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: April 26, 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 April 25, 2022 and April 26, 2022, the Registrant issued press releases, each of which is attached hereto as Exhibits 99.1, 99.2, and 99.3 and incorporated herein by reference.

Exhibit

99.1	Press release dated April 25, 2022
99.2	Press release dated April 26, 2022
99.3	Press release dated April 26, 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: April 26, 2022

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

Valneva Provides Regulatory Update on its inactivated COVID-19 Vaccine Candidate

Saint Herblain (France), April 25, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today provided an update on the rolling review process of its inactivated, COVID-19 vaccine candidate, VLA2001, with the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA").

Following last week's meeting, the CHMP provided another List of Questions ("LoQ"). This LoQ includes requests for additional data and for further justification of a Conditional Marketing Authorization.

Valneva will respond to these requests in the coming days. If the CHMP accepts the submissions, the Company would expect a Conditional Marketing Authorization this quarter.

Valneva continues to believe that its inactivated vaccine meets the conditions for a Conditional Marketing Authorization, including a positive benefit-risk profile. The Company remains focused on achieving a Conditional Marketing Authorization for VLA2001 in Europe after it was granted Conditional Marketing Authorization by the Medicines and Healthcare products Regulatory Agency ("MHRA") of the United Kingdom ("UK") two weeks ago[1].

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We are disappointed that the EMA has not considered our submissions sufficient to date. We remain fully committed and dedicated to working jointly with the regulators towards a product approval. VLA2001 is the only inactivated COVID-19 vaccine candidate in Europe, and we continue to receive messages every day from people who are looking for a more traditional vaccine approach".

In its Phase 3 pivotal trial, Valneva demonstrated that two doses of VLA2001 induced superior neutralizing antibody levels and a significantly better tolerability profile compared to another EMA-approved vaccine (AZD1222)[2]. On April 14, 2022, the UK MHRA granted Conditional Marketing Authorization for VLA2001 for primary immunization in adults 18 to 50 years of age[3]. MHRA found that VLA2001 meets the required safety, quality and effectiveness standards. This authorization followed emergency use authorization from the Bahraini NHRA in March 2022[4].

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 pandemic and 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.

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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 of VLA2001 and with respect to possible regulatory approval of 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.

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1 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva
2 Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva
3 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva
4 *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

EXHIBIT 99.2

Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed

- Up to an additional $40 million made available as part of the agreement

Saint-Herblain (France), April 26, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced an agreement to increase the principal amount of its existing $60 million debt financing agreement with funds managed by leading US-based healthcare investment firms Deerfield Management Company and OrbiMed. This extension will provide Valneva immediate access to $20 million, with an additional $20 million available upon potential conditional approval of its inactivated COVID-19 vaccine candidate, VLA2001, by the European Medicines Agency. The increased funding will be used to further invest in R&D, including market access preparations for Valneva's chikungunya vaccine candidate, VLA1553.

Peter B✔hler, Chief Financial Officer of Valneva, commented, "We are extremely pleased to have access to additional non-dilutive funding from our existing financial partners. Extension of our loan provides additional flexibility to execute on our strategy and deliver shareholder value. We appreciate the continued support from Deerfield and OrbiMed as we pursue expansion of our global portfolio of marketed vaccines."

The loan interest rate remains unchanged. The interest-only period has been extended to the third quarter of 2024, and the loan will now mature in the first quarter of 2027.

In January 2021, Valneva announced an amendment[1] to the terms of this debt facility, which was originally signed in February 2020[2].

About Deerfield
Deerfield is an investment management firm committed to advancing healthcare through investment, information and philanthropy.

About OrbiMed
OrbiMed is a leading healthcare investment firm, with $15 billion in assets under management. OrbiMed invests globally across the healthcare industry, from start-ups to large multinational corporations, utilizing a range of private equity funds, public equity funds, and royalty/credit funds. OrbiMed maintains offices in New York City, San Francisco, Shanghai, Hong Kong, Mumbai and Herzliya. OrbiMed seeks to be a capital provider of choice, providing tailored financing solutions and global team resources and support to help build world-class healthcare companies.

About Valneva SE

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1 Valneva Announces Amendment to Deerfield and OrbiMed Debt Facility Terms
2 Valneva Announces New $85 Million Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed

Attachment

- 2022_04_26_VLA_DO_Upsized_Financial_Arrangement_PR_EN_Final (https://ml-eu.globenewswire.com/Resource/Download/25530d09-1f9a-4982-8e18-66990f4f50e8)

EXHIBIT 99.3

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

- ***Strong immunogenicity profile observed in study participants aged 5-17 years one month after the primary vaccination series***
- ***Safety profile observed in pediatric participants similar to previously reported data in adult participants***
- ***Pediatric population to be included in planned Phase 3 trial – expected to start in Q3 2022, subject to regulatory approval***

Saint-Herblain (France) and New York, April 26, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today reported positive Phase 2 pediatric data for their Lyme disease vaccine candidate, VLA15. Based on these new results, Valneva and Pfizer plan to proceed with inclusion of pediatric participants in their planned Phase 3 trial. The trial will evaluate VLA15 in adults and pediatric subjects 5 years of age and above and is expected to be initiated in the third quarter of 2022, subject to regulatory approval.

The Phase 2 trial, VLA15-221, is the first clinical study with VLA15 which enrolled a pediatric population (5-17 years old). It compared the immunogenicity and safety 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 pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was found to be more immunogenic than in adults with both vaccination schedules tested. These data build on the strong immunogenicity profile already reported for adult participants (18-65 years old) in February 2022[1]. Like in adults, the immunogenicity and safety data support a three-dose primary vaccination schedule in pediatric participants in the Phase 3 study.

The safety and tolerability profile observed in the 5- to 17-year age group was similar to the previously reported profile in adult participants. No vaccine-related serious adverse events (SAEs) were observed.

Valneva and Pfizer plan to submit these data for publication and presentation at a future scientific congress.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "Lyme disease affects all age groups, but with their affinity for being active outdoors, the pediatric population is at the greatest risk of Lyme disease. These first pediatric results are therefore extremely important and support the inclusion of pediatric participants in our planned Phase 3 trial. In partnership with Pfizer, we are excited to further investigate our VLA15 vaccine candidate, which will hopefully help protect both adults and children against Lyme disease."

Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer, said: "The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens. These positive pediatric data mark an important step forward in the ongoing development of VLA15, and we are excited to continue working with Valneva to potentially help protect both adults and children from 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. Blocking OspA inhibits the bacterium's ability to leave the tick and infect humans. The vaccine covers the six most common OspA serotypes expressed by *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe. VLA15 has demonstrated a strong immunogenicity and safety profile 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[2]. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15[3].

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 which enrolled a pediatric population (5-17 years old).
585 healthy participants received VLA15 at two different immunization schedules (month 0-2-6 [N=190] or month 0-6 [N=187]) or three doses of placebo (month 0-2-6 [N=208]). 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 was performed one month after the primary vaccination series. 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.
VLA15 is tested as an alum-adjuvanted formulation and administered intramuscularly. The study is being conducted at U.S. sites located in areas where Lyme disease is endemic and has enrolled both 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[4]. 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[5] and 130,000 people in Europe[6]. 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 geographic footprint of the disease widens[7].

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.

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 April 26, 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 planned 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, 2021 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.

References

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

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

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

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

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

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

[7]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/

# # #

Attachment

- 2022_04_26_VLA15_Pediatric_Data_PR_EN_Final (https://ml-eu.globenewswire.com/Resource/Download/86a2f1d2-6cea-46f5-83c4-a8c5b936915e)