion (for example to different age groups or for use as a booster), technical or scientific failures, changing strategies of governments in response to the evolving nature of the pandemic and the vaccination status of local populations, difficulties in developing or reproducing biological manufacturing processes, inability to enter into agreements with key suppliers and manufacturers, inability or unwillingness of key suppliers to provide equipment or materials on time, rejection by health authorities of clinical trial or marketing applications, lower levels of efficacy of the current formulation of the vaccine against additional variants of the virus, or termination or amendment of a key customer agreement (such as the EC APA), supplier agreement (such as the agreement with Dynavax), or manufacturer agreement (namely, the agreement with IDT. Valneva and IDT are discussing potential ways of terminating their COVID-19 vaccine drug substance manufacturing agreement. Failure to reach agreement could result in litigation with an unpredictable outcome.

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 effect on the travel industry of the COVID-19 pandemic and other factors, such as rising oil prices and market volatility relating to the conflict in Ukraine, as well as Valneva's ability to adjust manufacturing in response to demand. Although the travel market recovered at a faster rate than the Company expected in the first half of 2022, there is no guarantee that such recovery will be sustained or that Valneva will be able to supply quantities of these vaccines that meet this greater demand. The evolving nature of the pandemic, particularly the emergence and impact of new variants of the virus, makes it difficult to predict when, where, at what rate, and for how long the travel industry will recover. Additionally, the demand from the U.S. DoD for IXIARO[®] depends on the frequency of troop rotation, among other things, and it is possible that the DoD will not exercise its remaining option year under the existing agreement in full or at all. 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. If Valneva's revenues are significantly impacted (for example by the rate of recovery of the travel market, Valneva's ability to meet increased demand for its existing products, or failure to commercialize its COVID-19 vaccine) and the Company is unable to adjust its cost base accordingly, the Company may have to seek additional financing to complete (or contribute to) the development of its vaccine candidates. 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 Section 1.5 of the Company's 2021 URD.

Manufacturing and procurement risks. The Company'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. 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 the Company's vaccine candidates. Such changes may be costly and may affect the Company'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 the Company has entered into manufacturing, supply, distribution or services agreements. The Company 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, and if manufacturing of its COVID-19 vaccine resumes, will be dependent on these facilities for such manufacturing as well. The destruction by fire or other catastrophic events of any of the Company's key manufacturing facilities or the facilities of a key manufacturer, such as IDT, would prevent the Company from manufacturing the relevant products and supplying its customers or its clinical trial centers, any of which would cause considerable losses. In addition, the Company's business requires the use of hazardous materials, which increases the Company'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 Company's performance and financial condition. Finally, the Company 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, the Company may not be able to supply one or more of its vaccines for several months, and consequently would face considerable losses. Should these third parties fail to meet requirements, the development and commercialization of the Company's product and product candidates may be limited or delayed, which would have a material adverse effect on the Company's business, financial condition, and results of operations.

Product development and approval risks. The Company's R&D activities, and in particular the clinical development of its Lyme disease and chikungunya vaccine candidates and its COVID-19 vaccine, are expensive and time-consuming. The result of these R&D activities is inherently uncertain, and the Company may experience delays or failures. In order to continue to develop and commercialize its product candidates, the Company will require regulatory approvals from regulatory agencies, which may be delayed or denied if the Company cannot establish the safety and efficacy of its product candidates, primarily through clinical trial data. Pfizer began the Phase 3 trial of the Company's Lyme disease vaccine candidate in the third quarter of 2022, and the Company expects to begin a rolling submission of a biologics license application for its chikungunya vaccine candidate with the U.S. FDA in the third quarter of 2022. Failure to demonstrate efficacy or safety in clinical trials, delays or failures in development or regulatory filings, changes in regulatory requirements, or other adverse events may force the Company 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 Company's business.

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 will not have sufficient financial resources to complete Phase 3 development of the Lyme disease vaccine candidate alone.

Listing on Nasdaq. As a company listed in the U.S., Valneva must comply with U.S. regulations relating to public disclosure and accounting, among other areas. Compliance with existing and anticipated requirements is complex, requires significant time and expense, and may divert the attention of management from other matters, which could negatively impact the Company's business. 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 Company's business. Failing to comply with applicable U.S. regulations or involvement in lawsuits with U.S. investors could have significant consequences for the Company and could materially impact the Company's business and results of operations.

Risks relating to the ongoing pandemic. In addition to the other risks of the ongoing COVID-19 pandemic described above, the Company may face further or additional operational challenges due to government restrictions imposed and/or illness at any of Valneva's sites. This risk may become greater if new variants of the virus prove more contagious and/or if existing vaccines prove less effective against such variants.

Litigation. Risks associated with litigation are set out in note 25 to the H1 financial statements (section 2 of this report).

Further risk factors are set out in Valneva's 2021 annual report on Form 20-F filed with the SEC on March 24, 2022.

1.6 Related Parties' Transactions

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. As at June 30, 2022, the aggregate amount of Valneva SE' R&D tax-credit financed by Bpifrance amounted to €2.4 million. Bpifrance was not a related party as at December 31, 2021.

2. UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2022 AND FOR THE SIX MONTHS ENDED JUNE 30, 2022 AND 2021



VALNEVA SE

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

A. Unaudited Interim Condensed Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	Note	Six months ended June 30,	
		2022	2021
Product sales	4	33,335	31,762
Other revenues	4	59,889	15,740
Revenues		93,224	47,502
Cost of goods and services	5	(171,479)	(34,778)
Research and development expenses	5	(51,883)	(78,737)
Marketing and distribution expenses	5	(7,837)	(9,643)
General and administrative expenses	5	(16,031)	(20,904)
Other income and expenses, net	6	3,597	10,389
OPERATING LOSS		(150,410)	(86,172)
Finance income	7	35	228
Finance expenses	7	(8,199)	(8,431)
Foreign exchange gain/(loss), net	7	(10,657)	8,735
Result from investments in associates		9	(90)
LOSS BEFORE INCOME TAX		(169,222)	(85,730)
Income tax expense		(2,271)	(668)
LOSS FOR THE PERIOD		(171,493)	(86,399)
Losses per share			
for loss for the period attributable to the equity holders of the Company, expressed in €			
per share			
■ basic		(1.58)	(0.91)
■ diluted		(1.58)	(0.91)

The accompanying notes form an integral part of these unaudited interim consolidated financial statements.

**B. Unaudited Interim Condensed Consolidated Statements of Comprehensive Income (Loss)**

€ in thousand	Note	Six months ended June 30,	
		2022	2021
Loss for the period		(171,493)	(86,399)
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences	17.2	(567)	(424)
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains	17.2	168	—
Other comprehensive loss for the period, net of tax		(399)	(424)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		(171,892)	(86,823)

The accompanying notes form an integral part of these unaudited interim consolidated financial statements.



II. UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

€ in thousand	Note	June 30 2022	December 31, 2021
ASSETS			
Non-current assets		221,330	231,520
Intangible assets	8	30,714	32,700
Right of use assets	9/11	46,752	48,285
Property, plant and equipment	10/11	123,240	125,545
Investments in associates		—	2,124
Deferred tax assets		2,676	3,582
Other assets	15	17,948	19,282
Current assets		503,776	585,832
Inventories	13	95,201	124,098
Trade receivables	14	16,251	44,013
Other assets	15	53,965	71,036
Cash and cash equivalents	16	336,225	346,686
Assets classified as held for sale		2,134	—
TOTAL ASSETS		725,105	817,352
EQUITY			
Capital and reserves attributable to the Company's equity holders		93,255	170,581
Share capital	17.1	17,603	15,786
Share premium	17.1	501,638	409,258
Other reserves	17.2	52,482	52,512
Retained earnings/(Accumulated deficit)		(306,974)	(233,549)
Loss for the period		(171,493)	(73,425)
LIABILITIES			
Non-current liabilities		195,722	277,791
Borrowings	18	67,058	50,726
Lease liabilities	9	51,931	53,687
Contract liabilities	19	5,110	4,741
Refund liabilities	20	66,689	158,970
Provisions	21	2,302	8,308
Deferred tax liabilities		1,978	1,290
Other liabilities	22	654	69
Current liabilities		436,128	368,979
Borrowings	18	11,543	7,107
Trade payables and accruals		83,704	68,119
Income tax liability		259	83
Tax and employee-related liabilities		15,199	17,249
Lease liabilities	9	2,989	3,135
Contract liabilities	19	119,711	124,017
Refund liabilities	20	142,585	95,611
Provisions	21	56,884	48,708
Other liabilities	22	3,254	4,950
TOTAL LIABILITIES		631,850	646,771
TOTAL EQUITY AND LIABILITIES		725,105	817,352

The accompanying notes form an integral part of these unaudited interim consolidated financial statements.



III. UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Six months ended June 30,	
		2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss for the period		(171,493)	(86,399)
Adjustments for non-cash transactions	24	5,673	17,003
Changes in non-current operating assets and liabilities	24	(92,844)	8,341
Changes in working capital	24	159,254	146,614
Cash generated from/(used in) operations	24	(99,410)	85,560
Income tax paid		(818)	(1,313)
Net cash generated from/(used in) operating activities		(100,228)	84,247
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	10/11	(15,952)	(39,173)
Purchases of intangible assets		(76)	(761)
Interest received	35	35	33
Net cash used in investing activities		(15,994)	(39,902)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions	17	94,308	85,177
Disposal/(Purchase) of treasury shares		—	209
Proceeds from borrowings, net of transaction costs	18	18,074	—
Repayment of borrowings		(1,793)	(1,764)
Payment of lease liabilities		(1,529)	(1,161)
Interest paid		(4,054)	(3,718)
Net cash generated from financing activities		105,006	78,743
Net change in cash and cash equivalents		(11,216)	123,088
Cash and cash equivalents at beginning of the period, excluding restricted cash		346,642	204,394
Exchange gains/(losses) on cash		751	2,242
Restricted cash	16	48	42
Cash and cash equivalents at end of the period	16	336,225	329,766

The accompanying notes form an integral part of these unaudited interim consolidated financial statements.



IV. UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand (except number of shares)	Note	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, 2021		90,970,562	13,646	244,984	52,342	(169,156)	(64,393)	77,422
Total comprehensive loss		—	—	—	(424)	—	(86,399)	(86,823)
Income appropriation		—	—	—	—	(64,393)	64,393	—
Share-based compensation expense:	17							
- value of services		—	—	—	1,217	—	—	1,217
- exercises		793,200	119	2,090	—	—	—	2,209
Treasury shares	17	—	—	—	209	—	—	209
Issuance of ordinary shares, May 2021	17	8,145,176	1,222	88,375	—	—	—	89,597
Cost of equity transactions, net of tax	17	—	—	(6,761)	—	—	—	(6,761)
Balance as at June 30, 2021		99,908,938	14,986	328,688	53,344	(233,549)	(86,399)	77,070
Balance as at January 1, 2022		105,239,085	15,786	409,258	52,512	(233,549)	(73,425)	170,581
Total comprehensive loss		—	—	—	(399)	—	(171,493)	(171,892)
Income appropriation		—	—	—	—	(73,425)	73,425	—
Share-based compensation expense:	17							
- value of services		—	—	—	369	—	—	369
- exercises		2,563,011	384	3,333	—	—	—	3,718
Treasury shares	17	—	—	—	—	—	—	—
Issuance of ordinary shares, June 2022	17	9,549,761	1,432	89,195	—	—	—	90,627
Cost of equity transactions, net of tax	17	—	—	(148)	—	—	—	(148)
Balance as at June 30, 2022		117,351,857	17,603	501,638	52,482	(306,974)	(171,493)	93,255

The accompanying notes form an integral part of these unaudited interim consolidated financial statements



SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT

1. Basis of preparation

The unaudited interim condensed consolidated financial statements of Valneva SE (“the Company”) together with its subsidiaries (the “Group” or “Valneva”) as at June 30, 2022 and for the six months ended June 30, 2022 and June 30, 2021, have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union (EC) 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, 2021.

The unaudited interim condensed consolidated financial statements of the Company were approved by the Management Board and authorized for issuance by the Supervisory Board on August 10, 2022.

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, 2021.

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.

The unaudited interim condensed consolidated financial statements have been prepared on a going concern basis. Although it is difficult to predict future liquidity requirements, Valneva believes that the existing cash and cash equivalents as of June 30, 2022 amounting to €336.2 million will be sufficient to fund its operations for at least the next 12 months from the date of authorization of publication of these consolidated financial statements. While certain risks may have an adverse effect on the Company’s cash runway, debt and equity financing options exist to provide necessary funding.

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

No standards, amendments to existing standards, or interpretations that were published but not yet applicable as of June 30, 2022, were early adopted or are expected to significantly impact the Company’s financial statements.

SIGNIFICANT EVENTS OF THE PERIOD AND SIGNIFICANT AGREEMENTS

COVID-19

Vaccine Supply Agreement with the UK Authority from 2020, its termination in 2021 and Settlement Agreement of 2022

In September 2020, Valneva entered into a supply agreement (“UK Supply Agreement”), with the Secretary of State for Business, Energy and Industrial Strategy of the United Kingdom (“UK Authority”), pursuant to which Valneva was obligated to develop, manufacture and supply SARS-CoV-2 vaccines, to the UK Authority in the United Kingdom of Great Britain, and Northern Ireland (“the UK”), including an obligation for Valneva to upgrade its manufacturing facilities in Scotland.

In September 2021, Valneva received notice of the UK Authority’s decision to terminate the UK Supply Agreement, and the termination became effective in October 2021.

In June 2022, Valneva and the UK Authority signed a settlement agreement. The settlement agreement resolves certain matters relating to the obligations of the Company and UK Authority following the termination of the UK Supply Agreement and in relation to the separate agreement relating to clinical trials of Valneva’s inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001, in the UK, which remains in place. The Company continues to have certain other obligations (as stated below) pursuant to provisions of the UK Supply Agreement that survive its termination. Valneva has recognized an additional revenue of €89.4 million in the six months ended June 30, 2022; see Note 4.



Valneva's other obligations relate to a royalty payable to the UK Authority for non-UK COVID sales ("royalty obligation") as well as to investments in manufacturing, such as Valneva's Almeida manufacturing facility, which was constructed with funds advanced by the UK Authority. Valneva assessed the likelihood of this royalty obligation and concluded it as remote, therefore no refund liability was accounted for as at June 30, 2022. Valneva may have certain obligations to the UK Authority, such as a partial return of funding received, with respect to assets acquired if they are sold, disposed, or repurposed ("CAPEX obligation") on or before December 31, 2022. As of June 30, 2022, Valneva included €81.9 million in refund liabilities related to the CAPEX obligation as at June 30, 2022; see Note 20.

Advance Purchase Agreement with the European Commission in 2021 and notice of intent to terminate the Advance Purchase Agreement in 2022

In November 2021, Valneva signed an Advance Purchase Agreement ("APA") with the European Commission ("EC") to supply up to 60 million doses of VLA2001 over two years. Under the terms of the APA, Valneva was to deliver 24.3 million doses in 2022 (starting in April 2022), subject to approval of VLA2001 by the European Medicines Agency ("EMA"). The EC had an option to purchase a further 35.7 million doses for delivery in 2023. During 2021, no revenue was recognized, as the deliveries were to start in the second quarter of 2022. Advanced payments of €116.9 million were included as contract liabilities as at December 31, 2021.

In May 2022, Valneva received a notice from the EC of its intent to terminate the APA on the basis of a right to terminate the APA if VLA2001 had not received a marketing authorization from the EMA by April 30, 2022. Based on the terms of the APA, Valneva had 30 days from May 13, 2022, to obtain a marketing authorization, which Valneva did not obtain within this period. Valneva did, however, obtain a marketing authorization in June 2022. As at the balance sheet date June 30, 2022, Valneva was still working with the EC and the participating EC Member States to agree to a remediation plan. As at June 30, 2022, €116.6 million in advance payments are recorded as contract liabilities; see Note 19. VLA signed an amended APA in July 2022; please refer to Note 27 for more details. The APA does not require reimbursement of down payments that have already been committed. Pursuant to the terms of the APA, a period now opens during which Valneva will provide a financial statement to the EC describing the use of the advance payments.

Authorizations and Emergency Use granted by Health Authorities for Valneva's inactivated, adjuvanted COVID-19 vaccine, VLA2001 in 2022

In March 2022, Valneva announced that the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain had granted an Emergency Use Authorization for VLA2001.

In April 2022, Valneva announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK had granted Conditional Marketing Authorization for VLA2001, for primary immunization in adults 18 to 50 years of age.

In May 2022, Valneva announced that the United Arab Emirates granted Emergency Use Authorization for VLA2001.

In June 2022, Valneva announced that the EC had granted a marketing authorization for VLA2001 in Europe, for use as primary vaccination in people from 18 to 50 years of age. With this approval, VLA2001 became the first COVID-19 vaccine to receive a standard marketing authorization in Europe. The marketing authorization covers all 28 European Union Member States as well as Iceland, Liechtenstein, and Norway.

**LYME**

In April 2020, Valneva signed an agreement with Pfizer (the “Collaboration and License Agreement”) to co-develop and commercialize the Group’s Lyme disease vaccine candidate (VLA15). This is classified as an agreement with a customer as defined by IFRS 15 guidance on revenue contracts with customers, and accordingly, amounts received or payable by Valneva under the Collaboration and License Agreement are accounted for in the Group’s revenues. The Collaboration and License Agreement included a €116.9 million (\$130 million) upfront payment to Valneva, which was received in June 2020. Valneva is obligated to reimburse certain development costs incurred by Pfizer up to an agreed amount, through completion of the development program, which is expected to finish in 2025. The transaction price according to IFRS15 was determined taking into consideration the expected refund obligation of Valneva relating to Valneva’s share of the development costs. The agreement includes research & development and service performance obligations for which revenue is recognized over time as well as a license performance obligation for which revenue is recognized at a point in time when Pfizer can benefit and use the license without the further involvement of Valneva. The transaction has been allocated according to the various performance obligations in proportion to their standalone selling price. In the year ended December 31, 2021, €14.3 million was recognized as other revenues. €3.0 million of costs to obtain a contract was included in other non-current assets as at December 31, 2021, and €79.6 million was recognized as discounted refund liabilities.

In June 2022, Valneva and Pfizer updated the terms of their Collaboration and License agreement which was signed in April 2020. From May 1, 2022, onward Valneva will 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 eligible for up to \$100 million on the achievement of cumulative sales targets. Other development and early commercialization milestones remain \$168 million, including a \$25 million payment to Valneva upon Pfizer’s initiation of the Phase 3 study. In the six months ended June 30, 2022, €36.1 million was recognized as net negative other revenues as Valneva’s expected repayment obligations relating to development costs incurred by Pfizer increased compared to the original agreement; as this agreement is accounted for as an IFRS 15 contract with customers, payments to Pfizer are treated as negative revenue. As at June 30, 2022, the discounted refund liability amounted to €118.4 million (December 31, 2021: €79.6 million), of which €59.8 million was recognized as a non-current refund liability. €3.0 million of costs to obtain a contract were included in other non-current assets as at June 30, 2022, For more details, see Note 4 and Note 20.



US DEPARTMENT OF DEFENSE (DoD)

In September 2020, the U.S. Department of Defense (DoD) awarded Valneva a new contract for the supply of IXIARO. The terms of the agreement, as subsequently amended in September 2021, include an initial base year followed by two option years, each with a range of minimum and maximum potential orders. The base year had a minimum value of approximately \$53 million for 370,000 doses, and the first option year, which the DoD exercised in September 2021, had a minimum value of approximately \$28.8 million for 200,000 doses. The second option year, if exercised, has a minimum value of approximately \$36 million for 250,000 doses. In order to support its customer through this pandemic period, Valneva also agreed to provide additional inventory to the DoD after September 2023 to mitigate the potential impact of unused stock that may expire. This replacement inventory will be provided free of charge and resulted in a contract liability of \$5.4 million recognized as at June 30, 2022 (December 31, 2021: \$5.4 million).

FINANCING

In February 2022, Valneva announced that its subsidiary Valneva Scotland was awarded research and development funding of up to £20 million by Scottish Enterprise, Scotland's national economic development agency. The investment is comprised of two grants, which build on the agency's long standing engagement with Valneva and will benefit the Company's manufacturing site in Livingston. The grants are expected to be received over the next three years. The first grant of up to £12.5 million will support development related to the manufacture of Valneva's COVID-19 vaccine. The second grant of up to £7.5 million will support development connected to Valneva's manufacturing processes for other vaccines. As at June 30, 2022, no cash had been received. Valneva could also have to repay the grant funding for the COVID-19 program if it fails to comply with the terms of the grant. Also, the amount and conditions of the grant for the COVID-19 program could change depending on the evolution of the program.

In April 2022, Valneva signed an amendment to increase the principal amount of its existing €54.1 million (\$60 million) debt financing agreement with funds managed by leading U.S.-based healthcare investment firms Deerfield Management Company and OrbiMed. The original loan agreement was signed in February 2020. This amendment provided Valneva immediate access to €18.2 million (\$20 million), with an additional \$20 million available upon potential approval of VLA2001, by the European Medicines Agency. The increased funding will be used to further invest in Research & Development projects, including market access preparations for VLA1553. The loan interest rate remains unchanged at 9.95% (equivalent to 10.09% on an annual basis). The interest-only period was extended from the second quarter of 2023 to the third quarter of 2024, and the loan will now mature in the first quarter of 2027 instead of the first quarter of 2026. As at June 30, 2022, a total of €72.4 million (\$80.0 million) was drawn down, including the tranches originally drawn in 2020. As at December 31, 2021, €54.1 million (\$60.0 million) was drawn down. As at June 30, 2022, the carrying amount was €71.0 million (December 31, 2021: €49.7 million). The loan is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries.

In June 2022, Valneva signed an Equity Subscription Agreement with Pfizer. Pursuant to the Equity Subscription Agreement, Pfizer invested €90.5 million (\$95 million) in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share. The per share purchase price was determined based on the average closing price of the Company's shares on Euronext Paris during the 10 trading days preceding the date of the Equity Subscription Agreement. The equity investment closed on June 22, 2022.



KEY SOURCES OF ESTIMATION UNCERTAINTY

Below are listed the key assumptions concerning the future, and other key sources of estimation uncertainty in the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year. Those assumptions and estimates are discussed below as an update of the key sources of estimation uncertainty provided as at December 31, 2021

- Notes 1, 4, and 20: The likelihood of the royalty obligation towards the UK Authority was updated. As at December 31, 2021, the royalty obligation was assessed at the maximum amount, as significant COVID sales were expected to occur outside the UK (refer to Note 1). As at June 30, 2022, the terms of the royalty obligation were redefined under the 2022 settlement agreement. As at June 30, 2022 management assessed the likelihood for this future obligation as remote. This resulted in a value of € nil, and the refund liability was updated in this respect. This led to other revenues recognized of €89.4 million (refer to Note 20). Note 4 contains details on the other revenue recognized following the re-assessment of the royalty obligation.
- Note 13: Write-down analysis for inventories: For the assessment of write-down of raw material the current production plans have been taken into account. Raw material which will not be used before expiry date was written down. For this assessment, the status of the expiry dates as of the balance sheet date was taken. For the assessment of write-downs of work in progress, finished goods and purchased goods, the forecast sales plans and a minimum shelf life at the time of the most current sales expectations have been taken into account. Given the significant changes to the ordered volumes and the expected future demand for VLA2001, a certain amount of related inventory was written-off. The release of write-down for travel vaccines that occurred in the wake of a recovering travel industry during 2022 has likewise been re-considered.
- Note 25: Recognition and measurement of litigations and contingencies: key assumptions were made about the likelihood and magnitude of an outflow of resources. In estimating the provision for onerous contracts, the management made assumptions regarding the estimated amount of termination costs for certain agreements.



2. Group structure

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	June 30, 2022	December 31, 2021
BliNK Biomedical SAS	FR	Equity method*	48.9%	48.9%
Vaccines Holdings Sweden AB	SE	Consolidation	100%	100%
Valneva Austria GmbH	AT	Consolidation	100%	100%
Valneva Canada Inc.	CA	Consolidation	100%	100%
Valneva France SAS	FR	Consolidation	100%	100%
Valneva Scotland Ltd.	UK	Consolidation	100%	100%
Valneva Sweden AB	SE	Consolidation	100%	100%
Valneva UK Ltd.	UK	Consolidation	100%	100%
Valneva USA, Inc.	US	Consolidation	100%	100%

* The investment in BliNK Biomedical SAS was reclassified from “Investments in associates” to “Assets classified as held for sale” as at June 30, 2022.

3. Segment reporting

The Company’s Management Board, as its chief operating decision maker, considers the operational business from a product rather than geographic perspective and has identified four reportable segments. Key performance indicators include revenue and operating profitability.

The individual segments consist of the following:

- + “Commercialized products” (marketed vaccines, currently the Group’s vaccines IXIARO and DUKORAL as well as third-party products),
- + “COVID” (development, manufacturing, and distribution related to Valneva’s SARS-CoV-2 vaccine candidate),
- + “Vaccine candidates” (proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies, excluding COVID-19 vaccine candidates, which is presented separately), and
- + “Technologies and services” (services and inventions at the commercialization stage, i.e. revenue generated through collaborations, service, and licensing agreements).



Income statement by segment for the six months ended June 30, 2021:

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	31,762	—	—	—	—	31,762
Other revenues	10	—	1,849	13,880	—	15,740
Revenues	31,772	—	1,849	13,880	—	47,502
Cost of goods and services	(19,326)	(4,156)	—	(11,295)	—	(34,778)
Research and development expenses	(878)	(46,105)	(29,513)	(2,241)	—	(78,737)
Marketing and distribution expenses	(7,086)	(444)	(2,037)	(75)	—	(9,643)
General and administrative expenses	(2,519)	(9,438)	(3,256)	(2,194)	(3,498)	(20,904)
Other income and expenses, net	2,126	4,690	2,952	900	(279)	10,389
Operating income/(loss)	4,089	(55,454)	(30,005)	(1,025)	(3,776)	(86,172)

Income statement by segment for the six months ended June 30, 2022:

€ in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Corporate Overhead	Total
Product sales	29,537	3,798	—	—	—	33,335
Other revenues	15	89,383	956	(30,465)	—	59,889
Revenues	29,552	93,181	956	(30,465)	—	93,224
Cost of goods and services	(12,296)	(154,883)	—	(4,301)	—	(171,479)
Research and development expenses	(406)	(44,223)	(6,702)	(551)	—	(51,883)
Marketing and distribution expenses	(4,156)	(1,483)	(2,182)	(16)	—	(7,837)
General and administrative expenses	(3,236)	(8,359)	(1,759)	(924)	(1,752)	(16,031)
Other income and expenses, net	110	5,099	1,365	381	(3,359)	3,597
Operating income/(loss)	9,568	(110,667)	(8,322)	(35,876)	(5,111)	(150,410)

**Revenue from contracts with customer by geographical segment**

In presenting information on the basis of geographical segments, segment revenue is based on the final location where our distribution partner sells the product or where the customer/partner is located.

Six months ended June 30, 2021				Technologies and services	
€ in thousand	Commercialized products	COVID	Vaccine candidates		Total
Canada	2,006	—	—	—	2,006
United States	23,589	—	—	5,781	29,370
United Kingdom	901	—	—	—	901
Austria	1,074	—	—	40	1,114
Nordics ¹	—	—	—	15	15
Germany	3,006	—	—	4,126	7,131
Other Europe	1,181	—	—	3,001	4,182
Other markets	15	—	1,849	466	2,330
Revenues from contracts with customers	31,772	—	1,849	13,429	47,050

Six months ended June 30, 2022				Technologies and services	
€ in thousand	Commercialized products	COVID	Vaccine candidates		Total
Canada	6,683	—	—	—	6,683
United States	4,632	—	—	(36,073)	(31,442)
United Kingdom	5,523	89,383	—	1,025	95,931
Austria	3,744	—	—	2,410	6,154
Nordics ¹	2,535	—	—	—	2,535
Germany	2,177	—	—	20	2,197
Other Europe	4,119	—	—	1,357	5,476
Other markets	139	3,798	956	431	5,325
Revenues from contracts with customers	29,552	93,181	956	(30,830)	92,859

In the six months ended June 30, 2022, revenues from Technologies and services in the U.S. include €36.1 million net negative revenue from the updated terms of the Collaboration and License Agreement with Pfizer (see Note 1). In 2020, €31.6 million of revenue linked to this agreement with Pfizer was booked into Vaccine candidates segment. With the transfer of the VLA15 Lyme vaccine candidate to Pfizer in December 2020, all related revenues and costs were presented in technologies and services segment for periods from January 1, 2021 onward.

¹ Includes Denmark, Finland, Norway and Sweden



4. Revenues from contracts with customers

Revenues, as presented in the unaudited Consolidated Interim Income Statement and in the Segment Reporting (see Note 3), include both revenues from contracts with customers and other revenues, which are out of the scope of IFRS 15:

Six months ended June 30, 2021	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	31,772	—	1,849	13,429	47,050
Miscellaneous revenues	—	—	—	451	451
Revenues	31,772	—	1,849	13,880	47,502

Six months ended June 30, 2022	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
Revenues from contracts with customers	29,552	93,181	956	(30,830)	92,859
Miscellaneous revenues	—	—	—	365	365
Revenues	29,552	93,181	956	(30,465)	93,224

In six months ended June 30, 2022, revenues from the COVID segment included €89.4 million from the re-assessment of the likelihood of the royalty obligation towards the UK Authority following the settlement agreement. In addition, the COVID segment included product sales of € 3.8 million for shipments to Bahrain. Revenues from technologies and services included €36.1 million negative revenue from the collaboration and license agreement with Pfizer, which was amended in June 2022 (see Note 1).

**Disaggregated revenue information**

The Group's revenues from contracts with customers are disaggregated as follows:

Type of goods or service

Six months ended June 30, 2021 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO	25,394	—	—	—	25,394
DUKORAL	428	—	—	—	428
Third party products	5,950	—	—	—	5,950
Lyme VLA15	—	—	—	5,616	5,616
Chikungunya VLA1553	—	—	1,849	—	1,849
Services related to clinical trial material	—	—	—	5,727	5,727
Others	—	—	—	2,085	2,085
Revenues from contracts with customers	31,772	—	1,849	13,429	47,050

Six months ended June 30, 2022 € in thousand	Commercialized products	COVID	Vaccine candidates	Technologies and services	Total
IXIARO	12,283	—	—	—	12,283
DUKORAL	5,766	—	—	—	5,766
Third party products	11,503	—	—	—	11,503
COVID VLA2001	—	93,181	—	—	93,181
Chikungunya VLA1553	—	—	956	—	956
Lyme VLA15	—	—	—	(36,107)	(36,107)
Services related to clinical trial material	—	—	—	2,490	2,490
Others	—	—	—	2,786	2,786
Revenues from contracts with customers	29,552	93,181	956	(30,830)	92,859

In the six months ended June 30, 2022, revenues from the COVID segment included €89.4 million from the re-assessment of the likelihood of the royalty obligation towards the UK Authority following the settlement agreement. In addition, the COVID segment included product sales of €3.8 million for shipments to Bahrain. Revenues from Lyme VLA15 included €36.1 million negative revenue from the Collaboration and License Agreement with Pfizer, which was amended in June 2022 (see Note 1).



Geographical markets

In presenting information on the basis of geographical segments, segment revenue is based on the final location where our distribution partner sells the product or where the customer/partner is located. Refer to Note 3.

Sales channels for product sales

Commercialized products are sold via the following sales channels:

€ in thousand	Six months ended June 30,	
	2022	2021
Direct product sales	25,302	30,663
Indirect product sales	4,250	1,110
Total product sales	29,552	31,772

5. Operating expenses

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

Schedule of operating expenses

€ in thousand	Six months ended June 30,	
	2022	2021
Cost of services and change in inventory	(102,476)	(2,940)
Consulting and other purchased services ²	(87,171)	(76,213)
Employee benefit expense other than share-based compensation ³	(23,089)	(35,955)
Share-based compensation expense	5,480	(3,653)
Depreciation and amortization and impairment	(14,440)	(6,101)
Building and energy costs	(7,050)	(5,286)
Supply, office and IT-costs	(6,134)	(3,308)
Raw materials and consumables used	(5,536)	(5,371)
Advertising costs	(2,740)	(1,318)
License fees and royalties	(1,650)	(2,490)
Travel and transportation costs	(849)	(126)
Warehousing and distribution costs	(686)	(745)
Other expenses	(889)	(554)
Operating expenses	(247,230)	(144,062)

² In the six months ended June 30, 2022, the position “employee benefit other than share-bases compensations” 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 (for the six months ended June 30, 2021: expense €5.0 million). This provision was calculated using the share price of Valneva as of the balance sheet date.

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 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. Refer to note 13 for more details. Consulting and other purchased services included €71.1 million (June 30, 2021: €33.4 million) in expenses related research and development as well as external manufacturing costs for VLA2001. Depreciation and amortization and impairment included €3.3 million of impairment (refer to note 11.1 for more details).

**6. Other income and expenses, net**

Other income and expenses, net include the following:

€ in thousand	Six months ended June 30,	
	2022	2021
Research and development tax credit	6,770	9,635
Grant income	89	1,145
Profit/(loss) on disposal of fixed assets, net	(46)	(21)
Taxes, duties, fees, charges, other than income tax	(227)	(133)
Miscellaneous income/(expenses), net	(2,989)	(237)
Other income and expenses, net	3,597	10,389

In terms of the Research and development tax credit, €6.2 million (June 30, 2021: €9.1 million) are related to Research & Development programs executed in Austria, mainly for COVID-19 and Lyme disease vaccine candidates, whereas €0.6 million (June 30, 2021: €0.6 million) related to France.

7. Finance income/(expenses) and foreign exchange gain/(losses), net

€ in thousand	Six months ended June 30,	
	2022	2021
Finance income		
Interest income from other parties	35	228
Total finance income	35	228
Finance expense		
Interest expense on loans	(2,695)	(3,820)
Interest expense on refund liabilities	(4,812)	(4,104)
Interest expense on lease liabilities	(457)	(419)
Other interest expense	(235)	(88)
Total finance expense	(8,199)	(8,431)
Foreign exchange gain/(losses), net	(10,657)	8,735
Finance income/(expense), net	(18,821)	532

This was mainly a result of a foreign exchange loss amounting to €10.7 million in the first half of 2022, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €8.7 million in the first half of 2021.



8. Intangible assets

As at June 30, 2022 and December 31, 2021, there were no acquired research and development technology assets with a definite useful life which are not yet amortized.

Significant intangible assets (included in acquired Research & Development technology and projects as well as in the development costs) with definite useful life are comprised primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €78.8 million and a net book value amounting to €29.1 million (December 31, 2021: €30.6 million).

For impairment test, see Note 11.

9. Leases (right of use assets and lease liabilities)

Right of use assets decreased from €48.3 million as at December 31, 2021 to €46.8 million as at June 30, 2022, mainly due to amortization (€1.5 million) and exchange rate differences (€0.9 million), partly offset by positive impact from revaluation of lease liabilities (€0.8 million).

Lease liability decreased from €56.8 million as at December 31, 2021 to €54.9 million as at June 30, 2022, mainly due lease payments (€2.0 million) and exchange rate differences (€1.3 million), partly offset by impact from revaluation of lease liabilities (€0.8 million), interest expenses (€0.5 million) and additions (€0.1 million).

Major lease agreements are for the premises in Austria (book value as at June 30, 2022: €23.5 million, December 31, 2021: €24.0 million) and Sweden (book value as at June 30, 2022: €21.1 million, December 31, 2021: €22.1 million).

10. Property, plant and equipment

In the first six months of 2022, property, plant and equipment decreased from €125.5 million as at December 31, 2021 to €123.2 million as at June 30, 2022. This decrease relates to depreciation expenses (€7.7 million), impairment expenses (€3.3 million) and exchange rate differences (€3.9 million) and is partly offset by additions (€12.6 million).



11. Impairment testing

11.1 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 correspond with the specific vaccine products and vaccine candidates. Nonfinancial assets, other than goodwill, that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

As at June 30, 2022, no triggering events were identified for IXIARO and DUKORAL.

During 2021 and 2022, the Company invested in manufacturing facilities in both Scotland and Sweden in order to fulfill COVID-19 vaccine demand from contracts with the UK Government, the EC member states as well as with the Kingdom of Bahrain. Given the significant changes to the ordered volumes and the expected future demand for VLA2001, impairment tests were performed as of June 30, 2022, for all assets utilized or expected to be utilized for the manufacturing of VLA2001.

The new Almeida manufacturing facility in Scotland is still under construction and to date no manufacturing of VLA2001 has taken place in this facility. As future utilization may not be limited to VLA2001 but will likely over time be extended to manufacturing of the company's commercial vaccine IXIARO and to manufacturing of VLA1553, the Company's vaccine against prevention of chikungunya, all future cash flows generated by utilizing this facility have been considered in calculating the value in use.

For impairment testing of the Company's new fixed assets held and utilized for the filling and packaging processes of COVID-19 in Sweden, the impairment testing included cash flows generated by the Company's commercial stage vaccine DUKORAL, which will go forward also be manufactured utilizing the newly established facility in Sweden.

Additional strategic options do exist for both facilities, however, at this moment are considered unlikely. Impairment testing procedures have been performed solely on the utilization of the established capacity through the Group's existing and future commercial stage vaccines. Different utilization options or a potential sale of any of the facilities were not considered during the performance of impairment testing procedures.

Impairment of manufacturing equipment:

As at June 30, 2022, impairment charges amounting to €3.3 million were recorded that were related to manufacturing equipment dedicated to the manufacturing of the Company's COVID vaccine VLA2001, which after suspension of manufacturing activities following the reduction of supply volumes to the EC, became idle.

Almeida Manufacturing facility in Scotland:

The new manufacturing facility in Scotland is still under construction. By June 30, 2022, the carrying value of the related property, plant and equipment amounted to €83.7 million. The Company's long range business model for IXIARO and VLA1553 (chikungunya), including assumptions on market size/market share, product sales and resulting profitability over a 5.5-year period as well as a Terminal Value for the period beyond 5.5 years, has been used as a basis to calculate the value in use.

Cash flows are expected to be generated starting in 2023 and considerable value in use is generated over the planning horizon of 5.5 years as well as through the Terminal Value for the period beyond the 5.5 years planning horizon. In total, the value in use far exceeded the current carrying value of €83.7 million.

The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 6.67% for IXIARO and 6.87% for chikungunya.



The discount rate of 6.67% for IXIARO was based on 1.53% risk-free rate, 6.31% market risk premium, minus 0.50% country risk premium, 0.36% currency risk, a levered beta of 1.15 and a peer group related equity-capital ratio.

The discount rate of 6.87% for chikungunya was based on 1.53% risk-free rate, 6.51% market risk premium, minus 0.45% country risk premium, 0.51% currency risk, a levered beta of 1.15 and a peer group related equity-capital ratio.

The impairment test for the manufacturing facility in Scotland has resulted in no impairment losses.

Filling & Packaging facility in Sweden:

The new Filling & Packaging facility in Sweden has been completed and was utilized for manufacturing activities for VLA2001 during the first half of 2022. Manufacturing processes are expected to continue until November 2022 and, in addition, manufacturing processes for DUKORAL are expected to be transferred to the new facility starting in 2023.

For impairment testing purposes it has been assumed that future cash flows will only be generated by DUKORAL. By June 30, 2022, the carrying value of the DUKORAL related property, plant and equipment, of utilized right-of-use assets as well as working capital amounted to €23.8 million. The Company's long range business model for DUKORAL, including assumptions on market size/market share, product sales and resulting profitability over a 5.5-year period as well as a Terminal Value for the period beyond 5.5 years, has been used as a basis to calculate the value in use.

Cash flows are generated over the planning horizon of 5.5 years as well as through the Terminal Value for the period beyond the 5.5 years planning horizon. In total, the value in use amounted to €82.4 million and exceeded the carrying value of €23.8 million of the DUKORAL CGU. The resulting overage amounting to €58.6 million is also sufficient to cover the carrying value of the generic filling & packaging facility amounting to €29.6 million.

The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 6.69%.

The discount rate of 6.69% for DUKORAL is based on 1.53% risk-free rate, 6.31% market risk premium, minus 0.56% country risk premium, 0.42% currency risk, a levered beta of 1.15 and a peer group related equity-capital ratio.

The impairment test for the Filling & Packaging facility in Sweden has resulted in no impairment losses..

11.2 Sensitivity to changes in assumptions

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

- discount rate
- reduction of expected revenues/royalties.

The net present value calculation uses a discount rate of 6.67% (December 31, 2021: 7.49%) for IXIARO, 6.87% for chikungunya and 6.69% (December 31, 2021: 7.23%) for DUKORAL. The recoverable amounts of these CGUs would equal its carrying amount if the key assumptions were to change as follows: increase in the discount rate from 6.67% to 44.89% would trigger an impairment loss for IXIARO (December 31, 2021: 4,562 basis points from 7.49% to 53.11%), increase from 6.87% to 47.94% would trigger an impairment loss for chikungunya and an increase from 6.69% to 12.52% (December 31, 2021: 587 basis points from 7.23% to 13.10%) would trigger an impairment loss for DUKORAL.



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 IXIARO, chikungunya and DUKORAL revenues of 10% would result in no impairment loss per June 30, 2022 unchanged to December 31, 2021.

Sensitivity analysis	June 30, 2022			December 31, 2021	
	IXIARO	DUKORAL	Chikungunya	IXIARO	DUKORAL
WACC	6.67%	6.69%	6.87%	7.49%	7.23%
Break-even WACC	44.89%	12.52%	47.94%	53.11%	13.10%
Impairment if WACC increases by 1%	NO	NO	NO	NO	NO
Impairment if sales reduce by 10%	NO	NO	NO	NO	NO

12. Financial Instruments

For the majority of the borrowings and other loans, the fair values are not materially different from their carrying amounts since the interest payable on those borrowings is either close to current market rates or the borrowings are of a short-term nature. As at June 30, 2022, material differences are identified only for guaranteed other loans. Based on an estimated arms' length interest rate of 9.87%, the fair value is €2.7 million (carrying amount is €3.0 million).

The fair values of all other financial instruments equal their book values as at June 30, 2022.

13. Inventories

Inventories include the following:

€ in thousand	June 30, 2022	December 31, 2021
Raw materials	99,195	102,082
Work in progress	116,188	55,681
Finished goods	14,636	8,135
Purchased goods (third party products)	3,638	7,362
Gross amount of Inventory before write-down	233,657	173,260
Less: write-down	(138,455)	(49,162)
Inventory	95,201	124,098

The increase in work in progress and finished goods is primarily related to the production of the COVID-19 vaccine.



Write-down provisions related to the inventory categories as follows:

€ in thousand	June 30, 2022	December 31, 2021
Raw materials	71,325	29,751
Work in progress	62,452	15,096
Finished goods	4,317	3,974
Purchased goods (third party products)	361	342
Total write-down provision	138,455	49,162

Valneva suspended the manufacturing of VLA 2001. As a result, raw material acquired to produce VLA2001 which cannot be repurposed and used for other products may go unused. As at the June 30, 2022, €71.3 million of the raw material write-down provision (December 31, 2021: €29.8 million) as well as €60.6 million of the work in progress write-down provision (December 31, 2021: €11.8 million) was related to VLA2001 due to the reduced expected sales volumes for VLA2001. As at June 30, 2022, VLA2001-related inventory amounted to €188.4 million gross and €56.5 million net. The remaining write-down provision was related to Valneva's commercialized vaccines IXIARO and DUKORAL due to the current COVID-19 pandemic. Commercial inventories not carrying a minimum residual shelf-life at the expected time of sale on the basis of the most current sales expectations have been written down. These write-downs totaled €6.2 million as at June 30, 2022 (December 31, 2021: €7.6 million), of which €4.3 million (December 31, 2021: €4.0 million) related to finished goods, €1.5 million (December 31, 2021: €3.3 million) related to work in progress and €0.4 million (December 31, 2021: €0.3 million) related to purchased goods.

In the six months ended June 30, 2022, the cost of inventories, which is recognized as an expense and is included in the position "Cost of goods and services", amounted to €110.0 million (six months ended June 30, 2021: €12.1 million), of which €97.0 million (six months ended June 30, 2021: €4.4 million) related to write-down of inventory. In the six months ended June 30, 2022, €100.6 million (six months ended June 30, 2021: €1.3 million) of these expenses related to the VLA2001 and stem from write-downs of inventory, which is expected not to be sold, failed batches and batches at risk of failure.

As the travel industry is recovering, the previous write-down of our travel vaccines was reassessed as of June 30, 2022. The release of write-downs relating to commercialized products which originally had been posted due to lower sales expectations and limited shelf life of the products led to an income of €3.5 million in the six months ended June 30, 2022 (six months ended June 30, 2021: €3.1 million expense).

14. Trade receivables

Trade receivables include the following:

€ in thousand	June 30, 2022	December 31, 2021
Trade receivables	16,253	44,030
Less: loss allowance of receivables	(2)	(17)
Trade receivables, net	16,251	44,013

During the six months ended June 30, 2022, and during the six months ended June 30, 2021, no material impairment losses were recognized. 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, 2022, trade receivables comprised of €16.2 million (December 31, 2021: €40.9 million) in receivables from contracts with customers.



15. Other assets

Other assets include the following:

€ in thousand	June 30, 2022	December 31, 2021
R&D tax credit receivables	40,031	35,390
Tax receivables	8,002	6,145
Prepaid expenses	5,359	5,131
Contract costs	3,010	3,010
Advance payments	2,035	27,375
Consumables and supplies on stock	1,414	1,722
Miscellaneous current assets	570	23
Other non-financial assets	60,422	78,796
Deposits	11,341	11,339
Miscellaneous financial assets	151	183
Other financial assets	11,491	11,522
Other assets	71,913	90,318
Less non-current portion	(17,948)	(19,282)
Current portion	53,965	71,036

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 increase in R&D tax credit receivables is mainly related to increased research and development expenditures primarily in connection to the COVID-19 and Lyme disease vaccine candidates.

As at June 30, 2022 and December 31, 2021, the deposits mainly related to a deposit associated with a lease agreement.

As at June 30, 2022, advance payments were mainly related to contract research agreements, while the balance as at December 31, 2021 included advance payments for material for the VLA2001 production as well.

Contract costs mainly relate to the collaboration with Pfizer (see Note 1) and refer to costs to obtain a contract. It will be amortized in line with the pattern of revenue recognition.



16. Cash and cash equivalents

Cash, cash equivalents and short-term deposits include the following:

€ in thousand	June 30, 2022	December 31, 2021
Cash on hand	8	3
Cash at bank	336,169	346,639
Restricted cash	48	44
Cash and cash equivalents	336,225	346,686

As at June 30, 2022, and December 31, 2021, the restricted cash was a Certificate of Deposit with restricted limited access to secure the credit limit for the Company's commercial card (\$50.0 thousand).

As at June 30, 2022, the minimum liquidity requirement for the Group according to the debt financing agreement with U.S. healthcare funds Deerfield and OrbiMed was €35.0 million (December 31, 2021: €50.0 million) (see Note 18).

17. Equity

17.1 Share capital and Share premium

Ordinary shares and the convertible preferred shares are classified as equity.

Number of shares	June 30, 2022	December 31, 2021
Ordinary shares issued (€0.15 par value per share)	117,331,343	105,190,223
Convertible preferred shares registered	20,514	48,862
Total shares issued	117,351,857	105,239,085
Less Treasury shares	(124,322)	(124,322)
Outstanding shares	117,227,535	105,114,763

In June 2022, Valneva and Pfizer entered into an Equity Subscription Agreement. For more details refer to Note 1.

Furthermore, 1,114,963 employee stock options (of which 615,918 were granted from ESOP 2013, 478,845 from ESOP 2015 and 20,200 from ESOP 2016) were exercised in the exercise period opened in January 2022, which resulted in an increase of 1,176,391 ordinary shares. On the other hand, 28,348 preferred shares for the Group's Executive Managers from the FCPS ("Free convertible preferred share") plan 2017-2021 were converted into 772,070 Company's ordinary shares. 636,648 free ordinary shares for the benefit of Management Board and Management Committee members from the free share plan 2019-2023 were fully vested and transferred to their beneficiaries on March 25, 2022.

**Conditional and authorized capital**

As at June 30, 2022, the Company had 3,900,994 shares of conditional capital in connection with :

- + the possible exercise of existing stock options;
- + the possible exercise of existing equity warrants (BSAs);
- + the possible final grant of existing Free Ordinary Shares.

Pursuant to resolution No. 28 of the Combined General Meeting held on June 23, 2022, the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future, under resolutions 20 to 27 of said Meeting, may not exceed €5,175 million, it being specified that to this maximum aggregate amount will be added the additional nominal amount of shares or securities to be issued in accordance with applicable legal or regulatory provisions and, if applicable, with contractual provisions providing for other forms of adjustment, in order to preserve the rights of the holders of securities or other rights giving immediate and/or future access to the capital of the Company.

17.2 Other reserves

€ in thousand	Other regulated reserves ⁴	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance as at January 1, 2021	52,820	(2,474)	(898)	12,368	(9,474)	52,342
Currency translation differences	—	(424)	—	—	—	(424)
Share-based compensation expense:						
- value of services	—	—	—	1,217	—	1,217
Purchase/sale of treasury shares	—	—	209	—	—	209
Balance as at June 30, 2021	52,820	(2,898)	(689)	13,585	(9,474)	53,344
Balance as at January 1, 2022	52,820	(5,146)	(645)	15,000	(9,517)	52,512
Currency translation differences	—	(567)	—	—	—	(567)
Defined benefit plan actuarial gains	—	168	—	—	—	168
Share-based compensation expense:						
- value of services	—	—	—	369	—	369
Purchase/sale of treasury shares	—	—	—	—	—	—
Balance as at June 30, 2022	52,820	(5,545)	(645)	15,369	(9,517)	52,482

4 Regulated non-distributable reserve relating to the merger with Intercell AG



18. Borrowings

In April 2022, Valneva signed an amendment to increase the principal amount of its existing €54.1 million (\$60 million) debt financing agreement with funds managed by leading U.S.-based healthcare investment firms Deerfield Management Company and OrbiMed. For more details refer to Note 1. As at June 30, 2022, a total of €72.4 million (\$80.0 million) was drawn down (December 31, 2021: €54.1 million (\$60.0 million)). As at June 30, 2022, the carrying amount was €71.0 million (December 31, 2021: €49.7 million), of which €11.2 million is reported as current (December 31, 2021: €5.3 million reported as current), refer to Note 1.

The loan is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries.

While the revenue covenant remained unchanged, the minimum cash requirement reduced from €50.0 million to €35.0 million upon execution of the amendment in April 2022.

The Group does not expect these limitations to affect its ability to meet its cash obligations. As at June 30, 2022, the Group's consolidated liquidity or net revenues did not fall below the covenant minimum values.

As of June 30, 2022, other loans included in borrowings related to financing of Research and Development expenses and CIR (R&D tax credit in France) of €2.4 million (December 31, 2021: €4.7 million) which are guaranteed by governmental parties and the CEPI loan in the amount of €4.7 million (December 31, 2021: €3.5 million), which relates to advanced payments received which are expected to be paid back in the future.

19. Contract liabilities

Development of contract liabilities:

€ in thousand	Six months ended June 30, 2022	Year ended December 31, 2021
Balance as at January 1	128,758	89,636
Revenue recognition	(4,090)	(89,364)
Exchange rate differences	368	7
Additions	290	128,479
Other releases	(506)	-
Closing balance	124,821	128,758
Less non-current portion	(5,110)	(4,741)
Current portion	119,711	124,017

As at June 30, 2022 and as at December 31, 2021, contract liabilities consisted mainly of advance payments received and related to the supply of VLA2001 and other commercial products. As at June 30, 2022 and as at December 31, 2021, €116.9 million were related to the APA with the EC (for more details refer to note 1).



VALNEVA SE

In the six month ended June 30, 2022, with regards to revenue recognized in 2022, €1.5 million related to the supply agreement with the Kingdom of Bahrain, and €1.2 million to Pfizer.

In 2021, €87.0 million of the revenue recognized related to the UK Supply Agreement; see Note 1.

**20. Refund liabilities**

Development of refund liabilities:

€ in thousand	Six months ended June 30, 2022	Year ended December 31, 2021
Balance as at January 1	254,581	111,426
Revenue Recognition	(89,356)	—
Additions	48,751	159,179
Payments	(12,771)	(18,022)
Other releases	-	(15,198)
Interest expense capitalized	4,812	8,478
Exchange rate difference	3 255	8,718
Closing balance	209,274	254,581
Less non-current portion	(66,689)	(158,970)
Current portion	142,585	95,611

As at June 30, 2022, €118.4 million related to the collaboration with Pfizer (refer to Note 4), of which €59.8 million non-current; €81.9 million (of which nil non-current) related to the CAPEX obligation, and €6.9 million related to an expected payment to GSK (thereof €6.9 million non-current) with regards to the termination of an agreement in 2019.

In the six months ended June 30, 2022, other revenue recognized in the amount of €89.4 million resulted from and new contractual terms of the royalty obligation and the reassessment of the likelihood towards the UK Authority following the settlement agreement.

As at December 31, 2021, €79.6 million (thereof €75.2 million non-current) related to the collaboration with Pfizer, €166.9 million (thereof €77.3 million non-current) related to the UK Supply Agreement, €6.4 million (thereof €6.3 million non-current) related to the expected payment to GSK related to the termination of an agreement in 2019. Other releases related to reductions in refund liabilities which have been reclassified in contract liabilities.

21. Provisions**21.1 Provisions for employee commitments**

€ in thousand	June 30, 2022	December 31, 2021
Employer contribution costs on share-based compensation plans	7,050	26,520
Phantom shares	4,977	14,267
Retirement termination benefits	297	422
Balance at June 30	12,324	41,210
Less non-current portion	(2,302)	(8,308)
Current portion	10,022	32,901



Employer contribution costs on share-based compensation plans and phantom shares are calculated at the balance sheet date. The share price of Valneva as at June 30, 2022, was €10.86 (December 31, 2021: €24.50). The decrease in the provision for employer contribution costs on share-based compensation plans as well as on phantom shares related to the exercise of programs in the period ended June 30, 2022 as well as related to the decrease in share-price.

21.2 Other provisions

€ in thousand	Six months	Year ended
	ended	December 31,
	June 30,	2021
	2022	
Balance as at January 1	15,806	2,124
Additions	31,305	13,682
Usage	(250)	—
Closing balance	46,862	15,806
Less non-current portion	—	—
Current portion	46,862	15,806

As at June 30, 2022, the increase in other provisions included €27.8 million of expected legal and settlement costs in connection with judicial or contractual claims and an increased provision of €3.1 million for the court proceeding related to the Intercell AG/Vivalis SA merger. For more information see Note 25.

22. Other liabilities

€ in thousand	June 30,	December 31,
	2022	2021
Deferred income	3,859	4,966
Other financial liabilities	47	44
Miscellaneous liabilities	3	8
Other liabilities	3,908	5,019
Less non-current portion	(654)	(69)
Current portion	3,254	4,950

**23. Contractual obligations**

The following tables disclose aggregate information about the Group's material long-term contractual obligations and the periods in which payments are due. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

At December 31, 2021								
€ in thousand	<1 year	1-2 years	2-3 years	3-5 years	5- 10 years	10-15 years	>15 years	Total
Borrowings	7,121	27,061	21,499	20,534	1,765	—	—	77,980
Lease liabilities	4,060	26,142	2,870	5,761	12,798	9,928	1,905	63,464
Refund liabilities	101,070	82,654	49,701	55,000	12,720	—	—	301,145
Trade payables and accruals	68,119	—	—	—	—	—	—	68,119
Tax and employee-related liabilities ⁵	10,101	—	—	—	—	—	—	10,101
Other liabilities	27	25	—	—	—	—	—	52
	190,499	135,882	74,070	81,295	27,282	9,928	1,905	520,861

At June 30, 2022								
€ in thousand	<1 year	1-2 years	2-3 years	3-5 years	5- 10 years	10-15 years	>15 years	Total
Borrowings	9,723	17,764	31,426	50,726	1,902	—	—	111,540
Lease liabilities	3,873	25,605	2,839	5,672	12,129	9,918	1,029	61,065
Refund liabilities	142,585	59,784	7,000	—	—	—	—	209,369
Trade payables and accruals	83,704	—	—	—	—	—	—	83,704
Tax and employee-related liabilities ³	9,555	—	—	—	—	—	—	9,555
Other liabilities	24	25	—	—	—	—	—	49
	249,464	103,179	41,265	56,398	14,031	9,918	1,029	475,283

⁵ Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required only for financial instruments.

**24. Cash Flow information**

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

€ in thousand	Six months ended June 30,	
	2022	2021
Profit/(Loss) for the year	(171,493)	(86,399)
Adjustments for non-cash transactions:		
■ Depreciation and amortization	11,153	6,101
■ Write-off / impairment fixed assets/intangibles	3,286	—
■ Share-based compensation expense/(income)	(8,921)	3,484
■ Income tax expense/(income)	2,271	668
■ (Profit)/loss from disposal of property, plant, equipment and intangible assets	46	23
■ Share of (profit)/loss from associates	(9)	90
■ Provision for employer contribution costs on share-based compensation plans	(19,290)	4,596
■ Other non-cash income/expense	8,972	(6,163)
■ Interest income	(35)	(228)
■ Interest expense	8,199	8,431
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):		
■ Other non-current assets	1,335	1,413
■ Long term contract liabilities	—	(58)
■ Long term refund liabilities	(94,780)	6,988
■ Other non-current liabilities and provisions	601	(2)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
■ Inventory	26,041	(97,006)
■ Trade and other receivables	44,960	(13,271)
■ Contract liabilities	(4,304)	248,910
■ Refund liabilities	44,654	(11,157)
■ Trade, other payables and provisions	47,904	19,139
Cash generated from/(used in) operations	(99,410)	85,560

25. 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; 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, 2021: €2.1 million). €3.1 million of additional expenses related to this litigation was included in "other expenses" in the period ended June 30, 2022.



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 is expected in the first half of 2023. After consultation with its external advisors the Company believes that this claim is unsubstantiated, and the filed litigation is not likely to succeed in court. 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.

26. Related party transaction

Key management compensation

The aggregate compensation of the members of the Company's Management Board includes the following:

€ in thousand	Six months ended June 30,	
	2022	2021
Salaries and other short-term employee benefits	886	677
Other long-term benefits	18	15
Share-based payments (expense of the period)	288	448
Key management compensation	1,192	1,140

Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounted to €162 thousand (six months ended June 30, 2021: €140 thousand).

R&D tax-credit

As at June 30, 2022, the aggregate amount of Valneva SE' R&D tax-credit financed by Bpifrance amounted to €2.4 million. Bpifrance was not a related party as at December 31, 2021.

Rendering of services

Services provided by Valneva to Groupe Grimaud La Corbière SAS, being 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.



€ in thousand	Six months ended June 30,	
	2022	2021
Provision of services:	37	47
Operating activities	1,099	73
Provision of services	1,136	120

Operating activities amounting to € 1.1 million included Valneva's agreement with Vital Meat SAS (part of Group Grimaud La Corbière SAS) according to which Valneva transferred certain assets (patent and cell lines) to Vital Meat SAS for a consideration of €1.0 million.

27. Events after the reporting period

Following the receipt of the EC's notice to terminate the APA for VLA2001 in May 2022, both parties entered into negotiations for a remediation plan. In July 2022, the EC approved an amendment to the APA, which was signed in July 2022. Under this amendment the Member States will purchase 1.25 million doses of VLA2001 in 2022, with the option to purchase an equivalent quantity later this year for delivery in 2022.

These conditions arose after the reporting period that ended on June 30, 2022 and there was no evidence of conditions that already existed at the end of this reporting period.

3. RESPONSIBILITY STATEMENT

We, hereby, declare that, to the best of our knowledge, the condensed consolidated financial statements for the half year ended June 30, 2022 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

AUGUST 11, 2022

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