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: December 23, 2021

Commission File Number: **001-40377**

Valneva SE
(Translation of registrant's name into English)

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

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [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 December 21 and December 23, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibits 99.1 and 99.2 and are incorporated herein by reference.

Exhibit

99.1	Press release dated December 21, 2021
99.2	Press release dated December 23, 2021

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: December 23, 2021

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

EXHIBIT 99.1

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

Saint Herblain (France), December 21, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive topline results from the lot-to-lot Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. The VLA1553-302 trial met its primary endpoint, demonstrating that three consecutively manufactured vaccine lots elicited equivalent immune responses measured by neutralizing antibody titer GMT ratios on Day 29 after vaccination.

Lot-to-lot trials demonstrate manufacturing consistency, one of the standard requirements for vaccine licensure. The trial, which included 408 participants aged 18 to 45 years, confirmed the excellent immunogenicity profile demonstrated in the pivotal Phase 3 trial, VLA1553-301. All three lots were equally well tolerated and the safety profile was consistent with results in the pivotal Phase 3 trial. Study VLA1553-302 therefore confirmed clinical equivalence as well as manufacturing consistency of the three lots.

Juan Carlos Jaramillo, Chief Medical Officer of Valneva commented, "We are extremely pleased with these lot-to-lot Phase 3 data, which come in addition to the compelling pivotal Phase 3 results we reported in August. The lot-to-lot data will be part of our submission with the US Food and Drug Administration (FDA), which we plan to start in 2022. Chikungunya is a major, growing and unmet public health threat, yet no vaccine or specific treatment is currently available to prevent this debilitating disease. We will continue to work assiduously to bring VLA1553 to market as soon as possible."

The lot-to-lot trial will continue towards final six-month analysis with final trial results expected in the second quarter of 2022.

Valneva's chikugunya program was awarded Breakthrough Therapy Designation by the US FDA in July 2021. This new milestone followed the US FDA's Fast Track designation and the European Medicines Agency (EMA)'s PRIME designation which the Company received in December 2018 and in October 2020, respectively. The sponsor of the first chikungunya vaccine Biologics License Application (BLA) to be approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV) [1].

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. Infection leads to symptomatic disease in 72-92% of humans after 4 to 7 days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia. As of September 2020, there were more than 3 million reported cases in the Americas[2] and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

About VLA1553

VLA1553 is a live-attenuated, single dose vaccine candidate targeting the chikungunya virus, which has spread to more than 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

In August 2021, Valneva reported positive topline results for pivotal Phase 3 clinical trial, VLA1553-301. In this double-blind, multi-center, randomized Phase 3 clinical trial, 4,115 participants aged 18 years and above were randomized 3:1 into two groups to receive either 0.5mL of VLA1553 or a placebo. The trial met its primary endpoint, inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 96.2-99.6). The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a submission for approval of VLA1553 under the accelerated approval pathway. VLA1553 was highly immunogenic, with a GMT of approximately 3,270.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. The majority of solicited adverse events were mild or moderate and resolved within 3 days.

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

VLA1553-301 will continue towards final analysis including the 6-month safety data. The Company expects to report final trial results in early 2022.

VLA1553 would expand Valneva's existing travel vaccine portfolio and as such, Valneva intends to commercialize this vaccine, if approved, leveraging its existing manufacturing and commercial operations. The global market for chikungunya vaccines is estimated to exceed $500 million annually by 2032[3].

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing and marketing of VLA1553[4]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[5], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program.

About Phase 3 study VLA1553-302

VLA1553-302 clinical lot-to-lot consistency Phase 3 study is a prospective, multicenter, randomized, pivotal Phase 3 study

including 408 participants aged 18 to 45 years. Lyophilized VLA1553 are administered as a single intramuscular immunization. Equivalence of immune responses will be determined based on neutralizing antibody titers. The primary objective of the study is to evaluate a pair-wise comparison of the 95% Confidence Interval (CI) on the ratio of GMTs on Day 29 after vaccination in the three vaccine lots. The two-sided 95% CI on the GMT ratio should be within 0.67 and 1.5 in order to demonstrate consistency. Study volunteers will be followed for six months after vaccination. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04786444).

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. Valneva has leveraged its expertise and capabilities to successfully commercialize two wholly owned vaccines and rapidly advance multiple vaccine candidates into late-stage clinical development, including candidates against Lyme disease (partnered with Pfizer), the chikungunya virus and COVID-19.

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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, 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.

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1 *https://priorityreviewvoucher.org/*
2 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas. https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 13 Oct 2020.
3 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020
4 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries
5 CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

EXHIBIT 99.2

Valneva and Scottish Enterprise in Advanced Discussions for Major Grant to Complete Livingston Site

Saint Herblain (France), December 23, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that it is in advanced discussions, with Scottish Enterprise, for a multi-million pound grant which will enable it to fully complete its strategic manufacturing site in Livingston, Scotland.

Following the termination of the supply agreement with the UK Government (HMG) for Valneva's inactivated COVID-19 vaccine candidate, VLA2001, Valneva paused its site plans. Valneva and Scottish Enterprise have since engaged in a highly constructive dialogue, and under the proposed grant, the Livingston site will be fully developed as a key vaccine production site for the long term.

Both Valneva and Scottish Enterprise would invest in the plant. Scottish Enterprise's contribution is expected to be through a series of grants totalling £10-20 million to enable Valneva to commence production at the plant. Discussions between the Company and the Scottish Government also include potential supply of VLA2001 for Scotland in the future, subject to regulatory approval. Valneva has also offered to make up to 25,000 doses of VLA2001 available for primary immunisation, free of charge, to National Health Service and frontline workers in Scotland, subject to regulatory approval. The grant is subject to contract and final due diligence and is expected to include commitments to jobs for the future in Livingston.

Commenting, **David Lawrence, Acting Chief Financial Officer**, said "We're pleased that we've been able to advance discussions with Scottish Enterprise quickly, following the UK Government's unexpected decision to terminate our supply agreement with them. We've reported excellent Phase 3 data and homologous booster data in the past couple of months, underlining the potential importance of VLA2001 – our inactivated, adjuvanted whole virus vaccine. Subject to regulatory approval we want to make VLA2001 available to people who need it, as soon as we can. We already have some vaccine stock available for distribution, upon approval. The grant will be very welcome and, subject to contract, will ensure that Livingston becomes a strategic vaccine manufacturing site for the future, successfully completing the work we began with HMG".

Ivan McKee, Scottish Government Minister for Business, Trade, Tourism and Enterprise, said "Valneva is a valued contributor to our life sciences sector and the Livingston facility is an important asset, developing vaccines for the treatment of several important infectious diseases and supporting high quality jobs. Ministers and Scottish Enterprise are in advanced discussions with the company to agree a package of support which would underpin the company's operations in Scotland."

Hannah Bardell, MP for Livingston, added "I am delighted that the Scottish Government and Scottish Enterprise have listened to my constituency colleagues and I by agreeing to invest in Valneva's vaccine manufacturing site in Livingston. This funding will enable Valneva to complete its expansion, boosting vital production capacity and protecting skilled jobs. It has been a pleasure to work with all involved in securing this agreement and I can only hope the UK Government will see the faith that we in Scotland have in Valneva."

Valneva is continuing to try to reach an amicable resolution with HMG regarding its termination of the supply agreement and performance of the ongoing clinical trial agreement. The Company continues to reserve all rights in the event that an amicable outcome is not achieved.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate against COVID-19 in clinical trials 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. The manufacturing process for VLA2001, 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 degrees 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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