

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

FORM 6-K

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

Date of Report: May 5, 2022

Commission File Number: **001-40377**

Valneva SE

(Translation of registrant's name into English)

6 rue Alain Bombard

44800 Saint-Herblain, France

(Address of principal executive office)

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

Form 20-F [X] Form 40-F []

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

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

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

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

On May 4, 2022, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. On May 5, 2022, the Registrant announced its results of the first quarter of 2022 and issued a press release, unaudited consolidated interim financial statements, and a presentation, copies of which are attached hereto as Exhibits 99.2, 99.3, and 99.4, respectively, and incorporated herein by reference.

Exhibit

[Exhibit 99.1](#) [Press release dated May 4, 2022](#)

[Exhibit 99.2](#) [Press release dated May 5, 2022](#)

[Exhibit 99.3](#) [Unaudited Consolidated Interim Financial Statements at March 31, 2022](#)

[Exhibit 99.4](#) [Analyst Presentation dated May 5, 2022](#)

SIGNATURES

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

Valveva SE
(Registrant)

Date: May 5, 2022

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

Valneva Initiates Heterologous Booster Trial of Inactivated, COVID-19 Vaccine Candidate

Saint-Herblain (France), May 4, 2022 – Valneva SE, a specialty vaccine company, today announced the initiation of a heterologous booster trial of its inactivated whole-virus COVID-19 vaccine candidate VLA2001. The VLA2001-307 trial will be the Company's first clinical trial to provide booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection. Data, if positive, could support potential use as heterologous booster, subject to applicable regulatory recommendations and approvals.

The VLA2001-307 trial is expected to include approximately 150 participants who will receive a VLA2001 booster vaccination at least six months after primary vaccination with a licensed mRNA COVID-19 vaccine or following natural COVID-19 infection. The trial will be conducted in the Netherlands and topline results are expected in the third quarter of 2022.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This trial is extremely important as it will provide the first booster data in unvaccinated adults following natural COVID-19 infection. It will also provide data on VLA2001's capability for use as a heterologous booster and could potentially nicely complement the positive homologous booster data we already generated. We would like to thank all those who are demonstrating continued interest in our vaccine; we remain fully committed to bring our inactivated solution to as many people as we can."

Valneva announced positive homologous booster results at the end of December 2021¹. The data showed an excellent immune response after a third dose of VLA2001 administered seven to eight months after the second dose of primary vaccination with VLA2001. The third dose of VLA2001 showed a strong boosting effect, increasing levels of binding antibodies against the Wuhan virus 42- to 106-fold, depending on the pre-boosting levels of antibodies. In April 2022, VLA2001 was granted Conditional Marketing Authorization by the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for primary immunization in adults 18 to 50 years of age². This authorization followed emergency use authorization from the Bahraini NHRA in March 2022³. The Company is still in a rolling review process with the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and remains focused on achieving a Conditional Marketing Authorization for VLA2001 in the European Union this quarter.

About Trial VLA2001-307

VLA2001-307 is a multicenter, open-label, single-arm clinical study investigating the safety, tolerability and immunogenicity of a VLA2001 booster vaccination in participants aged 18 years and older. Approximately 150 participants, either generally healthy or with a stable medical condition, will be enrolled in the trial. The VLA2001 booster will be given to adults 6 to 12 months after completion of primary vaccination with an mRNA COVID-19 vaccine or unvaccinated adults 6 to 12 months after PCR confirmation of natural SARS-CoV-2 infection.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines. VLA2001 is 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 US FDA- and EMA-approved HEPLISAV-B[®] vaccine. VLA2001's manufacturing process, which has already been upscaled to final industrial scale, includes chemical inactivation to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 to 8 degrees Celsius).

About Valneva SE

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

Media & Investor Contacts

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, design, data read-outs, anticipated results and completion of clinical trials for VLA2001. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future results. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection and the impact of the COVID-19 pandemic. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

¹ Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

² Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva

³ Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva

Valneva Reports Q1 2022 Results and Provides Corporate Updates

Excellent progress on clinical programs**Lyme Disease Vaccine Candidate VLA15**

- Further positive Phase 2 results reported, including first pediatric data
- Phase 3 expected to commence in the third quarter of 2022

Inactivated COVID-19 Vaccine Candidate VLA2001

- Conditional Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK)
- Emergency use authorization granted by the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain and first vaccinations confirmed
- Rolling review ongoing with the European Medicines Agency (EMA); Valneva has provided responses to the latest list of questions (LOQ)

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Final positive pivotal Phase 3 results reported
- Pre-submission discussions initiated with the US Food and Drug Administration (FDA)

First COVID-19 vaccine sales and strong cash position

- **Total revenue of €21.8 million in the first quarter of 2022 compared to €23.2 million in the first quarter of 2021**
 - Includes product sales of €16.2 million (vs €16.1 million in the first quarter of 2021) with first COVID-19 vaccine sales of €3.8 million
 - €5.6 million of other revenues (vs €7.1 million in the first quarter of 2021)
- **Cash position of €311.3 million at March 31, 2022**
 - Up to an additional \$40 million made available in April 2022 as part of a recent upsized financing arrangement with leading US Healthcare Funds Deerfield and OrbiMed (of which \$20 million conditioned to EMA's approval of VLA2001)

FY 2022 financial guidance confirmed

The Company confirms it still expects its total 2022 revenues to be within the range announced in February (€430 million to €590 million). Considering the uncertainties on the timing of product deliveries, the distribution of total revenues by revenue category may differ from the figures announced in February.

Financial Information

(unaudited results, consolidated per IFRS)

€ in million	3 months ending March 31	
	2022	2021
Total revenues	21.8	23.2
Product sales	16.2	16.1
Net loss	(26.0)	(27.7)
Adjusted EBITDA ¹	(18.4)	(28.3)
Cash	311.3	235.9

Saint-Herblain (France), May 5, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its first quarter financial results ending March 31, 2022 and provided corporate updates. The condensed consolidated interim financial results are available on the Company's website (Financial Reports – Valneva).

Valneva will provide a live webcast of its first quarter financial results conference call beginning at 3 p.m. CEST or 9 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/pykk7aep>

Peter Böhler, Valneva's Chief Financial Officer, commented, "Valneva continued to achieve significant milestones in the first quarter of the year with the first approval and first sales of our COVID-19 vaccine, successful completion of the pivotal Phase 3 trial of our chikungunya vaccine candidate and further positive Phase 2 results for our Lyme disease vaccine candidate. More recently, receiving conditional approval from the UK MHRA is a great recognition for our inactivated COVID-19 vaccine and we are now focused on making it available to additional people in geographical Europe and other regions of the world. The first quarter was also marked by tangible signs of a travel industry recovery which has already started to positively impact our travel vaccine sales. I would like to take this opportunity to thank our shareholders, partners and employees for their ongoing support and contribution."

Clinical Stage Vaccine Candidates**LYME DISEASE VACCINE CANDIDATE – VLA15****Further positive Phase 2 results reported including first pediatric data**

Valneva and Pfizer² are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. The vaccine candidate covers the six OspA serotypes expressed by *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe.

In April 2022, Valneva and Pfizer reported first pediatric results for VLA15. In the Phase 2 study, VLA15 was found to be more immunogenic in pediatric participants (5-17 years old) than in adults with both two-dose or three-dose vaccination schedules. These positive data build on the strong immunogenicity profile reported for adult participants (18-65 years old) in February 2022. Based on these latest Phase 2 immunogenicity and safety data, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule for both adult and pediatric participants in a Phase 3 clinical trial planned to start in the third quarter of 2022.

SARS-CoV-2 INACTIVATED VACCINE CANDIDATE – VLA2001**UK MHRA Conditional Marketing Authorization granted**

VLA2001 is currently the only whole virus, inactivated, adjuvanted COVID-19 vaccine candidate that has received an approval in geographical Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for the Company's commercial Japanese encephalitis vaccine, IXIARO[®].

Valneva recently initiated a heterologous booster trial of VLA2001 to provide booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection³. These data, if positive, could support potential use of VLA2001 as heterologous booster, subject to applicable regulatory recommendations and approvals. Topline results are expected in the third quarter of 2022.

In April 2022, VLA2001 was granted Conditional Marketing Authorization by the UK Medicines and Healthcare products Regulatory Agency (MHRA) for primary immunization in adults 18 to 50 years of age⁴. This authorization followed emergency use authorization from the Bahraini NHRA in March 2022⁵.

Valneva remains focused on achieving a Conditional Marketing Authorization for VLA2001 within the European Union. The Company is still in a rolling review process with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Following its April meeting, the CHMP provided another List of Questions, to which Valneva has already responded. If the CHMP accepts these responses, the Company would expect a Conditional Marketing Authorization this quarter.

The Company signed a supply agreement with the European Commission (EC) in November 2021⁶.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553**Final Positive Phase 3 Results reported**

Valneva is developing a single-dose vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to over 100 countries.

In March 2022, Valneva announced successful completion of the Phase 3 pivotal trial of VLA1553⁷. The final six-month analysis confirmed the very high level of seroprotection reported in August 2021. Six months after receiving a single vaccination, 96.3% of participants showed protective chikungunya virus-neutralizing antibody titers. VLA1553's safety and tolerability profile was also consistent with topline Phase 3 data. Valneva has initiated pre-submission discussions with the US FDA and expects to submit its Biologics License Application (BLA) in the second half of 2022.

The Company also previously reported positive topline lot-to-lot manufacturing consistency trial results for VLA1553⁸. This is one of the standard requirements for vaccine licensure, and final lot-to-lot results are expected in the second quarter of 2022.

Valneva also initiated a Phase 3 trial in adolescents in January 2022. The trial, conducted in Brazil by Instituto Butantan, is designed to support label extension to this age group following a potential initial regulatory approval in adults in the US⁹. Funded by the Coalition for Epidemic Preparedness Innovations, the trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

Commercial Vaccines

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

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

IXIARO[®]/JESPECT[®] product sales decreased by 68.6% (70.5% at constant exchange rates) to €4.2 million in the first quarter of 2022 compared to €13.3 million in the first quarter of 2021. Sales to the private travel markets showed significant recovery with IXIARO[®]/JESPECT[®] sales reaching €3.9 million in the first quarter of 2022 compared to €1.0 million in the first quarter of 2021 while sales to the US Government's Department of Defense (DoD) were lower in the first quarter of 2022 compared to the same period last year as per the planned delivery schedule.

CHOLERA / ETEC¹⁰-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 ETEC.

DUKORAL[®] product sales increased significantly to €2.5 million in the first quarter of 2022 compared to €0.1 million in the first quarter of 2021 equally attributable to a recovery of the travel business across all markets.

First Quarter 2022 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €21.8 million in the first quarter of 2022 compared to €23.2 million in the first quarter of 2021, a decrease of 5.9%.

Product sales, including first COVID-19 vaccine sales, increased by 0.2% to €16.2 million in the first quarter of 2022 compared to €16.1 million in the first quarter of 2021. On a constant exchange rate (CER) basis, product sales decreased by 4.8% in the first quarter of 2022 as compared to the first quarter of 2021. Product sales excluding COVID-19 vaccine sales amounted to €12.4 million in the first quarter of 2022, a decrease of 23.3% (27.2% at CER) compared to the first quarter of 2021.

IXIARO[®]/JESPECT[®] product sales decreased by 68.6% (70.5% at CER) to €4.2 million in the first quarter of 2022 compared to €13.3 million in the first quarter of 2021. Sales to the private travel markets showed significant recovery while sales to the US Government's Department of Defense (DoD) were lower in the first quarter of 2022 compared to the same period last year as per the planned delivery schedule. DUKORAL[®] also benefited from the travel market recovery as sales increased significantly to €2.5 million in the first quarter of 2022 compared to €0.1 million in the first quarter of 2021. COVID-19 product vaccine sales amounted to €3.8 million resulting from first shipments of VLA2001 to Bahrain. Third Party product sales more than doubled to €5.6 million in the first quarter of 2022 from €2.7 million in the first quarter of 2021 driven by growth related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur[®]/RabAvert[®] and Encepur[®].

Other revenues, including revenues from collaborations, licensing and services amounted to €5.6 million in the first quarter of 2022 compared to €7.1 million in the first quarter of 2021.

Operating Result and EBITDA

Costs of goods and services sold (COGS) were €13.9 million in the first quarter of 2022. Gross margin on product sales excluding COVID-19 sales was 68.5% compared to 41.7% in the first quarter of 2021. Both IXIARO[®] and DUKORAL[®]'s gross margins, of 99.3% and 92.0% respectively, were affected by inventory revaluation gains and releases of write-off provisions resulting from increased sales projections as well as the positive effect from the Company's share price development on the employee share-based compensation programs. Of the remaining COGS for the first quarter of 2022, €3.7 million were related to the Third-Party product distribution business, €8.0 million to the COVID-19 business and €1.9 million to cost of services. In the first quarter of 2021, overall COGS were €14.7 million, of which €9.6 million related to cost of goods and €5.1 million related to cost of services.

Research and development investments amounted to €20.7 million in the first quarter of 2022 compared to €27.7 million in the first quarter of 2021. This decrease was mainly driven by the progression of Valneva's chikungunya vaccine program, VLA1553, towards BLA submission and the lower clinical trial costs resulting from it as well as lower investments in Valneva's COVID-19 vaccine candidate VLA2001. Marketing and distribution expenses in the first quarter of 2022 amounted to €2.0 million compared to €4.9 million in the first quarter of 2021. Marketing and distribution expenses in the first quarter of 2022 notably included €0.9 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate, VLA1553, (compared to €1.2 million in the first quarter of 2021). In the first quarter of 2022, general and administrative expenses declined to €5.8 million from €10.0 million in the first quarter of 2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a provision release of €11.7 million related to the positive effect of the Company's share price development on the employee share-based compensation programs. This income compares to a cost of €4.8 million in the first quarter of 2021.

Other income, net of other expenses, reduced to €2.1 million in the first quarter of 2022 from €3.0 million in the first quarter of 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending.

Valneva recorded an operating loss of €18.4 million in the first quarter of 2022 compared to an operating loss of €31.1 million in the first quarter of 2021. Adjusted EBITDA loss in the first quarter of 2022 was €12.7 million compared to an EBITDA loss of €28.3 million in the first quarter of 2021.

Net Result

In the first quarter of 2022, Valneva generated a net loss of €26.0 million compared to a net loss of €27.7 million in the first quarter of 2021.

Finance expense and currency effects in the first quarter of 2022 resulted in a net finance expense of €7.1 million, compared to a net finance income of €3.1 million in the first quarter of 2021.

This was mainly a result of a foreign exchange loss amounting to €2.4 million in the first quarter of 2022, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €7.7 million in the first quarter of 2021. Interest charges slightly increased to €4.7 million in the first quarter of 2022 compared to €4.6 million in the first quarter of 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €26.9 million in the first quarter of 2022 compared to €47.6 million of cash generated in operating activities in the first quarter of 2021. Cash outflows in the first quarter of 2022 were mainly related to the operating loss generated in the period, while during the first quarter of 2021 cash inflows mainly resulted from pre-payments related to the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €9.4 million in the first quarter of 2022 compared to €16.9 million in the first quarter of 2021, both mainly as a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €1.0 million in the first quarter of 2022, which was mainly a result of proceeds from the issuance of new shares in relation to employee stock option and free share programs. Cash outflows in the first quarter of 2021 amounted to €1.6 million and mainly consisted of payments related to interest and lease liabilities.

Liquid funds decreased to €311.3 million as of March 31, 2022, compared to €346.7 million as of December 31, 2021. The cash decrease mainly resulted from ongoing COVID-19-related investments into fixed assets and R&D expenses.

Non-IFRS Financial Measures

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

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

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

€ in million (unaudited results, consolidated per IFRS)	3 months ending March 31	
	2022	2021
Operating Loss	(18.4)	(31.1)
Add:		
Amortization	1.6	1.5
Depreciation	3.6	1.3
Impairment of Tangible Assets	-	-
Adjusted EBITDA	(13.3)	(28.3)

About Valneva SE

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

Valneva Investor and Media Contacts

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including but not limited to statements regarding expected total revenues for full fiscal year 2022, possible regulatory approvals of product candidates, and initiation of clinical trials. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future results. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, including but not limited to the VLA2001 supply agreement with the UK government, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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

² Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

³ Valneva Initiates Heterologous Booster Trial of Inactivated, COVID-19 Vaccine Candidate

⁴ Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva

⁵ Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva

⁶ Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001

⁷ Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva

⁸ Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate

⁹ Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva

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.

Q1 2022

**VALNEVA SE
CONDENSED
CONSOLIDATED INTERIM
FINANCIAL STATEMENTS**

May 5, 2022

VALNEVA SE
Campus Bio-Ouest
6 rue Alain Bombard
44800 Saint-Herblain, France
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CONSOLIDATED FINANCIAL STATEMENTS 2022

VALNEVA

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

Registered offices:

6 rue Alain Bombard, 44800 SAINT-HERBLAIN - France
Nantes Companies Register (RCS) No. 422 497 560

**Unaudited Consolidated Interim financial statements
as at March 31, 2022**



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

1.1 Unaudited Interim Condensed Consolidated Statements of Income (Loss)

€ in thousand (except per share amounts)	Three months ended March 31,	
	2022	2021
Product sales	16,162	16,124
Other revenues	5,686	7,092
Revenues	21,847	23,215
Cost of goods and services	(13,860)	(14,650)
Research and development expenses	(20,689)	(27,732)
Marketing and distribution expenses	(2,034)	(4,941)
General and administrative expenses	(5,770)	(10,010)
Other income and expenses, net	2,084	2,979
OPERATING LOSS	(18,422)	(31,138)
Finance income	13	7,695
Finance expenses	(7,130)	(4,607)
Result from investments in associates	-	(19)
LOSS BEFORE INCOME TAX	(25,539)	(28,070)
Income tax income/(expense)	(502)	368
LOSS FOR THE PERIOD	(26,041)	(27,702)
Losses per share for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share		
- basic	(0.24)	(0.30)
- diluted	(0.24)	(0.30)

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

€ in thousand	Three months ended March 31,	
	2022	2021
Loss for the period	(26,041)	(27,702)
Other comprehensive income/(loss)		
Items that may be reclassified to profit or loss		
Currency translation differences	(244)	(337)
Items that will not be reclassified to profit or loss		
Defined benefit plan actuarial gains/(losses)	-	-
Other comprehensive loss for the period, net of tax	(244)	(337)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY	(26,285)	(28,038)

**2 UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

€ in thousand	March 31,	December 31,
	2022	2021
ASSETS		
Non-current assets	232,690	231,520
Intangible assets	31,765	32,700
Right of use assets	47,562	48,285
Property, plant and equipment	128,418	125,545
Investments in associates	2,124	2,124
Deferred tax assets	3,304	3,582
Other non-current assets	19,516	19,282
Current assets	545,021	585,832
Inventories	139,725	124,098
Trade receivables	25,061	44,013
Other current assets	68,972	71,036
Cash and cash equivalents	311,264	346,686
TOTAL ASSETS	777,711	817,352
EQUITY		
Capital and reserves attributable to the Company's equity holders	148,406	170,581
Share capital	16,170	15,786
Share premium	412,799	409,258
Other reserves	52,452	52,512
Accumulated deficit	(306,974)	(233,549)
Loss for the period	(26,041)	(73,425)
LIABILITIES		
Non-current liabilities	266,049	277,791
Borrowings	48,005	50,726
Lease liabilities	52,663	53,687
Contract liabilities	4,830	4,741
Refund liabilities	156,229	158,970
Provisions	2,975	8,308
Deferred tax liabilities	1,280	1,290
Other liabilities	68	69
Current liabilities	363,257	368,979
Borrowings	11,730	7,107
Trade payables and accruals	66,268	68,119
Income tax liability	72	83
Tax and Employee-related liabilities	19,838	17,249
Lease liabilities	3,122	3,135
Contract liabilities	122,478	124,017
Refund liabilities	100,279	95,611
Provisions	30,554	48,708
Other liabilities	8,917	4,950
TOTAL LIABILITIES	629,305	646,771
TOTAL EQUITY AND LIABILITIES	777,711	817,352



3 UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

€ in thousand	Three months ended March 31,	
	2022	2021
Cash flows from operating activities		
Loss for the period	(26,041)	(27,702)
Adjustments for non-cash transactions	(6,922)	6,232
Changes in non-current operating assets and liabilities	(4,763)	1,951
Changes in working capital	11,193	68,373
Cash generated from/(used in) operations	(26,533)	48,855
Income tax paid	(318)	(1,296)
Net cash generated from/(used in) operating activities	(26,851)	47,559
Cash flows from investing activities		
Purchases of property, plant and equipment	(9,385)	(16,333)
Purchases of intangible assets	(76)	(543)
Interest received	13	19
Net cash used in investing activities	(9,447)	(16,857)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of costs of equity transactions	3,726	2,209
Disposal of treasury shares	-	154
Payment of lease liabilities	(835)	(518)
Interest paid	(1,909)	(3,396)
Net cash generated from/(used in) financing activities	982	(1,550)
Net change in cash and cash equivalents	(35,316)	29,152
Cash and cash equivalents at beginning of the period	346,642	204,394
Exchange gains/(losses) on cash	(107)	2,324
Restricted cash	45	43
Cash and cash equivalents at end of the period	311,264	235,913



4 UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

€ in thousand (except number of shares)	Number of shares issued	Share capital	Share premium	Other reserves	Retained earnings/ (Accumula- ted deficit)	Profit/ (loss) for the period	Total equity
Balance as at January 1, 2021	90,970,562	13,646	244,984	52,342	(169,156)	(64,393)	77,422
Total comprehensive loss	-	-	-	(337)	-	(27,702)	(28,038)
Income appropriation	-	-	-	-	(64,393)	64,393	-
Share-based compensation expense:							
- value of services	-	-	-	608	-	-	608
- exercises	793,200	119	2,090	-	-	-	2,209
Treasury shares	-	-	-	154	-	-	154
Balance as at March 31, 2021	91,763,762	13,765	247,074	52,768	(233,549)	(27,702)	52,355
Balance as at January 1, 2022	105,239,085	15,786	409,258	52,512	(233,549)	(73,425)	170,581
Total comprehensive loss	-	-	-	(244)	-	(26,041)	(26,285)
Income appropriation	-	-	-	-	(73,425)	73,425	-
Share-based compensation expense:							
- value of services	-	-	-	185	-	-	185
- exercises	2,563,011	384	3,541	-	-	-	3,925
Treasury shares	-	-	-	-	-	-	-
Balance as at March 31, 2022	107,802,096	16,170	412,799	52,452	(306,974)	(26,041)	148,406

Valneva Reports Q1 2022 Results and Provides Corporate Updates

Analyst Presentation
May 5, 2022





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Excellent progress on clinical programs

- **Lyme disease:** Further positive Phase 2 results reported, including first pediatric data
- **COVID-19:**
 - MHRA Conditional Marketing Authorization received
 - NHRA Emergency use authorization received, first vaccinations in Bahrain confirmed
 - EMA rolling review ongoing
- **Chikungunya:**
 - Final positive pivotal Phase 3 results reported
 - Pre-submission discussions initiated with the US FDA

First COVID-19 vaccine sales and strong cash position

- Total revenue of €21.8 million in Q1 2022
 - Positive signals from travel market and first COVID-19 sales
- Cash position of €311.3 million at March 31, 2022



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VLA15 – Multivalent Lyme Disease Vaccine Candidate



Only Lyme Disease Program in Advanced Clinical Development Today



- 1 FDA Fast Track Designation granted
- 2 Exclusive, worldwide partnership with Pfizer
- 3 Positive results reported from Phase 2 trials^{1,2,3}, incl. first pediatric data and booster response⁴; Phase 3 schedule selected
- 4 Multivalent vaccine (six serotypes) to help protect against Lyme disease in the United States and Europe
- 5 Follows proven Mechanism of Action for a Lyme disease vaccine

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 Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; ⁴ Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate



VLA15: Development Progress and Outlook

Positive Phase 2 Results in Adults^{1,2,3,4} and Pediatric Participants⁵ Reported

The Phase 2 trial VLA15-221 recruited 625 randomized participants, 5 to 65 years of age²

- Strong immunogenicity profile for both adult and pediatric participants reported in February³ and April 2022⁵ respectively
- VLA15 was found to be more immunogenic in pediatric participants (5-17 years old) than in adults with both two-dose or three-dose vaccination schedules


Phase 3 clinical trial planned to start in the third quarter of 2022

- Based on the latest Phase 2 immunogenicity and safety data, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule for both adult and pediatric participants⁵
- Clinical readout, based on one tick season, projected by end of 2023
- \$25m milestone payment due to Valneva upon trial initiation

¹ Valneva and Pfizer Announces Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate, ² Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate, ³ Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate, ⁴ Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate, ⁵ Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate

VLA1553: Single Shot Chikungunya Vaccine Candidate

Most Clinically Advanced Chikungunya Vaccine Program Worldwide



- 1 Final positive pivotal Phase 3 results¹ and topline lot-to-lot data² reported; Adolescent Phase 3 trial initiated in January 2022³
- 2 FDA Breakthrough Therapy⁴, Fast Track⁵ and EMA PRIME⁷ designations granted; Potentially eligible for Priority Review Voucher⁶; FDA Pre-submission process initiated
- 3 Single shot, live attenuated⁸ prophylactic vaccine targeting chikungunya virus neutralization
- 4 Up to \$23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs⁹
- 5 Excellent fit with existing commercial and manufacturing capabilities
- 6 Global market, including endemic regions, estimated to exceed \$500 million annually by 2032¹⁰

Note: Photo credit: James Gathany. 1 [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate](#); 2 [Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate](#); 3 [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate](#); 4 [Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate](#); 5 [Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate](#); 6 <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-oder/tropical-disease-priority-review-voucher-program>; 7 [Valneva's Chikungunya vaccine candidate awarded EMA prime designation](#); 8 [CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 \(alphavirus-replicase\)](#); 9 [Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-income countries](#); 10 [VacZineAnalytics Chikungunya virus vaccines Global demand analysis](#). February 2020.

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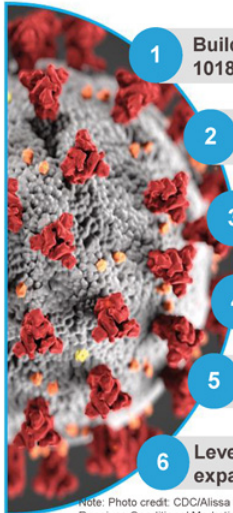
First and only program to have reported positive Phase 3 results worldwide

- Six-month follow-up completed - all Phase 3 immunogenicity and safety endpoints met - seroresponse in 98.9% of participants after one month and 96.3% after six months - good safety and tolerability profile confirmed
- Positive topline lot-to-lot consistency trial results reported (VLA1553-302)², final data expected in Q2 2022
- Antibody persistence follow-up trial (VLA1553-303) ongoing: up to 375 volunteers from the VLA1553-301 trial will be followed annually for five years
- Adolescent Phase 3 trial initiated in January 2022 to support potential label expansion, funded by the Coalition for Epidemic Preparedness Innovations (CEPI)³

¹ Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; ² Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; ³ Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate

VLA2001: Inactivated whole virus COVID-19 Vaccine Candidate

Only Inactivated COVID-19 Vaccine Program in the Clinics in Europe



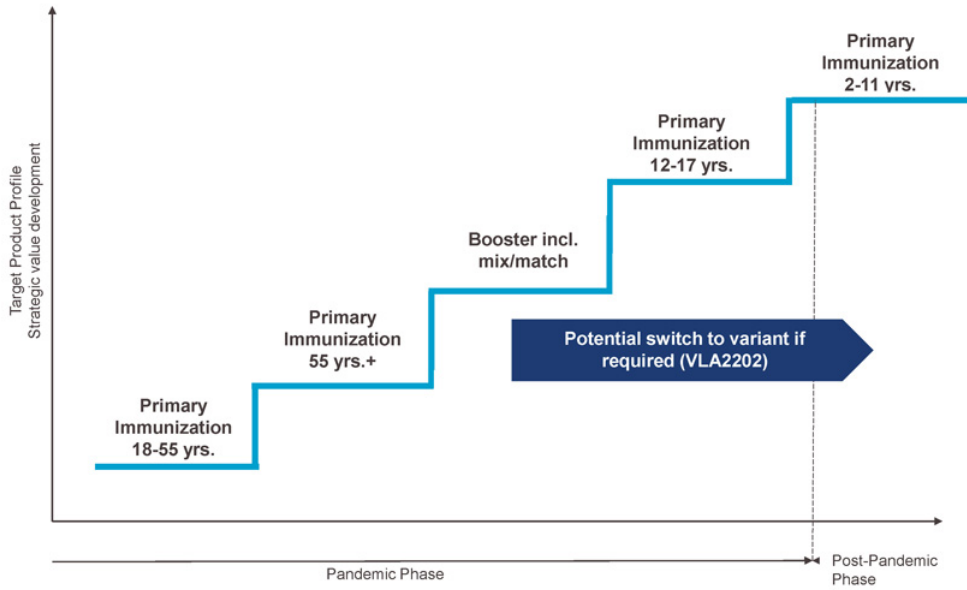
- 1 Builds on Valneva's IXIARO[®] manufacturing technology combined with Dynavax's CpG 1018 adjuvant¹
- 2 UK MHRA Conditional Marketing Authorization² and Bahraini NHRA Emergency Use Authorization received³; EMA rolling review ongoing
- 3 Advance purchase agreements for up to 60 million doses with European Commission⁴ and for one million doses with Bahrain⁵
- 4 Pivotal Phase 3 trial showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability⁶; Positive topline homologous booster data reported⁷; Shown to neutralize Omicron and Delta variants in laboratory studies⁸
- 5 Ongoing clinical trials aiming to gradually extend target product profile (label)
- 6 Leveraging Valneva's manufacturing sites in Scotland and Sweden; capacity being expanded, including CMO⁹ – targeting >100m doses per annum¹⁰

Note: Photo credit: CDC/Alissa Eckert, MSM; Dan Higgins, MAM. 1 Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; 2 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine; 3 Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; 4 Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001; 5 Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; 6 Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001; 7 Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva; 8 Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variants; 9 Valneva and IDT Biologics Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001; 10 Based on a combination of in-house capacity and external/contracted manufacturing.

VLA2001: Planned Label Extensions



Ongoing and Future Clinical Studies Expected To Strengthen Product Profile





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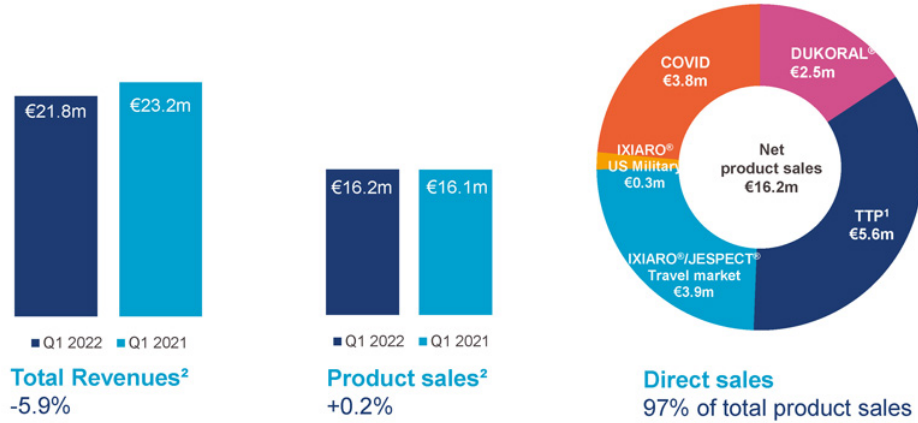
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First Quarter 2022 Financials: Total Revenues of €21.8 million
 First COVID-19 Product Sales Recognized in Q1 2022



¹ Third party products sold by Valneva, ² YoY comparison for same period
 Valneva Q1 2022 Analyst Presentation

First Quarter 2022 Financials: Product Sales of €16.2 million
Private Travel Markets Showing Significant Recovery



€m (unaudited)	Q1 2022	Q1 2021	Q1 2021 at CER*	Q1 2022 vs. Q1 2021 %
IXIARO®/JESPECT®	4.2	13.3	14.2	-70.5%
DUKORAL®	2.5	0.1	0.1	>2000%
Third party products	5.6	2.7	2.7	+110.9%
COVID	3.8	-	-	-
Total product sales	16.2	16.1	17.0	-4.8%
IXIARO®/JESPECT® (excluding US Military)	3.9	1.0	1.0	>3500%

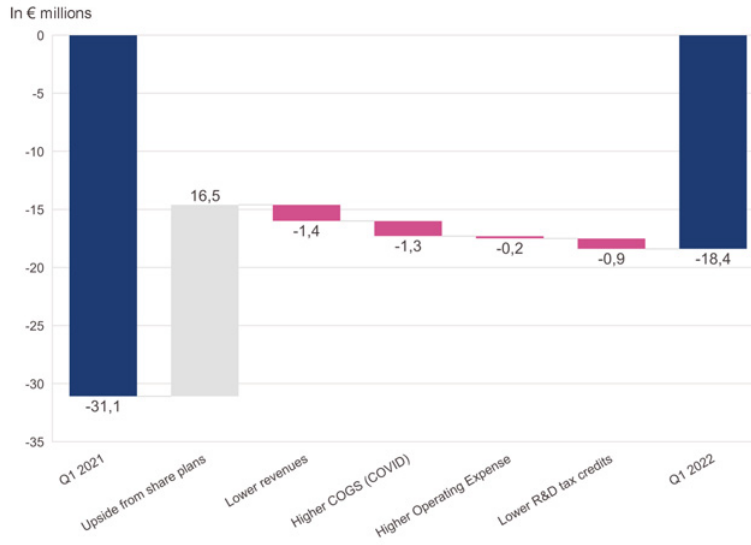
* Q1 2021 recalculated at actual average Q1 2022 exchange rates
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First Quarter 2022 Financials: Adjusted EBITDA of - €13.3 million 
 Positive OPEX Effects Driven by Share-based Compensation Programs

€m (unaudited)	Q1 2022	Q1 2021
Product sales	16.2	16.1
Other Revenues	5.7	7.1
Revenues	21.8	23.2
Cost of goods and services	(13.9)	(14.7)
Research and development expenses	(20.7)	(27.7)
Marketing and distribution expenses	(2.0)	(4.9)
General and administrative expenses	(5.8)	(10.0)
Other income / (expense), net	2.1	3.0
Operating loss	(18.4)	(31.1)
Finance, investment in associates & income taxes	(7.6)	3.4
Profit/loss for the period	(26.0)	(27.7)
Adjusted EBITDA¹	(13.3)	(28.3)

¹ Q1 2022 Adjusted EBITDA was calculated by excluding €5.2 million (Q1 2021: €2.8 million) of depreciation and amortization from the €18.4 million (Q1 2021: €31.1 million) operating loss as recorded in the consolidated income statement under IFRS.

First Quarter 2022 Net Operating Profit Main P&L Movements Compared to Q1 2021



First Quarter 2022 Financials: Impact of COVID-19 Program on P&M
 Negative Adjusted EBITDA Mostly Attributable to COVID-19 Investments

€m (unaudited)	Q1 2022	Q1 2022	Q1 2022
	Group	COVID only	excl. COVID
Product sales	16.2	3.8	12.4
Other Revenues	5.7	-	5.7
Revenues	21.8	3.8	18.0
Cost of goods and services	(13.9)	(8.0)	(5.8)
Research and development expenses	(20.7)	(21.0)	0.3
Marketing and distribution expenses	(2.0)	(0.1)	(1.9)
General and administrative expenses	(5.8)	(2.9)	(2.8)
Other income / (expense), net	2.1	1.8	0.3
Operating loss	(18.4)	(26.5)	8.1
Finance, investment in associates & income taxes	(7.6)	-	(7.6)
Profit/loss for the period	(26.0)	(26.5)	0.5
Adjusted EBITDA¹	(13.3)	(22.7)	9.4

¹ Q1 2022 Adjusted EBITDA was calculated by excluding €5.2 million of depreciation and amortization from the €18.4 million operating loss as recorded in the consolidated income statement under IFRS.



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- Total revenues expected to be in the range announced in February 2022 (€430 million to €590 million).
- Distribution of total revenues by category may differ from the figures announced in February considering the uncertainties on the timing of product deliveries



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Lyme disease vaccine candidate VLA15

- Phase 3 trial initiation expected in Q3 2022

Chikungunya vaccine candidate VLA1553

- Final lot-to-lot Phase 3 data expected in Q2 2022
- Biologics License Application (BLA) expected in H2 2022

COVID-19 vaccine candidate VLA2001

- Potential additional regulatory approvals
- Supplies and potential further purchase agreements
- Further clinical trials and data expected

Thank you
Merci
Danke
Tack

 valneva