
**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 10, 2021

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.

Exhibit

[99.1](#) [Press release dated August 10, 2021](#)

[99.2](#) [H1 2021 Half-Year Financial Report, January 1 to June 30, 2021](#)

[99.3](#) [Analyst Presentation](#)

SIGNATURES

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

Valneva SE
(Registrant)

Date: August 10, 2021

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

Valneva Reports H1 2021 Financial Results and Provides Business Update

Key R&D Milestones Achieved

- Positive topline Phase 3 results for single-shot chikungunya vaccine candidate VLA1553
 - Protective neutralizing antibodies induced in 98.5% of trial participants
- Recruitment completed for Phase 2 trial VLA15-221 of Lyme disease vaccine candidate including pediatric age group
- Recruitment completed for pivotal Phase 3 trial of inactivated, adjuvanted COVID-19 vaccine candidate VLA2001
 - Phase 3 topline data now expected early in fourth quarter 2021

Strong financial position

- \$107.6 million of gross proceeds raised in a US initial public offering and a concurrent private placement in Europe
- Cash and cash equivalents of €329.8 million at June 30, 2021

2021 financial guidance (excluding COVID) reconfirmed

- Total revenues, excluding VLA2001, of €80 million to €105 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, "Valneva is continuing to hit its major R&D objectives. We have just reported great results in the world's first ever Phase 3 trial for a chikungunya vaccine alongside excellent progress for our unique COVID and Lyme disease programs. Our successful Nasdaq listing marked a significant strategic step for Valneva as we look to continue to build our Company. Our team has delivered phenomenally well this year already and I would like to thank them for their continued commitment and dedication."

Financial Information

(unaudited results, consolidated under IFRS)

€ in million	6 months ending June 30	
	2021	2020
Total revenues	47.5	47.9
Product sales	31.8	40.9
Net profit/(loss)	(86.4)	(25.6)
EBITDA	(80.1)	(17.2)
Cash (at end of period)	329.8	200.0

Saint Herblain (France), August 10, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical needs, today reported its consolidated financial results for the first half of the year, ended June 30, 2021. 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 www.valneva.com.

Valneva will provide a live webcast of its first half financial results conference call beginning at 3 p.m. CEST today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/pror7sgm>

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15

Acceleration of Pediatric Development

Valneva is developing VLA15, a vaccine candidate targeting *Borrelia*, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of *Borrelia* representing the most common strains found in the United States and Europe. VLA15 is currently the only vaccine undergoing clinical trials against Lyme disease.

Valneva has previously announced a collaboration with Pfizer for late phase development and, if approved, commercialization of VLA15¹. Valneva has reported positive initial results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults.

To accelerate VLA15's pediatric development, Valneva and Pfizer initiated an additional Phase 2 trial in March 2021, VLA15-221. In July 2021, Pfizer and Valneva announced recruitment completion for VLA15-221 with a total of 625 participants, 5 to 65 years of age, randomized in the trial. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3. Topline results for VLA15-221 are expected in the first half of 2022.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553

Positive Phase 3 Results reported

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, to Valneva's knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials worldwide.

At the beginning of August 2021, Valneva announced positive topline results for the Phase 3 pivotal trial of VLA1553. The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the U.S., met its primary endpoint inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95%CI: 96.2-99.6). The seroprotection rate result of 98.5% exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission of VLA1553 under the accelerated approval pathway. The vaccine candidate was highly immunogenic with a Geometric Mean Titer of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 trial.

Additionally, VLA1553 was also highly immunogenic in elderly study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events. The trial will continue towards final analysis including the six-month safety data. Final trial results are expected within the next six months.

Valneva's chikungunya program was awarded Breakthrough Therapy Designation by the FDA in July 2021. This new milestone came in addition to the FDA Fast Track designation and the European Medicines Agency (EMA)'s PRIME designation which the Company received in December 2018 and in October 2020, respectively. The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

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 VLA1553². The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019³, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

SARS-CoV-2 VACCINE CANDIDATE – VLA2001

Recruitment Completed for Pivotal Phase 3 Trial

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO[®].

At the beginning of June 2021, Valneva announced that recruitment had been completed for VLA2001's pivotal Phase 3 trial "Cov-Compare" (VLA2001-301) with over 4,000 randomized participants. In the Phase 1/2 clinical trial, VLA2001 showed high immunogenicity and was generally well tolerated, with no safety concerns identified⁴. Cov-Compare phase 3 topline data are expected early in the fourth quarter of 2021. Valneva expects to commence rolling submission with the UK Medicines and Healthcare products Regulatory Agency in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

In parallel to the Cov-Compare trial, Valneva is studying COVID-19 variants to be in a position to manufacture variant-based vaccines. Valneva is also participating in a UK Government-funded clinical trial looking at different COVID-19 "booster" vaccines. The COV-Boost trial, led by University Hospital Southampton NHS Foundation Trust, looks at seven different COVID-19 vaccines, including VLA2001, as potential boosters, and is also evaluating dosage levels. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus. The COV-Boost trial is fully recruited. Valneva has also commenced production of VLA2001 at its facilities in Scotland and Sweden in order to optimize the timeline for potential deliveries of the vaccine.

Although vaccines against SARS-CoV-2 have already been approved, given the potential advantages often associated with inactivated whole virus vaccines, Valneva believes its vaccine candidate could play a role in the overall portfolio of SARS-CoV-2 vaccines that will address the global need during the pandemic and in the future.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025⁵. So far, the UK Government has ordered 100 million doses for supply in 2021 and 2022.

Commercial Vaccines

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

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

Sales of IXIARO[®] were €25.4 million in the first half of 2021 compared to €28.4 million in the first half of 2020. While the COVID-19 pandemic is continuing to adversely impact the travel industry and vaccine sales to the private market, the impact on IXIARO[®] sales during the first half of 2021 was mitigated by the Company's contract with the U.S. Government's Department of Defense (DoD).

CHOLERA / ETEC⁶-DIARRHEA VACCINE (DUKORAL[®])

DUKORAL[®] is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC, 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 ETEC⁵.

DUKORAL[®] recorded sales of €0.4 million in the first half of 2021 compared to €12.1 million in the first half of 2020. First half 2021 sales continued to be significantly affected by the COVID-19 pandemic's impact on the travel industry.

First Half 2021 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €47.5 million in the first half of 2021 compared to €47.9 million in the first half of 2020. Product sales declined by 22.4% to €31.8 million in the first half of 2021 compared to €40.9 million in the first half of 2020. On a constant exchange rate (CER) basis, product sales declined by 18.6% in the first half of 2021 compared to the first half of 2020 due to the impact of the COVID-19 pandemic on the travel industry. IXIARO[®]/JESPECT[®] sales declined by 10.6% (3.5% at CER) to €25.4 million and DUKORAL[®] sales by 96.5% (96.6% at CER) to €0.4 million in the first half of 2021 compared to €28.4 million and €12.1 million respectively in the first half of 2020. Third Party product sales grew to €5.9 million in the first half of 2021 from €0.4 million in the first half of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur[®]/RabAvert[®] and Encepur[®] in certain territories that commenced in 2021.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €15.7 million in the first half of 2021 compared to €7.0 million in the first half of 2020. This increase was attributable to higher revenues related to the Lyme R&D collaboration agreement with Pfizer, incremental revenues related to the collaboration with Instituto Butantan for providing VLA1553 in LMICs as well as higher revenues generated in the CTM Manufacturing unit in Sweden.

Operating Result and EBITDA

Costs of goods and services sold (COGS) were €34.8 million in the first half of 2021. Gross margin on product sales was 39.2% compared to 55.7% in the first half of 2020. The decline was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €11.7 million were related to IXIARO[®]/JESPECT[®] sales, yielding a product gross margin of 54.1%. COGS of €3.6 million were related to DUKORAL[®] sales, causing a negative product gross margin. Of the remaining COGS in the first half of 2021, €4.1 million were related to the Third-Party product distribution business, €4.2 million to start-up costs of the COVID-19 business and €11.3 million to cost of services. In the first half of 2020, overall COGS were €22.5 million, of which €18.1 million related to cost of goods and €4.4 million related to cost of services.

Research and development investments continued to increase in the first half of 2021, growing to €78.7 million compared to €33.1 million in the first half of 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine candidate VLA2001 as well as Phase 3 clinical study costs for Valneva's chikungunya vaccine program VLA1553. Excluding COVID-19, research and development investments amounted to €32.6 million in the first half of 2021 compared to

€31.5 million in the first half of 2020. Marketing and distribution expenses in the first half of 2021 amounted to €9.6 million compared to €10.0 million in the first half of 2020. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity as a result of the COVID-19 pandemic. Marketing and distribution expenses in the first half of 2021 notably included €2.0 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first half of 2020). In the first half of 2021, general and administrative expenses increased to €20.9 million from €10.6 million in the first half of 2020, mainly driven by increased costs to support corporate transactions and projects including increased resources in support of incremental COVID activities.

Other income, net of other expenses, increased to €10.4 million in the first half of 2021 from

€6.5 million in the first half of 2020. This increase was mainly driven by increased R&D tax credits directly resulting from increased R&D spending.

Valneva recorded an operating loss of €86.2 million in the first half of 2021 compared to an operating loss of €21.9 million in the first half of 2020. EBITDA loss in the first half of 2021 was €80.1 million compared to an EBITDA loss of €17.2 million in the first half of 2020.

Net Result

In the first half of 2021, Valneva generated a net loss amounting to €86.4 million compared to a net loss of €25.6 million in the first half of 2020.

Finance costs and currency effects in the first half of 2021 resulted in a net finance income of €0.5 million, compared to a net finance expense of €5.6 million in the first half of 2020. This was mainly a result of foreign exchange gains amounting to €8.7 million in the first half of 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss (net of gains on derivative financial instruments) of €1.7 million in the first half of 2020. Interest charges increased to €8.4 million in the first half of 2021 compared to €3.9 million in the same period of 2020. This growth was driven by increased interest charges related to refund liabilities as well as increased interest charges related to the financing agreement with U.S. healthcare funds Deerfield & OrbiMed entered into in 2020.

Cash Flow and Liquidity

Net cash generated by operating activities amounted to €84.2 million in the first half of 2021 compared to €113.2 million in the first half of 2020 mainly derived by milestone payments related to the COVID supply agreement concluded with the UK Government in September 2020. The net cash generated by operating activities in the first half of 2020 mainly derived from the \$130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement.

Cash outflows from investing activities amounted to €39.9 million in the first half of 2021 compared to €1.8 million in the first half of 2020 mainly as a result of purchases of equipment related to the site expansion activities for COVID vaccine manufacturing in both Scotland and Sweden.

Net cash generated from financing activities amounted to €78.7 million in the first half of 2021 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 inflows in the first half of 2020 amounted to €24.5 million and mainly consisted of net proceeds from the financing arrangement with U.S. healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank.

Liquid funds increased to €329.8 million as of June 30, 2021 compared to €204.4 million as of December 31, 2020. The main changes related to payments made by the UK Government within the framework of the UK COVID-19 partnership as well as the proceeds from the Global Offering in May 2021.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of 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 as an aid to further understand Valneva's current performance, performance trends, and financial condition.

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

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

€ in million	6 months ending June 30	
	2021	2020
Operating Loss	(86.2)	(21.9)
Add:		
Amortization	3.1	3.0
Depreciation	3.0	1.7
EBITDA	(80.1)	(17.2)

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and 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.

Media & Investors Contacts

Laëtitia Bachelot-Fontaine

VP Global Communications & European Investor Relations

M +33 (0)6 4516 7099

laetitia.bachelot-fontaine@valneva.com

Joshua Drumm

VP Global Investor Relations

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to expected total revenues and R&D expenses for full fiscal year 2021, the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates and estimates for future performance. 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 performance. 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 largely 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, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection, as well as those risks and uncertainties discussed or identified in Valneva's public filings with the Autorité des Marchés Financiers (AMF) in France, including those listed in the Company's 2020 Universal Registration Document filed with the AMF on April 9, 2021, which is available on the Company's website and on the website of the AMF (www.amf-france.org), and public filings and reports filed with the U.S. Securities and Exchange Commission. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing the information in these materials as of this press release, 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.

¹ Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

² Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

³ CEPI awards up to \$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

⁴ Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

⁵ Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program

⁶ 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.

H1 2021

**HALF-YEAR
FINANCIAL REPORT**

JANUARY 1 TO JUNE 30, 2021

August 10, 2021

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





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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 does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful.

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 2021". 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 2021 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 with the Autorité des Marchés Financiers (AMF) in France, including those listed in the Company's 2020 Universal Registration Document filed with the AMF on April 9, 2021, which is available on the Company's website and on the website of the AMF (www.amf-france.org), and public filings and reports filed with the U.S. Securities and Exchange Commission.



1. MANAGEMENT REPORT

1.1 Overview

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

The Company takes a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and 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.

Valneva has over approximately 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 assets and commercial products. Each of the assets in its portfolio are differentiated products that either target diseases currently lacking a preventative and effective therapeutic treatment option or that the Company believes may have meaningful therapeutic advantages relative to other existing vaccine and treatment options.

Valneva strives to develop products towards marketing approval; the Company will also continue to create value by monetizing its R&D assets through licensing and partnering as illustrated by the signing of its collaborations for its Lyme disease and COVID-19 vaccine candidates.

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 Hemisphere.

According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 people in the United States² are diagnosed with Lyme disease each year with at least a further 200,000 cases

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

² As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article



occurring annually in Europe³. Research suggests that Lyme disease cases may rise 92% by 2100 in the U.S. due to climate change. Although most patients recover from Lyme disease, 10-20% have persistent symptoms, which for some are chronic and disabling. Studies indicate that Lyme disease costs up to approximately \$1.3 billion each year in direct medical costs in the U.S. alone. The global market for a Lyme disease vaccine is estimated to reach \$1 billion by 2030.

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 and anticoagulants and, in the case of an infected tick, *Borrelia* bacteria as well.

Early symptoms of Lyme disease can often be overlooked or misinterpreted as they are often associated with other, often less severe, illnesses. These symptoms include fever, chills, headache, fatigue, muscle and joint aches, as well as swollen lymph nodes. In 70-80% of cases, a gradually expanding rash called "erythema migrans" forms. As this rash enlarges, it appears as a target or bulls-eye, three to thirty days after infection. Left untreated, the disease can disseminate beyond this initial area into the circulation, the joints, the heart, the brain and the rest of the central nervous system. If not treated, once the infection has progressed it can cause serious complications, including arthritis with severe joint pain, heart palpitations or irregular heartbeat, and inflammation of the brain and spinal cord.

When diagnosed sufficiently early, Lyme disease can be successfully treated with a two-week to four-week course of oral antibiotics. However, given that the disease is often misdiagnosed in its early stages, patients often miss this therapeutic window. Additionally, chronic symptoms can commonly persist beyond antibiotic treatment, a set of conditions referred to as Post-Treatment Lyme Disease Syndrome, or PTLDS. There are no proven treatments for PTLDS, which often resolves over time but unfortunately may take many months. There is therefore a strong emphasis on prophylactic approaches to preventing the disease through avoiding areas where ticks are prevalent, wearing clothing which minimizes tick exposure, using insect repellants and physically removing ticks that have attached. However, even with education and behavior modification, Lyme disease remains a serious and prevalent disease in the regions where it is endemic.

VLA15 Vaccine Candidate

Valneva is advancing a late-stage multivalent vaccine candidate, VLA15, which is currently the only vaccine undergoing clinical trials against Lyme disease. VLA15 is designed to prevent Lyme disease by generating antibodies that target the OspA protein 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 2017⁴ and, in April 2020, Valneva announced a collaboration with Pfizer for late clinical development and commercialization of VLA15. If approved, Pfizer will commercialize VLA15 and Valneva will be eligible to receive substantial milestone and royalty payments⁵.

Valneva has reported topline results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults, in which VLA15 generated high levels of antibodies against all six *Borrelia* strains. Valneva and Pfizer announced in December 2020 that they had accelerated the development of VLA15 for pediatric use with an additional Phase 2 clinical trial, VLA15-221, initiated in March 2021. The trial builds on previous positive Phase 2 trials and includes both adult and pediatric participants with the aim to support acceleration of the

³ As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed

⁴ Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

⁵ Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15



vaccine candidate's pediatric program. In July 2021, Pfizer and Valneva announced recruitment completion for VLA15-221 with a total of 625 participants, 5 to 65 years of age, randomized in the trial. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3. Topline results for VLA15-221 are expected in the first half of 2022.

Chikungunya Vaccine Candidate – VLA1553

Overview of the Chikungunya Virus

Chikungunya is a mosquito-borne virus posing a serious public health problem in tropical and sub-tropical regions. 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 and can cause a significant economic impact. There have been more than three million reported cases in the Americas since the virus first arrived there in 2013. In 2020, there were approximately 95,000 suspected cases reported in the Americas and well as approximately 32,000 suspected cases in India and 11,000 in Thailand. The true incidence of chikungunya is likely to be much higher due to the level of under-reporting, with available studies suggesting an under-reporting factor of five times due to difficulty in diagnosing the symptoms, which can be similar to those of dengue and Zika, and due to lack of access to good medical care in certain areas where outbreaks are prevalent.

Chikungunya infection is characterized by an acute onset of fever, rash, myalgia and sometimes debilitating arthritic pain in multiple joints. Chikungunya causes symptomatic infection in 72-92% of infected humans around four to seven days after infection. Mortality of chikungunya is low (<1%) but the chronicity of its joint pain (arthralgia) and inflammatory symptoms represent a significant burden of disease with potential long-term debilitating impact. In addition to having significant impact on patients 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. The current standard of care to treat individuals who have become infected with chikungunya is the application of non-steroidal anti-inflammatory drugs to relieve symptoms. To date, preventive measures rely on avoiding mosquito bites. 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. To Valneva's knowledge, VLA1553 is currently the only chikungunya vaccine candidate in Phase 3 clinical trials that targets long-term protection following the administration of a single dose. Valneva intends to commercialize VLA1553, if approved, as part of its travel vaccine portfolio through leveraging its existing manufacturing and commercial operations. The global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032.

At the beginning of August 2021, Valneva reported positive topline results for the Phase 3 pivotal trial of VLA1553. The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the U.S., met its primary endpoint inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95%CI: 96.2-99.6). The seroprotection rate result of 98.5% exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission of VLA1553 under the accelerated approval



pathway. The vaccine candidate was highly immunogenic with a GMT of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 trial.

Additionally, VLA1553 was also highly immunogenic in elderly Phase 3 study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

The trial will continue towards final analysis including the six-month safety data. Final trial results are expected within the next six months.

Valneva's chikungunya program was awarded Breakthrough Therapy Designation by the FDA in July 2021. This new milestone came in addition to the FDA Fast Track designation and the European Medicines Agency (EMA)'s PRIME designation which the Company received in December 2018 and in October 2020, respectively. The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

To make VLA1553 more accessible to Low- and Middle-Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing and marketing of VLA1553. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

SARS-CoV-2 Vaccine Candidate – VLA2001

Overview of COVID-19

COVID-19 is a disease caused by infection with SARS-CoV-2, a strain of coronavirus. Respiratory illness is the most common symptom associated with COVID-19 with a severity ranging from mild disease to life-threatening acute respiratory distress syndrome. Patients with advanced age, comorbidities such as obesity, diabetes and cardiovascular disease, or an immunocompromised state are at increased risk for poor outcomes. COVID-19 has been declared a pandemic by the World Health Organization (WHO). As of July 15, 2021, more than 190 million people have been infected and COVID-19 has caused more than 4 million deaths worldwide⁶.

While a number of vaccines against COVID-19 have already been approved for use and multiple candidates remain in late-stage development, VLA2001 currently is the only inactivated, whole virus vaccine candidate in clinical trials in Europe. Valneva believes VLA2001, if approved, could potentially offer clear benefits compared to other vaccines that obtain initial regulatory approvals in terms of safety, cost, ease of

⁶ [COVID Live Update: Worldometer \(worldometers.info\)](https://www.worldometers.info/coronavirus/)



manufacture and distribution, and could also be rapidly adapted to offer protection against mutations of the virus. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines.

VLA2001 Vaccine Candidate

VLA2001 is an inactivated, adjuvanted, whole-virus vaccine candidate produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO[®]. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. This adjuvant combination has consistently induced higher antibody levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. CpG 1018 adjuvant, supplied by Dynavax Technologies Corporation (Nasdaq: DVAX), is a component of the U.S. FDA- and EMA-approved HEPLISAV-B[®] vaccine. The manufacturing process for VLA2001 includes chemical inactivation with Betapropiolactone (BPL) to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

In September 2020, Valneva announced a collaboration with the UK government, which has the option to purchase up to 190 million doses through 2025⁷. So far, the UK government has ordered 100 million doses for supply in 2021 and 2022. Valneva is also in discussions with the European Commission.

At the beginning of June 2021, Valneva announced that recruitment had been completed for VLA2001's pivotal Phase 3 trial "Cov-Compare" (VLA2001-301) with over 4,000 randomized participants. In the Phase 1/2 clinical trial, VLA2001 showed high immunogenicity and was generally well tolerated, with no safety concerns identified⁸. Cov-Compare phase 3 topline data are expected early in the fourth quarter of 2021. Valneva expects to commence rolling submission with the UK Medicines and Healthcare products Regulatory Agency in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

In parallel to the Cov-Compare trial, Valneva has developed viral seed banks to be in a position to manufacture variant-based vaccines. Valneva is also participating in a UK government-funded clinical trial looking at different COVID-19 'booster' vaccines. The COV-Boost trial, led by University Hospital Southampton NHS Foundation Trust, looks at seven different COVID-19 vaccines, including VLA2001, as potential boosters. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus. The COV-Boost trial is now fully recruited and initial results are expected in September 2021. Valneva has also commenced production of VLA2001 at its facilities in Scotland and Sweden in order to optimize the timeline for potential deliveries of the vaccine.

1.2.2 Commercial products

Valneva commercializes two fully owned travel vaccines, IXIARO[®]/JESPECT[®] and DUKORAL[®]. Sales from these two products are complemented by sales from the distribution of third-party products in markets where Valneva operates its own marketing and sales infrastructure (US, Canada, Nordic countries, UK, Austria and France).

Sales in the first half of 2021 have been adversely affected by the COVID-19 pandemic's impact on the travel industry and amounted to €31.8 million compared to €40.9 million in the first half of 2020.

⁷ [Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program](#)

⁸ [Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001](#)

**Japanese encephalitis vaccine (IXIARO®/JESPECT®)**

Valneva's Japanese encephalitis vaccine is the only approved and available 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.

In March 2020, the FDA approved the extension of IXIARO®'s shelf life from 24 months to 36 months⁹, an important achievement supporting supply management flexibility.

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

Valneva distributes IXIARO® directly to the U.S. Government's Department of Defense (DoD). In September 2020, the Defense Logistics Agency, or 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. The current base year has a minimum value of approximately \$53 million for 370,000 doses, and the option years have minimum values of \$46 million for 320,000 doses and \$36 million for 250,000 doses, respectively, if DLA exercises those options.

In the first half of 2021, revenues from IXIARO®/JESPECT® product sales were €25.4 million compared to €28.4 million in the first half of 2020. Sales continued to be affected by the impact of the COVID-19 outbreak on the travel market.

Cholera / ETEC¹⁰ 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 2 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 WHO.

In the first half of 2021, revenues from DUKORAL® sales reached €0.4 million compared to €12.1 million in the first half of 2020. DUKORAL® sales were adversely impacted by the COVID-19 outbreak on the travel market.

1.2.3 Other additional sources of revenues

⁹ [Valneva Announces FDA Approval of IXIARO® Shelf Life Extension to 36 Months; New US Military RFP Issued](#)

¹⁰ *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.*



Third-party distribution

To further leverage its commercial infrastructure, 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 and tick-borne encephalitis, leveraging its commercial infrastructure in Canada, the United Kingdom, France and Austria.

In the first half of 2021, total revenues from third party distribution were €5.9 million compared to €0.4 million in the first half of 2020.

Collaborations, Licensing and Services

Valneva derives revenues from collaboration and partnership agreements. The Company's primary source of collaboration revenues is currently through its research collaboration and license agreement with Pfizer Inc., entered into in April 2020, 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 upfront payment of \$130 million. Under the terms of the agreement, Valneva and Pfizer will each contribute towards development costs, and Pfizer is obligated to pay Valneva up to \$178 million in development milestones and low double-digit tiered royalties starting at 19% on net sales of licensed products, subject to specified offsets and reductions.

In September 2020, Valneva also entered into a collaboration with the government of the UK, pursuant to which the government ordered 60 million doses of VLA2001, Valneva's COVID-19 vaccine candidate, for delivery in the second half of 2021 and in 2022. In January 2021, the UK government exercised its option to order 40 million doses of VLA2001 for supply in 2022. The UK government retains options over a further 90 million doses for supply between 2023 and 2025.

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 €15.7 million in the first half of 2021 compared to €7.0 million in the first half of 2020.

1.2.4 Other Business Updates

Closing of \$107.6 million Global Offering and Nasdaq listing

In May 2021, Valneva announced the closing of a global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares, after full exercise of the overallotment option granted to the underwriters (the "Option"). The public offering consisted of 2,850,088 American Depositary Shares ("ADSs"), each representing two ordinary shares, in the U.S. at an offering price of \$26.41 per ADS (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, after full exercise of the Option, before deducting underwriting commissions and estimated expenses payable by the Company, were



approximately \$107.6 million (€89.6 million). Valneva's ordinary shares are listed on Euronext Paris under the symbol "VLA" and its ADSs began trading on the Nasdaq Global Select Market on May 6, 2021, under the symbol "VALN".

Amendment to Deerfield and OrbiMed Debt Facility Terms

In January 2021, Valneva announced an amendment to the terms of its existing debt facility with U.S.-based healthcare investment firms Deerfield Management Company and OrbiMed. Noting the COVID-19 pandemic impact on the travel industry, and following a temporary waiver of the revenue covenant for the second half of 2020, Valneva, Deerfield and OrbiMed agreed to modify this covenant for 2021 and 2022, replacing the twelve month rolling €115 million with quarterly minimum revenues representing an annual total of €64 million in 2021 and an annual total of €103.75 million in 2022. The parties also agreed to modify the minimum cash requirement to €50 million for 2021 and 2022 and to €35 million for the following years.

Valneva joined Euronext SBF 120 and CAC Mid 60 Indices

In March 2021, Valneva announced that it joined the SBF 120 and CAC Mid 60 indices, following the recent quarterly review of Euronext Paris Indices Committee.

The SBF 120 index is one of the flagship indices of the Paris Stock Exchange, consisting of the top 120 stocks listed on Euronext Paris in terms of both liquidity and market capitalization. The CAC Mid 60 index includes 60 companies of national and European importance. It represents the 60 largest French equities beyond the CAC 40 and the CAC Next 20. This total of 120 companies composes the SBF 120.

Valneva announced Supervisory Board change

In March 2021, Valneva announced that MVM Partner Thomas Casdagli had stepped down from the Supervisory Board. Further to MVM's investment in Valneva in 2016, MVM had a right to appoint a Supervisory Board member. This right has now lapsed.

Termination of Liquidity Contract with Oddo BHF and Natixis

In June 2021, Valneva announced that it had terminated the liquidity agreement relating to its ordinary shares concluded with Oddo BHF and Natixis as the liquidity of the Company's securities had improved. 4,025 Valneva shares and €556,103.17 in cash were booked on the liquidity account on the termination date.



1.3 Financial Review

FIRST HALF 2021 FINANCIAL REVIEW (unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €47.5 million in the first half of 2021 compared to €47.9 million in the first half of 2020.

Product sales declined by 22.4% to €31.8 million in the first half of 2021 compared to €40.9 million in the first half of 2020. On a CER basis¹¹, product sales declined by 18.6% in the first half of 2021 compared to the first half of 2020 due to the impact of the COVID-19 pandemic on the travel industry. IXIARO®/JESPECT® sales declined by 10.6% (3.5% at CER) to €25.4 million and DUKORAL® sales by 96.5% (96.6% at CER) to €0.4 million in the first half of 2021 compared to €28.4 million and €12.1 million respectively in the first half of 2020. Third Party product sales grew to €5.9 million in the first half of 2021 from €0.4 million in the first half of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur®/RabAvert® and Encepur® in certain territories that commenced in 2021.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €15.7 million in the first half of 2021 compared to €7.0 million in the first half of 2020. This increase was attributable to higher revenues related to the Lyme R&D collaboration agreement with Pfizer, incremental revenues related to the collaboration with Instituto Butantan for providing VLA1553 in LMICs as well as higher revenues generated in the CTM Manufacturing unit in Sweden.

Operating Result and EBITDA

Costs of goods and services sold (COGS) were €34.8 million in the first half of 2021. Gross margin on product sales was 39.2% compared to 55.7% in the first half of 2020. The decline was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €11.7 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 54.1%. COGS of €3.6 million were related to DUKORAL® sales, causing a negative product gross margin. Of the remaining COGS in the first half of 2021, €4.1 million were related to the Third-Party product distribution business, €4.2 million to start-up costs of the COVID-19 business and €11.3 million to cost of services. In the first half of 2020, overall COGS were €22.5 million, of which €18.1 million related to cost of goods and €4.4 million related to cost of services.

Research and development investments continued to increase in the first half of 2021, growing to €78.7 million compared to €33.1 million in the first half of 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine candidate VLA2001 as well as Phase 3 clinical study costs for Valneva's chikungunya vaccine program VLA1553. Excluding VLA2001, research and development investments amounted to €32.6 million in the first half of 2021 compared to €31.5 million in the first half of 2020. Marketing and distribution expenses in the first half of 2021 amounted to €9.6 million compared to €10.0 million in the first half of 2020. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity as a result of the COVID-19 pandemic.

¹¹ CER: Constant Exchange Rate; First half 2020 actuals restated to first half 2021 average exchange rates



Marketing and distribution expenses in the first half of 2021 notably included €2.0 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first half of 2020). In the first half of 2021, general and administrative expenses increased to €20.9 million from €10.6 million in the first half of 2020, mainly driven by increased costs to support corporate transactions and projects including increased resources in support of incremental COVID activities.

Other income, net of other expenses, increased to €10.4 million in the first half of 2021 from €6.5 million in the first half of 2020. This increase was mainly driven by increased R&D tax credits directly resulting from increased R&D spending.

Valneva recorded an operating loss of €86.2 million in the first half of 2021 compared to an operating loss of €21.9 million in the first half of 2020. EBITDA loss in the first half of 2021 was €80.1 million compared to an EBITDA loss of €17.2 million in the first half of 2020.

Net Result

In the first half of 2021, Valneva generated a net loss amounting to €86.4 million compared to a net loss of €25.6 million in the first half of 2020.

Finance costs and currency effects in the first half of 2021 resulted in a net finance income of €0.5 million, compared to a net finance expense of €5.6 million in the first half of 2020. This was mainly a result of foreign exchange gains amounting to €8.7 million in the first half of 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss (net of gains on derivative financial instruments) of €1.7 million in the first half of 2020. Interest charges increased to €8.4 million in the first half of 2021 compared to €3.9 million in the same period of 2020. This growth was driven by increased interest charges related to refund liabilities as well as increased interest charges related to the financing agreement with U.S. healthcare funds Deerfield & OrbiMed entered into in 2020.

Cash Flow and Liquidity

Net cash generated by operating activities amounted to €84.2 million in the first half of 2021 compared to €113.2 million in the first half of 2020 mainly derived by milestone payments related to the COVID supply agreement concluded with the UK government in September 2020. The net cash generated by operating activities in the first half of 2020 mainly derived from the \$130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement.

Cash outflows from investing activities amounted to €39.9 million in the first half of 2021 compared to €1.8 million in the first half of 2020 mainly as a result of purchases of equipment related to the site expansion activities for COVID vaccine manufacturing in both Scotland and Sweden.

Net cash generated from financing activities amounted to €78.7 million in the first half of 2021 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 inflows in the first half of 2020 amounted to €24.5 million and mainly consisted of net proceeds from the financing arrangement with U.S. healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank.

Liquid funds increased to €329.8 million as of June 30, 2021 compared to €204.4 million as of December 31, 2020. The main changes related to payments made by the UK government within the framework of the UK COVID-19 partnership as well as the proceeds from the Global Offering in May 2021.



Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of 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 as an aid to further understand Valneva's current performance, performance trends, and financial condition.

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

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

€ in million	6 months ending June 30	
	2021	2020
Operating Loss	(86.2)	(21.9)
Add:		
Amortization	3.1	3.0
Depreciation	3.0	1.7
EBITDA	(80.1)	(17.2)

1.4 Operational and Strategic Outlook 2021

Noting the impact of the COVID-19 pandemic on Valneva's travel vaccines sales in the first half of the year and the revenue recognition of the Pfizer and UK government deals, Valneva reconfirms its 2021 guidance range for:

- Total revenues, excluding VLA2001, of €80 million to €105 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million

Strategically, Valneva will continue to utilize its proven product development capabilities to advance its clinical programs to regulatory approval and commercialization. As the Company advances its late-stage portfolio, it also remains committed to investing in its research and development pipeline in order to develop a balanced pipeline. This will include earlier stage R&D assets as well as new targets and indications where it believes it can make a significant difference.

To execute this strategy, Valneva is pursuing the following near-term goals:

- Advance VLA15 for the prevention of Lyme disease, in collaboration with Pfizer.
- Complete development and seek regulatory approval for VLA1553 as a prophylactic vaccine candidate against chikungunya virus.
- Complete development, seek regulatory approval for and commercialize VLA2001 as a prophylactic vaccine candidate for the prevention of COVID-19.
- Continue to fund its research and development pipeline and manufacturing platform.
- Pursue partnerships to maximize full potential of clinical and commercial portfolio.



- Deepen its pipeline of pre-clinical and clinical programs to develop new vaccines addressing diseases with significant unmet need.

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 2021. These risk factors track those in section 1.5 of the Company's universal registration document (*document d'enregistrement universel*) submitted to the French Financial Markets Authority (*Autorité des Marchés Financiers* or AMF), on April 9, 2021 (AMF number D.21-0286). 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 universal registration document and 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 (a) its COVID-19 vaccine is still being developed and (b) 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 expected to recover slowly. 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 develop Valneva's COVID-19 vaccine candidate. Valneva's COVID-19 vaccine candidate, VLA2001, is currently in Phase 3 clinical trials in the UK, and the Company expects to announce topline results of this trial early in the fourth quarter of 2021. Valneva expects to commence rolling submission with the UK Medicines and Healthcare products Regulatory Agency in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

Additionally, VLA2001 is one of the vaccines being tested in a booster trial sponsored by the UK government, and topline results from this study are expected in September 2021. If the results of the ongoing trials are not as expected, this could prevent or significantly delay regulatory approval and commercialization of VLA2001. Numerous other factors could also delay or prevent development and commercialization of VLA2001, including but not limited to technical or scientific failures, inability to enter into agreements with key suppliers, inability or unwillingness of key suppliers to provide equipment or materials on time, competition to recruit patients for clinical trials, difficulties in developing or reproducing biological manufacturing processes, rejection by health authorities of clinical trial or marketing applications, changes in customer priorities (for example, preference for a vaccine based on a particular strain of the virus or for a vaccine based on a particular technology), lower levels of efficacy of the current formulation of VLA2001 against additional variants of the virus, or termination of a key customer agreement (such as the agreement with the UK government) or supplier agreement (such as the agreement with Dynavax). A failure to develop this vaccine candidate may result in financial losses due to restructuring costs and development expenses. Further, Valneva's stock price and market capitalization, including through the Company's Nasdaq listing in May, have significantly increased since Valneva announced its COVID-19 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 experiences significant setbacks in the development or commercialization of VLA2001 or stops development altogether.



Slow recovery of product sales. In the context of the COVID-19 pandemic, Valneva plans for product sales recovery based on resumption of travel as expected by the travel industry, notably airlines. The evolving nature of the pandemic, particularly the emergence and impact of new variants of the virus, makes it difficult to predict when, where, and at what rate the travel industry will recover. If international travel does not resume as quickly or as much as planned, Valneva's revenues will be severely affected, and the Company may have to seek additional financing to complete (or contribute to) the development of its vaccine candidates. Such additional financing may then be very difficult to get under those circumstances. Additionally, the need of 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 option years under the existing agreement in full or at all. Further factors may also affect the level of product sales in 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.

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 (including relating to the construction of additional manufacturing facilities at its Livingston site), be unsuccessful in manufacturing or face difficulties in the ability to manufacture its products according to market demands or in meeting regulatory requirements. 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, and/or product recalls. 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's manufacturing facility in Livingston, Scotland, is the sole source of drug substances for IXIARO[®] and the chikungunya vaccine candidate. The Company's manufacturing facility in Solna, Sweden, is the sole source of commercial quantities of the DUKORAL[®] vaccine and will perform finishing operations on the COVID-19 vaccine candidate. The destruction of either of these facilities by fire or other catastrophic events 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. In addition, 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, including the COVID-19 vaccine candidate. 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, chikungunya and COVID-19 vaccine candidates, 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. The Company expects to report data from clinical trials of all of its vaccine candidates during the second half of 2021 and anticipates applying for initial regulatory approvals of its COVID-19 vaccine candidate during the same period. Failure to demonstrate efficacy or safety in clinical trials, delays or failures in development, changes in regulatory requirements, or other adverse events may force the Company to stop development of its product candidates, prevent regulatory approval of its product candidates, or impact its existing products, any of which could materially harm its business.

Risk relating to vaccine partnerships. The Company's strategic partnership with Pfizer to develop and commercialize Valneva's Lyme disease vaccine candidate and the Company's cooperation with the UK Vaccines Task Force to develop and manufacture Valneva's COVID-19 vaccine candidate are of critical importance to the Company. If either of these partnerships 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, and Valneva may be unable to complete development of its COVID-19 vaccine candidate as anticipated or at all.

Listing on Nasdaq. The Company completed an initial public offering of American Depositary Shares on the Nasdaq Global Select Market on May 11, 2021. As a company listed in the U.S., Valneva must now comply with U.S. regulations relating to public disclosure and accounting, among other areas. Compliance with these new regulations is complex, requires additional 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., and such risk may make it more difficult to attract and retain qualified candidates for Valneva's Supervisory Board or management. 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 3 of this report).

Further risk factors are set out in Valneva's universal registration document filed with the AMF on April 9, 2021 under number D.21-0286.

1.6 Related Parties' Transactions

In the first six months of 2021 and 2020, there was no transaction or change in transactions between related parties which materially affected Valneva's financial position or performance.



2. STATUTORY AUDITORS' REVIEW REPORT ON THE HALF YEAR FINANCIAL INFORMATION (PERIOD FROM JANUARY 1 TO JUNE 30, 2021)

This is a free translation into English of the Statutory Auditors' review report issued in French and is provided solely for the convenience of English speaking readers. This report includes information relating to the specific verification of information given in the Group's half-yearly management report. This report should be read in conjunction with, and construed in accordance with, French law and professional standards applicable in France.

To the Shareholders,

In compliance with the assignment entrusted to us by your annual general meetings and in accordance with the requirements of article L. 451-1-2 III of the French Monetary and Financial Code ("*Code monétaire et financier*"), we hereby report to you on:

- the review of the accompanying condensed half-yearly consolidated financial statements of Valneva, for the period from January 1 to June 30, 2021;
- the verification of the information presented in the half-yearly management report.

Due to the global crisis related to the Covid-19 pandemic, the condensed half-yearly consolidated financial statements of this period have been prepared and reviewed under specific conditions. Indeed, this crisis and the exceptional measures taken in the context of the state of sanitary emergency have had numerous consequences for companies, particularly on their operations and their financing, and have led to greater uncertainties on their future prospects. Those measures, such as travel restrictions and remote working, have also had an impact on the companies' internal organization and the performance of our procedures.

These condensed half-yearly consolidated financial statements are the responsibility of the Management Board. Our role is to express a conclusion on these financial statements based on our review.

1. Conclusion on the financial statements

We conducted our review in accordance with professional standards applicable in France. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with professional standards applicable in France and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed half-yearly consolidated financial statements are not prepared, in all material respects, in accordance with IAS 34- standard of the IFRSs as adopted by the European Union applicable to interim financial information.



2. Specific verification

We have also verified the information presented in the half-yearly management report on the condensed half-yearly consolidated financial statements subject to our review. We have no matters to report as to its fair presentation and consistency with the condensed half-yearly consolidated financial statements.

Neuilly-sur-Seine and Bordeaux, August 9, 2021

The Statutory Auditors

French original signed by

PricewaterhouseCoopers Audit

Deloitte & Associés

Cédric Mazille

Stéphane Lemanissier



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

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

Unaudited Interim Condensed Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	Note	Six months ended June 30,	
		2021	2020
Product sales	4	31,762	40,942
Revenues from collaboration, licensing and services	4	15,740	6,965
Revenues		47,502	47,907
Cost of goods and services	5	(34,778)	(22,546)
Research and development expenses	5	(78,737)	(33,081)
Marketing and distribution expenses	5	(9,643)	(10,046)
General and administrative expenses	5	(20,904)	(10,615)
Other income and expenses, net	6	10,389	6,453
OPERATING PROFIT/(LOSS)		(86,172)	(21,928)
Finance income	7	8,962	549
Finance expenses	7	(8,431)	(6,109)
Result from investments in associates		(90)	90
PROFIT/(LOSS) BEFORE INCOME TAX		(85,730)	(27,398)
Income tax		(668)	1,759
PROFIT/(LOSS) FOR THE PERIOD		(86,399)	(25,639)
Earnings/(Losses) per share			
for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share			
▪ basic		(0.91)	(0.28)
▪ diluted		(0.91)	(0.28)

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

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

€ in thousand	Note	Six months ended June 30,	
		2021	2020
Profit/(Loss) for the period		(86,399)	(25,639)
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences	17.2	(424)	(673)
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)		-	-
Other comprehensive income/(loss) for the period, net of tax		(424)	(673)
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY		(86,823)	(26,312)

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

**UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

€ in thousand	Note	June 30 2021	December 31, 2020
ASSETS			
Non-current assets		183,145	140,737
Intangible assets	8	34,424	35,409
Right of use assets	9/11	48,239	43,374
Property, plant and equipment	10/11	74,789	34,779
Equity-accounted investees		2,039	2,130
Deferred tax assets		5,591	5,570
Other non-current assets	15	18,063	19,476
Current assets		561,962	308,427
Inventories	13	125,664	26,933
Trade receivables	14	18,007	19,232
Other current assets	15	88,526	57,828
Cash and cash equivalents	16	329,766	204,435
TOTAL ASSETS		745,107	449,164
EQUITY			
Capital and reserves attributable to the Company's equity holders		77,070	77,422
Share capital	17.1	14,986	13,646
Share premium	17.1	328,688	244,984
Other reserves	17.2	53,344	52,342
Retained earnings/(Accumulated deficit)		(233,549)	(169,156)
Profit/(loss) for the period		(86,399)	(64,393)
LIABILITIES			
Non-current liabilities		211,119	195,872
Borrowings	18	47,402	46,375
Lease liabilities	9	53,916	49,392
Contract liabilities	19	-	58
Refund liabilities	0	104,493	97,205
Provisions	21	4,648	2,358
Deferred tax liabilities		590	412
Other liabilities	22	70	72
Current liabilities		456,917	175,870
Borrowings	18	7,079	6,988
Trade payables and accruals		71,502	36,212
Tax and employee-related liabilities		12,265	13,165
Lease liabilities	9	3,089	2,696
Contract liabilities	19	338,474	89,578
Refund liabilities	0	6,875	14,222
Provisions	21	14,973	10,169
Other liabilities	22	2,660	2,841
TOTAL LIABILITIES		668,037	371,742
TOTAL EQUITY AND LIABILITIES		745,107	449,164

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



UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Note	Six months ended June 30,	
		2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES			
Profit/(Loss) for the period		(86,399)	(25,639)
Adjustments for non-cash transactions	24	17,003	11,256
Changes in non-current operating assets and liabilities	24	8,341	63,467
Changes in working capital	24	146,614	64,382
Cash generated from operations	24	85,560	113,466
Income tax paid		(1,313)	(247)
Net cash generated from operating activities		84,247	113,219
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	10/11	(39,173)	(1,816)
Purchases of intangible assets		(761)	(82)
Interest received		33	67
Net cash used in investing activities		(39,902)	(1,831)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions	17	85,177	8
Disposal/(Purchase) of treasury shares		209	99
Proceeds from borrowings, net of transaction costs		-	48,773
Repayment of borrowings		(1,764)	(21,521)
Payment of lease liabilities		(1,161)	(1,082)
Interest paid		(3,718)	(1,791)
Net cash generated from financing activities		78,743	24,468
Net change in cash and cash equivalents		123,088	135,874
Cash and cash equivalents at beginning of the period, excluding restricted cash		204,394	64,439
Exchange gains/(losses) on cash		2,242	(267)
Restricted cash	16	42	-
Cash and cash equivalents at end of the period	16	329,766	200,046

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



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 reserve s	Retained earnings/ (Accumula -ted deficit)	Profit/ (loss) for the period	Total equity
Balance as at January 1, 2020		90,943,812	13,642	244,912	45,756	(167,412)	(1,744)	135,153
Total comprehensive loss		-	-	-	(673)	-	(25,639)	(26,312)
Income appropriation		-	-	-	-	(1,744)	1,744	-
Share-based compensation expense:	17							
- value of services		-	-	-	2,112	-	-	2,112
- exercises		3,125	-	8	-	-	-	8
Treasury shares	17	-	-	-	98	-	-	98
Balance as at June 30, 2020		90,946,937	13,642	244,920	47,293	(169,156)	(25,639)	111,059
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

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 of June 30, 2021 and for the six months ended June 30, 2021 and June 30, 2020, have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union 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, 2020 included in the Company's Universal Registration Document.

Since December 31, 2020, no separate line for "amortization and impairment of fixed assets/intangibles" in the consolidated income statement is shown, but those amounts are included in the lines "Cost of goods and services" and "Research and development expenses". This split was made to improve the profit and loss disclosure per function. For the six months ended June 30, 2020, the amount of €1,440 thousand of amortization and impairment of fixed assets/intangible was reclassified to "Cost of goods and services" in the amount of €1,406 thousand and to "Research and development expenses" in the amount of €34 thousand. In addition the presentation of equity changed to a more detailed presentation to provide additional information on the balance sheets as well as on the statements of changes in equity. The comparable period was adjusted accordingly to maintain comparability.

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 9, 2021.

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, 2020.

Standards, amendments to existing standards and interpretations adopted by the European Union whose application has been mandatory since January 1, 2021

A number of amended standards became applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these amended standards.

Standards, amendments to existing standards and interpretations adopted by the European Union whose application is not yet mandatory

No standards, amendments to existing standards, or interpretations published that were not yet applicable as of June 30, 2021, are expected to significantly impact the Company's financial statements.

No standards or interpretations were adopted early if they are not mandatory to apply in 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.

Interest rate benchmark reform

The Group does not expect a material impact from the interest rate benchmark reform on the financial statements.

**SIGNIFICANT EVENTS OF THE PERIOD****COVID-19**

The Group has been and could continue to be materially adversely affected by the current COVID-19 pandemic in regions where Valneva has significant manufacturing facilities, concentrations of clinical trial sites, or other business operations. COVID-19 has adversely impacted sales of travel vaccines to the general public, with travel to endemic areas significantly reduced compared to 2019. DUKORAL and IXIARO are aimed at diseases that primarily threaten travelers to particular regions. As a result, sales of these vaccines have decreased significantly, adversely impacting the Company's financial results. The Group expects to remain impacted by the significant reduction in international travel following the onset of the global COVID-19 pandemic. In its July 2021 report, the United Nations World Tourism Organization, or UNWTO, noted that international travel, as measured by international arrivals, is slowly picking up, though the recovery remains fragile and uneven. Rising concerns over the Delta variant of the virus have led several countries to re-impose restrictive measures. In addition, the volatility and lack of clear information on entry requirements could continue to affect the resumption of international travel during the Northern Hemisphere's summer season. However, vaccination programs worldwide, together with softer restrictions for vaccinated travelers and the use of digital tools such as the EU Digital COVID Certificate, contribute to the gradual normalization of travel. The recovery of international travel is forecasted by leading international travel organizations, such as the International Air Transport Association and the UNWTO, to begin in 2021 and to recover to 2019 demand levels between mid-2023 to end of 2024. If international travel does not resume as quickly or as much as expected, the Company's revenues will continue to be severely affected, and Valneva may not be able to complete the development of its vaccine candidates without additional financing. Valneva continues to closely monitor how the pandemic and related response measures are affecting the Company's business. Valneva reported cash and cash equivalents of €329.8 million as of June 30, 2021. Valneva is prepared to take further cost management measures if required and has implemented a cost reduction of non-mission critical projects and expenses. Although it is difficult to predict future liquidity requirements, the Group believes that the existing cash and cash equivalents as of June 30, 2021 will be sufficient to fund its operations for at least the next 12 months from the authorization of publication of these consolidated financial statements. For details on liquidity risk see Note 23.

Impact from COVID-19 is described in following notes as of June 30, 2021:

Impact from COVID-19	Note	
COVID-19 R&D program	1	Agreement with the UK Government to provide up to 190 million doses of the Group's SARS-CoV-2 vaccine candidate - €60.1 million expenses (of which €46.1 million were for research and development) included in first six months of 2021, €94.9 million included in inventories (of which €82.8 million were for raw material), €46.9 million prepayments included in other current assets, €349.7 million included in contract and refund liabilities, as of June 30, 2021.
Revenues from contracts with customers	4	Decline of revenues of commercialized products for non-military market from Q2 2020 onward and therefore reduced cash inflows.
Impairment testing	11	Impairment test on Property, plant and Equipment, Intangible assets, and Right of Use assets performed after triggering events – no impairment required as of June 30, 2021

**Significant agreements signed in the period**

In January 2021, Valneva and Instituto Butantan ("Butantan"), producer of immunobiologic products, announced the signing of definitive agreements for the development, manufacturing, and marketing of Valneva's single-shot chikungunya vaccine candidate, VLA1553, in Low and Middle-Income Countries (LMICs). This finalization follows the signing of a binding term sheet in May 2020. The collaboration falls within the framework of the \$23.4 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations ("CEPI") in July 2019 (see Note 6). Under the collaboration, Valneva will transfer its chikungunya vaccine technology to Butantan, who will develop, manufacture and commercialize the vaccine in LMICs. In addition, Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. The agreement includes small upfront and technology transfer milestones. In the first half of 2021, €1.8 million were recognized as Revenues from collaboration, licensing, and services. As of June 30, 2021, €1.0 million are included in contract liabilities (December 31, 2020: €1.0 million).

Valneva's share price development and capital increase the six months ended June 30, 2021

The Company's share price increased by almost 50% during the six months ended June 30, 2021, with high fluctuations throughout the period.

On May 11, 2021, Valneva announced the closing, which occurred on May 10, 2021, of its previously announced global offering to specified categories of investors of an aggregate of 8,145,176 new ordinary shares. The full exercise of the over-allotment option granted to the underwriters (the "Option") consisted of a public offering of 2,850,088 American Depositary Shares, each representing two ordinary shares, in the United States at an offering price of \$26.41 per ADS (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States at the corresponding offering price of €11.00 per ordinary share (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"). Aggregate gross proceeds of the Global Offering, after full exercise of the Option, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately \$107.6 million (€89.6 million), see Note 17.



2. Group structure

List of direct or indirect interests held by the Company:

Name	Country of incorporation	Consolidation method	June 30, 2021	December 31, 2020
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%

3. Segment reporting

The Company's Management Board, as its chief decision maker, considers the business from a product rather than geographic perspective and has identified four reportable segments.

As of January 1, 2021, the following changes were implemented into the Group's segment reporting structure.

- Given the expected materiality of the Group's COVID-19 business, a separate segment was introduced covering all activities related to the development, manufacturing, and distribution of the SARS-CoV-2 vaccine candidates.
- With the transfer of the license of Valneva's VLA15 Lyme vaccine candidate to Pfizer in December 2020, all related revenues and costs were moved from the "Vaccine candidates" segment to the "Technologies and services" segment.

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 candidates)
- "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 vaccine candidates, which is presented separately)
- "Technologies and services" (services and inventions at the commercialization stage, i.e. revenue generating through collaborations, service, and licensing agreements)

As of January 1, 2021, the Group changed its internal reporting process and amended the following allocation rule: general and administrative (G&A) costs were allocated to the four operational segments based on three key criteria (each equally weighted): 1) Revenues, 2) R&D spend and 3) FTE's. The allocation of local G&A spend is based on the above criteria measured on local level, whereas the allocation



of global functional G&A spend is based on global key criteria. The Group also monitors G&A spend dedicated to corporate projects and any project which is 1) material in spend, 2) one-time in nature, and 3) supports the entire business remains reported under "Corporate Overhead". In 2021 the major item included in "Corporate Overhead" were costs related to the placement of new shares on NASDAQ in May 2021.

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

Income statement by segment for the six months ended June 30, 2020:

€ in thousand	Commer- cialized products	COVID	Vaccine candi- dates	Techno- logies and services	Corporate Overhead	Total
Product sales	40,942	-	-	-	-	40,942
Revenues from collaboration, licensing and services	-	-	1,333	5,632	-	6,965
Revenues	40,942	-	1,333	5,632	-	47,907
Cost of goods and services	(18,148)	-	-	(4,397)	-	(22,546)
Research and development expenses	(1,514)	(1,548)	(29,568)	(451)	-	(33,081)
Marketing and distribution expenses	(9,817)	-	(179)	(50)	-	(10,046)
General and administrative expenses	(5,482)	-	(4,151)	(930)	(52)	(10,615)
Other income and expenses, net	71	307	5,835	107	133	6,453
Operating profit/(loss)	6,051	(1,241)	(26,730)	(89)	81	(21,928)

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

€ in thousand	Commer- cialized products	COVID	Vaccine candi- dates	Techno- logies and services	Corporate Overhead	Total
Product sales	31,762	-	-	-	-	31,762
Revenues from collaboration, licensing and services	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 profit/(loss)	4,089	(55,454)	(30,005)	(1,025)	(3,776)	(86,172)

**Product sales per geographical segment**

€ in thousand	Six months ended June 30,	
	2021	2020
United States	23,589	19,068
Canada	2,006	8,126
Austria	3,006	324
United Kingdom	1,067	1,653
Nordics	897	2,691
Germany	-	4,441
Other Europe	1,181	1,539
Other markets	15	3,099
Product sales	31,762	40,942

4. Revenues from contracts with customers**4.1 Overview**

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 scope of IFRS 15:

Six months ended June 30, 2020	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
€ in thousand					
Revenues from contracts with customers	40,942	-	1,333	5,121	47,396
Other revenues	-	-	-	511	511
Revenues	40,942	-	1,333	5,632	47,907

Six months ended June 30, 2021	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
€ in thousand					
Revenues from contracts with customers	31,772	-	1,849	13,429	47,050
Other revenues	-	-	-	451	451
Revenues	31,772	-	1,849	13,880	47,502

In the second quarter 2020 and in the first half of 2021, commercialized products revenues were affected by the worldwide reduction in traveling due to the COVID-19 pandemic.

**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, 2020					
€ in thousand	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
IXIARO product	28,406	-	-	-	28,406
DUKORAL product	12,140	-	-	-	12,140
Third party products	396	-	-	-	396
Lyme VLA15	-	-	1,333	-	1,333
Chikungunya VLA1553	-	-	-	-	-
Services related to clinical trial material	-	-	-	3,420	3,420
Others	-	-	-	1,701	1,701
Revenues from contracts with customers	40,942	-	1,333	5,121	47,396

Six months ended June 30, 2021					
€ in thousand	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
IXIARO product	25,394	-	-	-	25,394
DUKORAL product	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

4.2 Information on specific contracts

In April 2020, a new collaboration to co-develop and commercialize the Group's Lyme disease vaccine (Lyme VLA15) was signed with Pfizer Inc. (NYSE: PFE). This agreement was entered into with a customer as defined by IFRS 15 guidance on revenue contracts with customers. It included a \$130 million (€116.9 million) upfront payment, which was received in June 2020. Valneva will refund 30% of all development costs through completion of the development program, which is planned for 2025. Therefore, as of June 30, 2021, €90.0 million has been recognized as discounted refund liabilities. The transaction price was determined while taking into account the refund obligation of Valneva. The agreement includes R&D and service performance obligations for which revenue is recognized over time as well as a license performance obligation for which revenue was recognized in the year 2020, when Pfizer benefited and



started to use the license without further involvement of Valneva. The transaction has been allocated to various performance obligations in proportion to their standalone selling price. In the first half of 2021, €5.6 million were recognized as Revenues from collaboration, licensing and services. €3.0 million of costs to obtain a contract are included in other assets (see Note 15) and €0.9 million are included in contract liabilities (see Note 19) as of June 30, 2021.

In June 2020, Valneva and Bavarian Nordic A/S (OMX: BAVA) announced a marketing and distribution partnership for the marketing and distribution of their commercial products. Valneva is acting as principal according to IFRS and will commercialize Bavarian Nordic's marketed vaccines leveraging its commercial infrastructure in Canada, the UK, France and Austria. Valneva will also take responsibility for Belgium and the Netherlands. The partnership includes vaccines that protect against rabies, Japanese encephalitis, tick-borne encephalitis and cholera. Revenues are recognized at a point in time when products are delivered to the customer. In the first half of 2021, Valneva recognized €4.7 million of revenue with Bavarian Nordic's vaccines. This partnership also caused an increase in purchased goods (third party products) (see Note 13).

In September 2020, the US 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. The current base year has a minimum value of approximately \$54 million for 370,000 doses, and the option years have minimum values of \$46 million for 320,000 doses and \$36 million for 250,000 doses, respectively, if DLA exercises those options.

In September 2020, Valneva announced a vaccine partnership with the UK Government for Valneva's inactivated COVID-19 vaccine, VLA2001. Under the agreement, if the vaccine development is successful, Valneva will provide the UK Government with 60 million doses of VLA2001 beginning in the second half of 2021. The UK Government then has options over 40 million additional doses in 2022 and a further 90 million doses, in aggregate, from 2023 to 2025. If VLA2001 is approved and the options are exercised in full, the contract has the potential to generate aggregate revenue of up to €1.4 billion. The UK Government is also investing up-front in the manufacturing scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the collaboration. The COVID-19 vaccine candidate will be manufactured at Valneva's facilities in Livingston, Scotland and fill-finishing activities will take place at Valneva's facilities in Solna, Sweden. As part of its broader COVID-19 response, Valneva plan to further invest in the manufacturing facilities in Livingston, Scotland and Solna, Sweden. The UK Government is obligated to provide Valneva advance payments to fund certain manufacturing-related expenses (related to the expansion of Valneva's Livingston, Scotland facility) over the life of the project, subject to Valneva's continued supply of product in accordance with the terms of the UK Supply Agreement. According to IFRS 15, this agreement includes two performance obligations: First is the delivery of 60 million doses, second is an option to sell an additional 40 million doses at a lower price than the expected market price and furthermore an option to sell an additional 90 million doses at the expected market price. In June 2021, none of these performance obligations were satisfied, therefore no revenue was recognized in this period. In December 2020, the option period to order 40 million doses was extended from December 31, 2020, to January 31, 2021. In January 2021, the UK Government has exercised its option to order 40 million doses. As of June 30, 2021, €335.6 million are included in contract liabilities (see Note 19), and €14.1 million are included in refund liabilities (see Note 0) and relate to a payment obligation of Valneva to the UK Government for sales that are expected to occur outside UK. Total expenses for research and development for the COVID-19 vaccine were €46.1 million in the first half of 2021. As of June 30, 2021, €94.9 million of inventories (see Note 13) relate to the COVID-19 vaccine.

**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.

Six months ended June 30, 2020 € in thousand	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
United States	19,068	-	1,333	-	20,401
Canada	8,126	-	-	-	8,126
Germany	4,441	-	-	50	4,491
Austria	324	-	-	3,420	3,744
United Kingdom	1,653	-	-	707	2,360
Nordics	2,691	-	-	-	2,691
Other Europe	1,539	-	-	679	2,219
Other markets	3,099	-	-	264	3,363
Revenues from contracts with customers	40,942	-	1,333	5,121	47,396

Six months ended June 30, 2021 € in thousand	Commer- cialized products	COVID	Vaccine candidates	Techno- logies and services	Total
United States	23,589	-	-	5,781	29,370
Canada	2,006	-	-	-	2,006
Austria	3,006	-	-	4,126	7,131
United Kingdom	1,074	-	-	40	1,114
Nordics	901	-	-	-	901
Germany	-	-	-	15	15
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

Sales channels for product sales

Commercialized products are sold via the following sales channels:

€ in thousand	Six months ended June 30,	
	2021	2020
Direct product sales	30,663	31,025
Sales through distributors	1,110	9,917
Total product sales	31,772	40,942

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



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:

€ in thousand	Six months ended June 30,	
	2021	2020
Consulting and other purchased services	(76,213)	(27,860)
Employee benefit expense other than share-based compensation ¹²	(35,955)	(26,376)
Share-based compensation expense	(3,653)	(2,631)
Depreciation and amortization and impairment	(6,101)	(4,687)
Raw materials and consumables used	(5,371)	(5,494)
Building and energy costs	(5,286)	(3,732)
Supply, office and IT-costs	(3,308)	(1,527)
Cost of services and change in inventory	(2,940)	2,257
License fees and royalties	(2,490)	(2,379)
Advertising costs	(1,318)	(1,810)
Warehousing and distribution costs	(745)	(1,219)
Travel and transportation costs	(126)	(419)
Other expenses	(554)	(410)
Operating expenses	(144,062)	(76,288)

Consulting and other purchased services include €33.4 million (June 30, 2020: €0) expenses related to the COVID program.

6. Other income and expenses, net

Other income and expenses, net include the following:

€ in thousand	Six months ended June 30,	
	2021	2020
Research and development tax credit	9,635	3,889
Grant income	1,145	2,995
Profit/(loss) on disposal of fixed assets, net	(21)	(7)
Taxes, duties, fees, charges, other than income tax	(133)	(116)
Miscellaneous income/(expenses), net	(237)	(308)
Other income/(expenses), net	10,389	6,453

¹² As of June 30, 2021 the position "employee benefit other than share-based compensations" includes additions to a provision in the amount of €4.6 million of employer contribution fees, which are payable at the exercise of the IFRS 2 programs (as of June 30, 2020: €1.3 million).



Of the Research and development tax credit, €9.1 million (June 30, 2020: €3.3 million) related to R&D programs executed in Austria, mainly for COVID-19 and chikungunya vaccine candidates, whereas €0.6 million (June 30, 2020: €0.6 million) related to France.

In July 2019, the Group signed a funding agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI"). Under this funding agreement, Valneva is eligible to receive up to \$23.4 million for vaccine manufacturing and late-stage clinical development of a single-dose, live attenuated vaccine (VLA1553) against chikungunya. In line with CEPI's commitment to equitable access, the funding will underwrite a partnership effort to accelerate regulatory approval of Valneva's single-dose Chikungunya vaccine for use in regions where outbreaks occur and support World Health Organization, or WHO, prequalification to facilitate broader access in lower and middle income countries. To satisfy the CEPI obligation, Valneva has entered into an agreement with Instituto Butantan ("Butantan") in January 2021, where Valneva transferred the chikungunya vaccine technology. Butantan will develop manufacture and commercialize the vaccine in LMICs. In addition, Butantan will provide certain clinical and Phase 4 observational studies that Valneva will use to meet regulatory requirements. CEPI work packages where Butantan is the beneficiary are recognized as revenue related to Butantan, while work packages where Valneva is the beneficiary are still recognized as grant income (IAS 20) and presented as other income within the operating income. Valneva is obligated to repay up to \$7.0 million to CEPI when certain sales milestones are reached or if and when a Priority Review Voucher ("PRV") is granted. Since the inception of the CEPI agreement, Valneva has recognized €6.7 million of grant income. In the period ended June 30, 2021, a negative grant income of €1.1 million was recognized due to the increase of the probability of reaching the PRV milestone. This negative amount was offset by €2.2 million of grants from government authorities related to the current COVID-19 pandemic situation to cover fixed costs of the commercial activities.

7. Finance income/(expenses), net

€ in thousand	Six months ended June 30,	
	2021	2020
Finance income		
Interest income from other parties	228	74
Fair value gains on derivative financial instruments	-	475
Foreign exchange gains, net	8,735	-
Total finance income	8,962	549
Finance expense		
Interest expense on loans	(3,820)	(2,961)
Interest expense on refund liabilities	(4,104)	(486)
Interest expense on lease liabilities	(419)	(447)
Other interest expense	(88)	(16)
Foreign exchange losses, net	-	(2,200)
Total finance expenses	(8,431)	(6,109)
Finance income/(expense), net	532	(5,560)

For more details regarding interest expense on loans see Note 18. For more details regarding interest on refund liabilities see Note 0.



8. Intangible assets

Significant intangible assets with definite useful life are comprised primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO), with acquisition costs amounting to €78.2 million and a net book value amounting to €32.0 million (December 31, 2020: €33.2 million). Other intangible assets with a definite useful life are comprised primarily of the IC31 technology amounting to €0.4 million (December 31, 2020: €0.5 million) and the EB66 technology amounting to €0.1 million (December 31, 2020: €0.1 million).

9. Right of use assets

In the first six months of 2021, right of use assets increased from €43.4 million as of December 31, 2020 to €48.2 million as of June 30, 2021, mainly due to a new lease contract for land and building in Sweden (addition €6.1 million), partly offset by amortization expenses (€1.3 million). Major lease agreements are for the premises in Austria (book value as of June 30, 2021: €24.4 million, December 31, 2020: €24.8 million) and Sweden (book value as of June 30, 2021: €22.9 million, December 31, 2020: €17.6 million).

10. Property, plant and equipment

In the first six months of 2021, property, plant and equipment increased from €34.8 million as of December 31, 2020 to €74.8 million as of June 30, 2021. This increase mainly relates to investments in land and building and equipment for the manufacturing of the COVID-19 vaccine on sites in the United Kingdom and Sweden. The increase was partly offset by depreciation expenses (€3.0 million).

11. Impairment testing

11.1 Impairment testing

Due to a reduction in product sales realized during the first half of 2021 caused by the COVID-19 pandemic and travel restrictions, a triggering event has been identified for DUKORAL. Consequently, an impairment test has been performed as of June 30, 2021. While there are no material intangible assets held for DUKORAL the carrying value of Property, plant and equipment and Right of use assets as well as working capital (net book value of €15.4 million as of June 30, 2021) was tested.

The Company's long range business model, 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. For DUKORAL, sales recovery to pre-COVID levels is expected to progress more slowly over the next 2 years. This is additionally driven by the expected entry of a competitor product in some European markets within the coming years. The uncertainty of whether sales can return to pre-COVID levels has been taken into account in the impairment test.

The calculation uses post-tax risk-adjusted cash flow projections and a discount rate of 6.93%.

The discount rate of 6.93% is based on 0.31% risk-free rate, 6.87% market risk premium, minus 0.37% country risk premium, 0.61% currency risk, a levered beta of 1.02 and a peer group related equity-capital ratio.

The impairment test for DUKORAL 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.

At the date of the impairment test for DUKORAL, the net present value calculation for DUKORAL uses a discount rate of 6.93%. An increase in the discount rate of 418 basis points from 6.93% to 11.11% would trigger an impairment loss.

The net present value calculations are based upon assumptions regarding market size, market share, and expected sales volumes resulting in sales value expectations. An additional reduction in revenues of 10.0% over the planning period of 5.5 years would result in no impairment loss in 2021.

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 of June 30, 2021, material differences are identified only for guaranteed other loans. Based on an estimated arms' length interest rate of 9.73%, the fair value is €3.6 million (carrying amount is €4.0 million).

The fair values of all other financial instruments equal their book values as of June 30, 2021.

13. Inventories

Inventories include the following:

€ in thousand	June 30, 2021	December 31, 2020
Raw materials	90,192	4,790
Work in progress	23,025	14,914
Finished goods	15,357	13,625
Purchased goods (third party products)	6,301	1,303
Gross amount of inventory before write-down	134,875	34,631
Less: write-down	(9,211)	(7,698)
Inventory	125,664	26,933

As of June 30, 2021, Raw materials include €82.8 million COVID-19 related inventories in total, whereas Work in progress includes €12.1 million (December 31, 2020: €0) for the COVID-19 product. The net realizable value of the COVID-19 related inventories is expected to exceed the net book value as a result of the contractual terms of the COVID-19 agreement with UK government (see Note 4.2). In addition payments to cover those costs have been received already and are non-refundable.

The increase in Purchased goods (third party products) is mainly caused by the partnership with Bavarian Nordic (see Note 4.2).

Given the expected reductions in product sales related to Valneva's commercial stage vaccines IXIARO and DUKORAL due to the current COVID-19 pandemic, the Company has performed a review of both commercial and raw material inventories and has included write-downs in the COGS as of June 30, 2020, December 31, 2020, and June 30, 2021. 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. The write-down of €9.2 million relates €5.5 million to finished goods, €3.0 million to work in progress (of which nil to faulty products), €0.7 million to raw materials and nil to purchased goods.



The cost of inventories is recognized as an expense and is included in the position "Cost of goods and services" amounted to 12.1 million (June 30, 2020: €12.8 million), of which €4.4 million (June 30, 2020: €2.2 million) related to defective products, which were written down.

In April 2020, Valneva and Dynavax announced a collaboration to advance vaccine development for COVID-19. Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAVB vaccine, to support the development of Valneva's COVID-19 vaccine candidate, while Valneva is leveraging its technical and platform capabilities to develop an inactivated, whole virus vaccine candidate against the current COVID-19 threat. In September 2020, Valneva and Dynavax announced a commercial partnership for the supply of Dynavax's CpG 1018 adjuvant for use in Valneva's SARSCoV-2 vaccine candidate, VLA2001. As of June 30, 2021, Valneva has included €73.5 million of CpG 1018 in Raw material inventories and €46.9 million in advance payments in other current assets.

14. Trade receivables

Trade receivables include the following:

€ in thousand	June 30, 2021	December 31, 2020
Trade receivables	18,022	19,237
Less: loss allowance of receivables	(15)	(6)
Trade receivables, net	18,007	19,232

During the six months ended June 30, 2021 and during the six months ended June 30, 2020, no material impairment losses have been recognized. Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

Trade receivables include €18.0 million (December 31, 2020: €18.7 million) receivables from contracts with customers.

15. Other assets

Other assets include the following:

€ in thousand	June 30, 2021	December 31, 2020
Advances	52,256	33,671
R&D tax credit receivables	24,017	19,637
Tax receivables	8,016	5,468
Prepaid expenses	6,479	2,544
Contract costs	3,034	2,846
Consumables and supplies on stock	1,238	1,061
Miscellaneous current assets	29	158
Other non-financial assets	95,070	65,385



Deposits	11,335	11,358
Miscellaneous financial assets	184	560
Other financial assets	11,519	11,918
Other assets	106,589	77,303
Less non-current portion	(18,063)	(19,476)
Current portion	88,526	57,828

As of June 30, 2021, Advances mainly included advances relating to the collaboration agreement with Dynavax, amounting to € 46.9 million (December 31, 2020: €31.1 million) (see Note 1).

As of June 30, 2021, Deposits related to a deposit in connection with a lease agreement, whereas Advances mainly related to advance payments in connection to advance payments for production components.

Contract costs were related to the collaboration with Pfizer (see Note 4.2) and refer to costs to obtain a contract. They will be amortized in line with the pattern of revenue recognition. In the six months ended June 30, 2021, €21 thousand (June 30, 2020: nil) in amortization was recognized as costs.

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.

16. Cash and cash equivalents

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

€ in thousand	June 30, 2021	December 31, 2020
Cash on hand	2	2
Cash at bank	329,721	173,107
Short-term bank deposits (maximum maturity of 3 months)	-	31,285
Restricted cash	42	41
Cash and cash equivalents	329,766	204,435

As of June 30, 2021, and as of December 31, 2020, Restricted cash pertained to a certificate of deposit with limited access that secures the credit limit for the Company's commercial card.

On June 30, 2021, the minimum liquidity requirement for the Group according to the debt financing agreement with US Healthcare Funds Deerfield and OrbiMed (see Note 18) was €50.0 million (December 31, 2020: €75.0 million). This requirement continues to be valid through 2022 and will be amended to €35.0 million from 2023 on (see Note 18).

Cash and cash equivalents net of the US Healthcare Funds Deerfield and OrbiMed financial liability amounted to €281.6 million (December 31, 2020: €158.2 million).



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,	December 31,
	2021	2020
Ordinary shares issued (€0.15 par value per share)	99,888,424	90,950,048
Convertible preferred shares registered	20,514	20,514
Total shares issued	99,908,938	90,970,562
Less Treasury shares	(128,347)	(146,322)
Outstanding shares	99,780,591	90,824,240

On May 10, 2021, the Company announced that the underwriters of its global offering of an aggregate of 7,082,762 new ordinary shares, consisting of a public offering of 2,318,881 American Depositary Shares ("ADSs"), each representing two ordinary shares (the "U.S. Offering"), and a concurrent private placement of 2,445,000 ordinary shares in Europe (including in France) and other countries outside of the United States (the "European Private Placement", and, together with the U.S. Offering, the "Global Offering"), had exercised in full their option to purchase up to 1,062,414 additional new ordinary shares in the form of 531,207 ADSs. The additional ADSs were delivered concurrently with the closing of the Global Offering.

As a result, the total number of Valneva's ordinary shares (including in the form of ADSs) issued in the Global Offering amounted to 8,145,176 ordinary shares, including 5,700,176 ordinary shares represented by 2,850,088 ADSs, each representing two ordinary shares, bringing the gross proceeds of the Global Offering to approximately \$107.6 million (€89.6 million). The Cost of equity transactions in the amount of €6.8 million, which were directly attributable to the issue of new shares, are shown in equity as a deduction, net of tax, if any, from the proceeds.

Furthermore, 790,075 employee stock options (of which 363,050 were granted from ESOP 2016 and 427,025 from ESOP 2017) were exercised in the exercise period opened in January 2021, which resulted in an increase in ordinary shares.

**17.2 Other reserves**

€ in thousand	Other regulated reserves ¹³	Other comprehensive income	Treasury shares	Capital from Share-based compensation	Other revenue reserves	Total
Balance at January 1, 2020	52,820	(4,836)	(1,112)	8,357	(9,474)	45,756
Currency translation differences	-	(673)	-	-	-	(673)
Share-based compensation expense:						
- value of services	-	-	-	2,112	-	2,112
Purchase/sale of treasury shares	-	-	98	-	-	98
Balance at June 30, 2020	52,820	(5,507)	(1,015)	10,468	(9,474)	47,293
Balance 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 at June 30, 2021	52,820	(2,898)	(689)	13,585	(9,474)	53,344

18. Borrowings

In February 2020, Valneva Austria GmbH signed a debt financing agreement with US Healthcare Funds Deerfield and OrbiMed for an amount of up to \$85.0 million. Amortization payments will start in 3 years, while the loan will mature in 6 years. The intended use of proceeds was to repay existing borrowings from the European Investment Bank and allow the Group to continue to advance its primary Lyme and chikungunya development programs in the short term. As of June 30, 2021, \$60.0 million (€54.1 million) had been drawn down in two tranches. The interest rate is 9.95% on a quarterly basis (equivalent to 10.09% on an annual basis). 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. Furthermore, the loan agreement contains covenants, including a minimum liquidity in the amount of €35.0 million and minimum consolidated net revenue in the amount of €115.0 million on a consecutive twelve month basis. To avoid a breach of covenants due to the decline in revenues caused by the COVID-19 pandemic, the initial agreement was amended in July 2020 to postpone the application of the minimum revenue covenant until December 31, 2020 (inclusive) in exchange for a minimum liquidity covenant of €75.0 million (instead of €35.0 million) during that period. On January 15, 2021, a new amendment was executed to (i) bring the minimum liquidity covenant to the amount of €50.0 million from 2021 onward and to €35.0 million from 2023 onward and (ii)

¹³ Regulated non-distributable reserve relating to the merger with Intercell AG



modify the minimum revenue covenant to include a quarterly minimum consolidated net revenue covenant (excluding grants) representing an annual total of €64.0 million in 2021, €103.8 million in 2022 and €115.0 million thereafter. If the Group's consolidated liquidity or net revenues were to fall below the covenant minimum values, Valneva would not be able to comply with the financial covenants in the financing agreement with Deerfield and OrbiMed, which could result in additional costs (up to an additional 10% of interest over the duration of the default) and an early repayment obligation (payment of the principal increased by 8% and of an indemnity representing the interests expected until March 2023). The Group does not expect these limitations to affect its ability to meet its cash obligations.

As of June 30, 2021, the liability relating to this financing agreement was €48.2 million, of which €5.1 million is reported as current (December 31, 2020: €46.2 million, of which €4.9 million is reported as current).

As of June 30, 2021, other loans included in borrowings related to financing of Research and Development expenses and CIR (R&D tax credit in France) of €4.0 million (December 31, 2020: €5.9 million) which are guaranteed by governmental parties and the CEPI loan in the amount of €2.3 million (December 31, 2020: €1.3 million), which relates to advanced payments received which are expected to be paid back in the future. For detailed information see Note 6.

19. Contract liabilities

Development of contract liabilities:

	June 30, 2021	December 31, 2020
€ in thousand		
Balance as at January 1	89,636	1,426
Revenue recognition	(2,228)	(594)
Exchange rate differences	(12)	101
Addition	251,078	88,703
Closing balance	338,474	89,636
Less non-current portion	-	(58)
Current portion	338,474	89,578

As of June 30, 2021, €335.7 million (as of December 31, 2020: €87.0 million) related to the agreement with the UK Government to supply up to 190 million doses of SARS-CoV-2 vaccine (see Note 4.2), €1.0 million (as of December 31, 2020: €1.0 million) related to the agreement with Butantan (see Notes 1 and 6), €0.9 million (as of December 31, 2020: €0) related to the collaboration with Pfizer Inc. (see Note 4.2) and €0.9 million (as of December 31, 2020: €1.6 million) related to other technologies and services provided to different customers.



20. Refund liabilities

Development of refund liabilities:

€ in thousand	June 30, 2021	December 31, 2020
Balance as at January 1	111,426	6,553
Additions	5,691	109,296
Payments	(3,699)	(477)
Other releases	(8,545)	-
Interest expense capitalized	4,104	3,640
Exchange rate difference	2,390	(7,586)
Closing balance	111,368	111,426
Less non-current portion	(104,493)	(97,205)
Current portion	6,875	14,222

As of June 30, 2021, €90.0 million (thereof €84.1 million non-current; as of December 31, 2020: €81.9 million, thereof €70.0 million non-current) related to the collaboration with Pfizer Inc. (see Note 4.2), €14.1 million (non-current; as of December 31, 2020: €20.9 million, non-current) related to the agreement with UK Government to develop and commercialize a SARS-CoV-2 vaccine (see Note 4.2), €6.5 million (thereof €6.3 million non-current; as of December 31, 2020: €6.3 million, non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreements in 2019 and €0.8 million (as of December 31, 2020: €2.3 million) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products.

Other releases mainly refer to changes in the refund liability related to changes in assumptions and estimates.

Expected cash outflows for refund liabilities are disclosed in Note 23.

21. Provisions

21.1 Provisions for employee commitments

€ in thousand	June 30, 2021	December 31, 2020
Employer contribution costs on share-based compensation plans	11,998	7,351
Phantom shares	4,657	2,390
Retirement termination benefits	581	550
Leaving indemnities	-	112
Balance at June 30	17,237	10,403
Less non-current portion	4,648	2,358
Current portion	12,589	8,045



Employer contribution costs on share-based compensation plans and Phantom shares are calculated at the balance sheet date using the share price of Valneva as of June 30, 2021: €11.14 (December 31, 2020: €7.75).

21.2 Other provisions

€ in thousand	June 30, 2021	December 31, 2020
Non-current	-	-
Current	2,384	2,124
Provisions	2,384	2,124

As of June 31, 2021, Other provisions included €2.1 million (December 31, 2020: €1.8 million) from a provision for expected legal and settlement costs under a court proceeding is related to the Intercell AG/Vivalis SA merger.

22. Other liabilities

€ in thousand	June 30, 2021	December 31, 2020
Deferred income	2,685	2,861
Other financial liabilities	44	51
Miscellaneous liabilities	1	2
Other liabilities	2,730	2,913
Less non-current portion	(70)	(72)
Current portion	2,660	2,841

Deferred income mainly includes conditional advances from government grants and a grant from CEPI (see Note 6).

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, 2020 € in thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,004	25,569	37,900	5,148	-	-	75,621
Lease liabilities	3,442	28,078	3,677	9,446	9,963	3,850	58,456
Refund liabilities	20,025	82,670	48,566	-	-	-	151,260
Trade payables and accruals	36,212	-	-	-	-	-	36,212
Tax and employee-related liabilities ¹⁴	8,300	-	-	-	-	-	8,300
Other liabilities	27	25	-	-	-	-	52
	75,010	136,342	90,142	14,594	9,963	3,850	329,901

At June 30, 2021 € in thousand	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	Between 5 and 10 years	Between 10 and 15 years	Over 15 years	Total
Borrowings	7,107	32,171	33,267	2,250	-	-	74,795
Lease liabilities	4,013	29,052	5,219	12,853	9,945	2,954	64,035
Refund liabilities	12,163	84,035	30,018	-	-	-	126,216
Trade payables and accruals	71,502	-	-	-	-	-	71,502
Tax and employee-related liabilities ³	8,516	-	-	-	-	-	8,516
Other liabilities	19	25	-	-	-	-	45
	103,320	145,283	68,504	15,103	9,945	2,954	345,110

¹⁴ 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,	
	2021	2020
Profit/(Loss) for the year	(86,399)	(25,639)
Adjustments for		
▪ Depreciation and amortization	6,101	4,687
▪ Share-based compensation expense	3,484	2,631
▪ Income tax expense/(income)	668	(1,759)
▪ (Profit)/loss from disposal of property, plant, equipment and intangible assets	23	7
▪ Share of (profit)/loss from associates	90	(90)
▪ Provision for employer contribution costs on share-based compensation plans	4,596	600
▪ Other non-cash income/expense	(6,163)	1,345
▪ Interest income	(228)	(74)
▪ Interest expense	8,431	3,909
Changes in non-current operating assets and liabilities (excluding the effects of acquisition and exchange rate differences on consolidation):		
▪ Other non-current assets	1,413	1,158
▪ Long term contract liabilities	(58)	(331)
▪ Long term refund liabilities	6,988	62,663
▪ Other non-current liabilities and provisions	(2)	(23)
Changes in working capital (excluding the effects of acquisition and exchange rate differences on consolidation):		
▪ Inventory	(97,006)	(6,274)
▪ Trade and other receivables	(13,271)	15,812
▪ Contract liabilities	248,910	47,790
▪ Refund liabilities	(11,157)	6,555
▪ Trade, other payables and provisions	19,139	500
Cash generated from operations	85,560	113,466

Cash generated from operations included payments of €241.6 million from the UK Government for the delivery of the COVID-19 vaccine. The payments are reported in short term contract liabilities (see Notes 4 and 19).

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. The Company has been discussing potential settlement agreements. The Company therefore holds a provision of €2.1 million of settlement costs and additional costs in connection with such potential settlements (December 31, 2020: €1.9 million). €0.3 million of additional expenses related to this litigation is included in "other expenses" in the period ended June 30, 2021.

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 now expected in the first half of 2022. 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,	
	2021	2020
Salaries and other short-term employee benefits	677	742
Other long-term benefits	15	8
Share-based payments (expense of the period)	448	924
Key management compensation	1,140	1,673

Supervisory Board compensation

The aggregate compensation of the members of the Company's Supervisory Board amounted to €140 thousand (six months ended June 30, 2020: €70 thousand).

27. Events after the reporting period

There are no events occurring between the reporting period and the time of publication that are expected to have a material effect on the financial statements.



4. RESPONSIBILITY STATEMENT

We, hereby, declare that, to the best of our knowledge, the condensed consolidated financial statements for the half year ended June 30, 2021 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
President and Chief Business Officer

Valneva Reports H1 2021 Financial Results and Provides Business Update

Analyst Presentation
August 10, 2021



Disclaimer



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Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including statements with respect to revenue guidance, the progress, timing, completion, and results of research, development and clinical trials for product candidates and estimates for future performance. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of 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 as an aid to further understand Valneva's current performance, performance trends, and financial condition.

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

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth in this presentation.



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Major R&D objectives achieved

- Positive topline Phase 3 results for chikungunya vaccine candidate VLA1553
 - › World's first ever Phase 3 trial results for a chikungunya vaccine
- Excellent progress on unique clinical assets
 - › Lyme – recruitment completed for Phase 2 trial VLA15-221 including pediatric age group
 - › COVID-19 – recruitment completed for pivotal Phase 3 trial VLA2001-301

Strong financial position and platform

- \$107.6 million raised in US IPO
- Cash and cash equivalents of €329.8m at June 30, 2021





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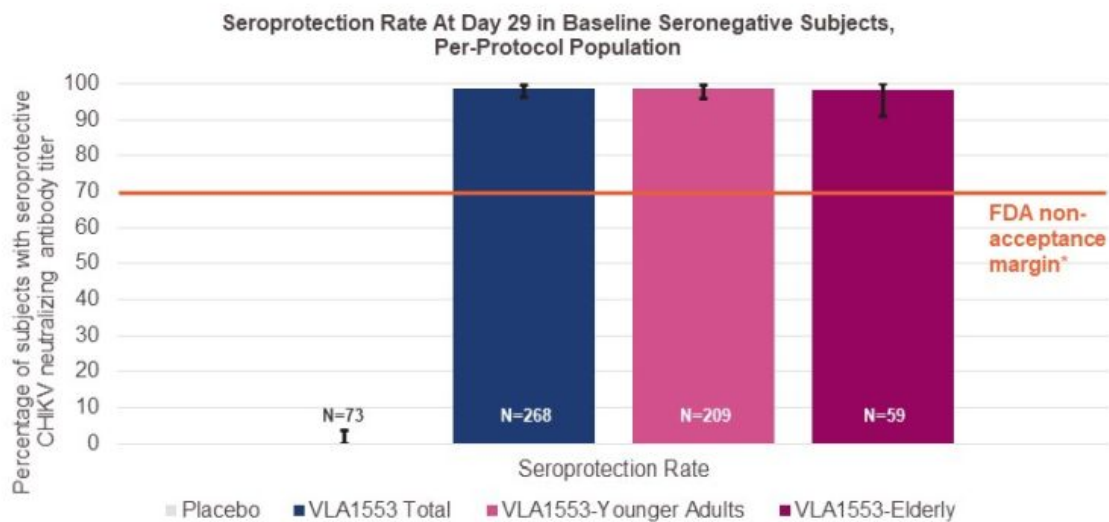
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VLA1553-301: Primary Endpoint Met

Protective CHIKV Neutralizing Antibody Titers Reported in 98.5% of Subjects After a Single Shot

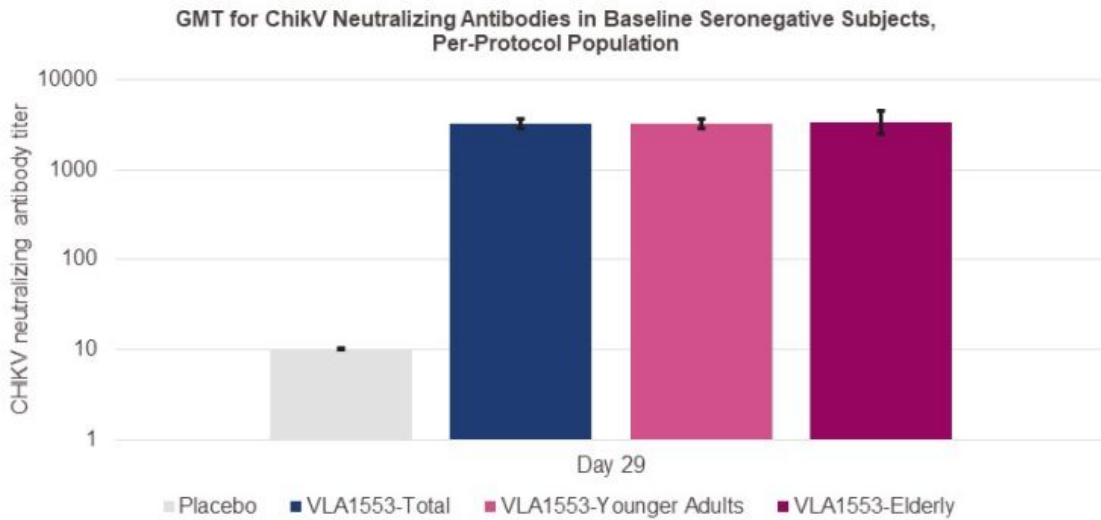


* The lower bound of the 95% Confidence Interval for the Seroprotection Rate needed to exceed 70% Neutralizing antibody titers determined using a μ PRNT₅₀ assay

Error Bars represent 95%CI

VLA1553-301: High Neutralizing Antibodies

Highly Immunogenic Across All Age Groups Including Elderly



Chikungunya virus neutralizing antibody titers were determined using a μ PRNT₅₀ assay. Values below the quantification limit are set to 10.

Error Bars represent 95%CI



Safety was evaluated in 3,082 participants who received VLA1553

- Independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns
- Safety profile consistent with Phase 1:
 - › Majority of solicited adverse events were mild or moderate and resolved within 3 days.
 - 1.6% reported severe solicited adverse events, most commonly fever
 - › Approximately 50% of study participants experienced solicited systemic adverse events, most commonly¹ headache, fatigue and myalgia
 - › Approximately 15% of participants experienced solicited local adverse events
- Equally good safety profile in elderly
- Final safety analysis expected within the next six months

¹ Seen in more than 20% of subjects



VLA1553: Development Outlook

Pivotal Phase 3 Trial – Final Data Expected Within the Next 6 Months

Most advanced clinical development program in the world

- Pivotal Phase 3 safety and immunogenicity trial progressing towards final analysis, expected within the next six months¹
- Lot-to-Lot consistency trial fully recruited (VLA1553-302), data expected late 2021²
- Antibody persistence follow-up trial (VLA1553-303) ongoing – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization¹

Valneva is discussing with the FDA to bring VLA1553 to a potential licensure as soon as possible

¹ Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; ² Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate; ³ In collaboration with development partner Instituto Butantan, under CEPI funding; ⁴ Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates ⁵ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>

VLA15 – Multivalent Lyme Disease Vaccine Candidate

Only Lyme Disease Program in Advanced Clinical Development Today



1 FDA Fast Track Designation granted

2 Initial results reported from Phase 2 trials ^{1,2}, Recruitment completed for Phase 2 trial VLA15-221 incl. pediatric participants³

3 Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe

4 Follows proven Mechanism of Action for a Lyme disease vaccine

5 Exclusive, worldwide partnership with Pfizer

¹ Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate; ² Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15; ³ Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate



VLA15: Development Progress

Phase 2 trial¹ in Adults and Pediatric Subjects Ongoing

VLA15-221 recruitment completed with a total of 625 participants, 5 to 65 years of age, randomized²

- The trial triggered a milestone payment of \$10 million, upon dosing of the first subject, from Pfizer to Valneva
- Topline results for VLA15-221 are expected in the first half of 2022.
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the 6 Month dose¹

Phase 3 pivotal efficacy trial planned to commence pending positive readout from VLA15-221 in 2022¹

- Clinical readout, based on one tick season, projected end 2023

Initial submission for regulatory approval anticipated in H2 2024, assuming positive data

¹Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate., ²Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate

VLA2001 – The Only Inactivated Vaccine in Clinical Development in Europe



- 1** UK government deal worth up to €1.4 billion¹ with development and manufacturing funding; ongoing dialogue with the European Commission
- 2** Program acceleration enabled through use of Valneva's FDA-registered facility in UK; commercial manufacturing commenced January 2021²
- 3** Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant³
- 4** Phase 1/2 clinical trial results reported⁴, Phase 3 trial "Cov-Compare" fully recruited
- 5** Regulatory submission to MHRA planned in autumn 2021, deliveries thereafter, subject to approval

Note: Photo credit: CDC/Aiissa Eckert, MSMI; Dan Higgins, MAM. ¹ Valneva announces major COVID-19 vaccine partnership with U.K. Government ² Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment ³ Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine ⁴ Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001



VLA2001: Development Outlook

Pivotal Phase 3 trial “Cov-Compare” Recruitment Completed¹

“Cov-Compare” (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in over 4,000 adults

- Immunological comparison against a licensed vaccine to reasonably predict efficacy (superiority of VLA2001 in a two-dose immunization schedule four weeks apart - GMTs of neutralising antibodies, at two weeks after the second vaccination)
- Study conducted in UK supported by DHSC/NIHR, including funding
- Protocol agreed with MHRA; discussion with other regulatory bodies ongoing
- Cov-Compare Phase 3 topline data expected early in the fourth quarter. Valneva expects to commence rolling submission with MHRA in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

Valneva participating in the world’s first COVID-19 vaccine booster trial in the UK²

Additional studies planned (including reduced booster dose)

Valneva studying other variants, to be in a position to manufacture variant-based vaccines

¹ Valneva Completes Phase 3 Trial Recruitment for its Inactivated COVID-19 Vaccine Candidate, ² Valneva to Participate in the World’s First COVID-19 Vaccine Booster Trial in the UK



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Updated guidance including COVID-19 expected

- Ongoing Phase 3 trials and regulatory discussions
- Role of VLA2001 as a booster
- Studying variants in order to be in a position to produce variant-based vaccines
- Ongoing discussions with EC

Valneva reconfirms its 2021 financial guidance (excluding COVID-19)

- Total revenues, excluding VLA2001, of €80 million to €105 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million



Product sales (Unaudited)²
-22% AER / -19% CER

Direct sales
98%

Gross margin³
39.2%

AER: Actual exchange rates, CER: Constant exchange rates; 1 Third party products sold by Valneva's commercial organization, 2 YoY comparison for same period, 3 Gross margin on product sales

EBITDA Loss Reflecting Increasing R&D Expenses

H1 2021 Profit & Loss Report (unaudited)



€m	H1 2021	H1 2020
Product sales	31.8	40.9
Revenues from collaboration, licensing and services	15.7	7.0
Revenues	47.5	47.9
Cost of goods	(23.5)	(18.1)
Cost of services	(11.3)	(4.4)
Research and development expenses	(78.7)	(33.1)
Marketing and distribution expenses	(9.6)	(10.0)
General and administrative expenses	(20.9)	(10.6)
Other income / (expense), net	10.4	6.5
Operating profit / (loss)	(86.2)	(21.9)
Finance, investment in associates & income taxes	(0.2)	(3.7)
Loss for the period	(86.4)	(25.6)
EBITDA¹	(80.1)	(17.2)

¹ EBITDA is a non-IFRS financial measure. A reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS, is included herein. H1 2021 EBITDA was calculated by excluding €6.1 million (H1 2020: €4.7 million) of depreciation and amortization from the €86.2 million operating loss (H1 2020: €21.9 million) as recorded in the consolidated income statement under IFRS.



Effect of COVID-19 Program on Group P&L

COVID-19 Program Reported as Separate Segment as of 2021

€m	H1 2021 Group	H1 2021 COVID only	H1 2021 excl. COVID
Product sales	31.8		31.8
Revenues from collaboration, licensing and services	15.7		15.7
Revenues	47.5		47.5
Cost of goods	(23.5)	(4.2)	(19.3)
Cost of services	(11.3)		(11.3)
Research and development expenses	(78.7)	(46.1)	(32.6)
Marketing and distribution expenses	(9.6)	(0.4)	(9.2)
General and administrative expenses	(20.9)	(9.4)	(11.5)
Other income / (expense), net	10.4	4.7	5.7
Operating profit / (loss)	(86.2)	(55.5)	(30.7)
Finance, investment in associates & income taxes	(0.2)		(0.2)
Loss for the period	(86.4)	(55.5)	(30.9)
EBITDA¹	(80.1)	(52.8)	(27.3)

Strong Cash Position of €329.8 million at End of June

Balance Sheet as of June 30, 2021



ASSETS	Jun 30, 2021	Dec 31, 2020
NON-CURRENT ASSETS	183,145	140,737
+ Intangible Assets	34,424	35,409
+ Right Of Use Assets	48,239	43,374
+ Property, plant & equipment	74,789	34,779
+ Other non-current assets	25,693	27,176
CURRENT ASSETS	561,277	308,427
+ Inventories	125,664	26,933
+ Trade receivables	18,007	19,232
+ Other current assets	87,841	57,828
+ Cash & current financial assets	329,766	204,435
TOTAL ASSETS	744,422	449,164
EQUITY & LIABILITIES	Jun 30, 2021	Dec 31, 2020
EQUITY	76,385	77,422
NON-CURRENT LIABILITIES	211,119	195,872
+ Borrowings, long term	47,402	46,375
+ Refund Liabilities	104,493	97,205
+ Other long term liabilities, including Lease Liabilities	59,224	52,292
CURRENT LIABILITIES	456,917	175,870
+ Trade payables and accruals	71,502	36,212
+ Borrowings, short term	7,079	6,988
+ Contract Liabilities	338,474	89,578
+ Refund Liabilities	6,875	14,222
+ Other current liabilities, including Lease Liabilities	32,987	28,871
TOTAL EQUITY AND LIABILITIES	744,422	449,164



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Chikungunya vaccine candidate VLA1553

- Final Phase 3 trial results
- Topline data of clinical lot-to-lot consistency Phase 3 trial

Lyme disease vaccine candidate VLA15

- Further Phase 2 milestones and read-outs

COVID-19 vaccine candidate VLA2001

- Clinical results including Cov-Compare and COV-Boost
- Marketing authorization submission, subject to data
- Further clinical development plans to complement UK trials

Supplemental Disclosures Regarding Non-IFRS Financial Measures



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

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth below:

€ in million	6 months ending June 30	
	2021	2020
Operating (loss)/Profit	(86.2)	(21.9)
Add:		
Amortization	3.1	3.0
Depreciation	3.0	1.7
EBITDA	(80.1)	(17.2)



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Thank you
Merci
Danke
Tack

