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: February 4, 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 February 3, 2022 and February 4, 2022, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1 and 99.2 and are incorporated herein by reference.

Exhibits

99.1	Press release dated February 3, 2022
99.2	Press release dated February 4, 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.

Valneva SE
(Registrant)

Date: February 4, 2022

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

EXHIBIT 99.1

Valneva Reports Full Year 2021 Revenue and Cash; Provides First 2022 Guidance

Total revenues of €348.1 million in 2021 compared to €110.3 million in 2020 – an increase of 216%

- Includes €94.8 million of product and other revenues (excluding COVID), at the higher end of the Company's previously communicated guidance of €85 to €100 million, and
- €253.3 million of COVID-related revenues under the terminated UK agreement

Strong cash position of €346.7 million at end of December 31, 2021

- Reflects $209.6 million of combined gross proceeds from Nasdaq Initial Public Offering (IPO) and European placement in May 2021, plus November 2021 follow-on offering, and
- Significant pre-payments under the EC COVID-19 vaccine supply agreement

Full year 2022 financial guidance

- Total revenues expected between €430 to €590 million, including:
  - €350 to €500 million of COVID-19 vaccine sales subject to regulatory approvals and deliveries of VLA2001[1],
  - €60 to €70 million of other vaccine sales
  - Approximately €20 million of Other Revenues (revenues from collaborations, licensing and services)

Key milestones achieved include:

Lyme Disease Vaccine Candidate VLA15

- Further positive Phase 2 results, including booster response

Inactivated COVID-19 Vaccine Candidate VLA2001

- Positive pivotal Phase 3 results
- Advance Purchase Agreement approved by European Commission (EC) for up to 60 million doses in 2022 and 2023
- Initiation of rolling submissions to the European Medicines Agency (EMA) as well as the UK and Bahraini agencies (MHRA and NHRA, respectively)
- Positive homologous booster results between seven to eight months after primary vaccination
- Confirmed neutralization of Omicron and Delta variants in laboratory studies

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Positive pivotal and lot-to-lot Phase 3 results

Raised approximately $210 million

- Successful Nasdaq IPO and concurrent private placement in Europe
- Successful follow-on equity offering in the US and Europe

Saint-Herblain (France), February 3, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today reported its revenue and cash balance for the full year 2021 and provided full year 2022 revenue guidance. The Company will report its 2021 audited consolidated financial statements in March 2022.

Peter Bühler, Valneva's Chief Financial Officer, commented, "2021 was an exceptional year for Valneva, marked by the EC COVID-19 supply agreement, our successful Nasdaq listing and the great progress made across our R&D pipeline. We reported positive Phase 3 results for two vaccine candidates (COVID-19 and chikungunya) and we expect both vaccines, if approved, to make a positive change to people's lives. With close to €350 million in cash, we entered 2022 in a strong position and will continue to focus on gaining regulatory approvals and preparing market entry for our key late stage programs."

Revenues

Valneva's total revenues were €348.1 million in 2021 compared to €110.3 million in 2020, an increase of 216%.

Product sales decreased by 4.5% to €63.0 million in 2021 compared to €65.9 million in 2020 as the travel industry continued to be impacted by the COVID-19 pandemic. On a constant exchange rate (CER) basis, product sales also decreased by 4.5% in 2021 as compared to 2020.

IXIARO®/JESPECT® sales decreased by 6.9% (5.7% at CER) to €45.1 million in 2021 compared to €48.5 million in 2020. The impact of the COVID-19 pandemic was mitigated by sales to the U.S. Government's Department of Defense (DoD) during the period.

DUKORAL® sales declined by 81.7% (82.4% at CER) to €2.4 million in 2021 compared to €13.3 million in 2020.

Third Party product sales grew by 271.3% to €15.4 million in 2021 from €4.2 million in 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®, which commenced in certain territories in 2021.
Other Revenues, including revenues from collaborations, licensing and services, amounted to €285.1 million in 2021 compared to €44.4 million in 2020. This increase was attributable to revenues recognized in relation to the terminated UK COVID-19 vaccine supply agreement for non-refundable payments received during the duration of the contract.

Liquidity
Cash and cash equivalents increased to €346.7 million as of December 31, 2021, compared to €204.4 million as of December 31, 2020, and included $209.6 million of combined gross proceeds from the two successful equity offerings the Company completed in 2021 as well as pre-payments for future COVID-19 vaccine deliveries to the EC.

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.

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 with respect to expected total revenues for full fiscal year 2022. 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, the cancellation of existing contracts, including but not limited to the HMG Supply Agreement, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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[1] *Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001*

EXHIBIT 99.2

Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate

- ***Dose selection complete for planned Phase 3 trial, expected to be initiated in 3Q2022***
- ***Sub-analysis compared the immunogenicity of VLA15 in adults 18-65 years of age after administration of two or three primary series doses***
- ***Stronger immune response observed in adult participants who received three priming doses vs. two priming doses; pediatric study ongoing with initial data expected in 1H2022***
- ***Three-dose priming schedule selected for use in adults moving forward***

Saint-Herblain (France) and New York, February 4, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today reported further positive Phase 2 data for their Lyme disease vaccine candidate, VLA15. Based on these new results, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule in a planned Phase 3 clinical trial. The trial will evaluate VLA15 in adults and pediatric subjects 5 years of age and above and is expected to be initiated in 2022, subject to regulatory approval.

The Phase 2 trial, VLA15-221, compared the immunogenicity of VLA15 after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In the sub-analysis of adult participants (18-65 years old) who received VLA15 in either the two-dose schedule (N=90) or the three-dose schedule (N=97), performed one month after the last vaccination dose, VLA15 was found to be immunogenic with both vaccination schedules tested. These data are consistent with the strong immunogenicity profile observed for this age group in previous Phase 2 studies. However, the induction of anti-OspA IgG (anti-outer surface protein A immunoglobulin G) antibody titers was higher in participants who received the three-dose primary series compared to those who received the two-dose primary series, supporting the use of a three-dose primary series schedule in the planned Phase 3 clinical trial. The VLA15-221 trial is ongoing to assess the safety and immunogenicity of VLA15 in 5-17 year olds. Initial pediatric data are expected in the first half of 2022.

The analysis was also consistent with the acceptable safety and tolerability profile observed in previous studies of VLA15. No vaccine-related serious adverse events (SAEs) were observed.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “I’m very pleased with these results, which are critical for determining the optimal vaccination schedule for our planned Phase 3 trial. In partnership with Pfizer, we are excited to further investigate this vaccine candidate, which will hopefully help provide protection against Lyme disease for both adults and children.”

Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer, said: “Lyme disease is increasingly impacting people throughout the northern hemisphere, potentially due to environmental changes and more active outdoor lifestyles. The continued positive data from the VLA15-221 trial support the ongoing development of this vaccine candidate, and we look forward to continuing to work with Valneva to potentially help protect people against Lyme disease.”

About VLA15
VLA15 is the only Lyme disease vaccine candidate currently in clinical development. This investigational multivalent protein subunit vaccine uses an established mechanism of action for a Lyme disease vaccine that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. The vaccine covers the six OspA serotypes expressed by *Borrelia burgdorferi* sensu lato species that are prevalent in North America and Europe. VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[1]. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15.[2]

About Clinical Study VLA15-221
VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 study. It is the first clinical study with VLA15 that enrolls a pediatric population aged 5 years and older.

294 healthy adult participants received VLA15 at two different immunization schedules (month 0-2-6 [N=97] or month 0-6 [N=90]) or three doses of placebo (month 0-2-6 [N=107]). Vaccine recipients received VLA15 at a dose of 180 µg, which was selected based on data generated in the two previous Phase 2 studies. The main safety and immunogenicity readout in adults was performed at month 7. A subset of participants will receive a booster dose of VLA15 or placebo at month 18 (booster phase) and will be followed for three additional years to monitor antibody persistence. The VLA15-221 trial is ongoing to assess the safety and immunogenicity of VLA15 in a pediatric population aged 5 years and above.

VLA15 is tested as an alum-adjuvanted formulation and administered intramuscularly. The study is conducted at sites located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with *Borrelia burgdorferi* as well as *Borrelia burgdorferi*-naïve volunteers.

About Lyme Disease
Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by infected *Ixodes* ticks[3]. It is considered the most common vector-borne illness in the Northern Hemisphere. While the true incidence of Lyme disease is

unknown, it is estimated to annually affect approximately 476,000 people in the United States[4] and 130,000 people in Europe[5]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *Erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[6].

References

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

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

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

[4]Source: https://www.cdc.gov/lyme/stats/humancases.html

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

[6]New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017. https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/

About Valneva SE

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About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

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Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials 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 sustained in the future. 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. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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 these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Pfizer Disclosure Notice
The information contained in this release is as of February 4, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits and a potential phase 3 clinical trial, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the impact of COVID-19 on Pfizer’s business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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