
**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: June 11, 2021

Commission File Number: **001-40377**

Valneva SE

(Translation of registrant's name into English)

6 rue Alain Bombard

44800 Saint-Herblain, France

(Address of principal executive office)

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

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

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

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

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

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

On June 10 and 11, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1 and Exhibit 99.2 and are incorporated herein by reference.

Exhibits

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

[99.2](#) [Press release dated June 11, 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: June 11, 2021

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

Valneva Completes Recruitment for Phase 3 Lot-to-Lot Consistency Trial of its Chikungunya Vaccine Candidate

Saint Herblain (France), June 10, 2021 – Valneva SE (“Valneva” or “the Company”), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced that it has completed recruitment for the clinical lot-to-lot consistency Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials at this time.

410 participants aged 18 to 45 years have been randomized in the Phase 3 trial VLA1553-302 and will be followed for a total of six months. The objective of the trial is to show manufacturing consistency of the vaccine by demonstrating that three consecutively manufactured lots elicit equivalent immune responses measured by neutralizing antibody titers on Day 29 after vaccination.

Juan Carlos Jaramillo, Chief Medical Officer of Valneva commented, “We are pleased to have reached this new recruitment milestone. We’ve now enrolled all participants for both our pivotal Phase 3 trial and lot-to-lot consistency trial so our VLA1553 program is progressing extremely well. Chikungunya virus is a major, growing public health threat and we are looking forward to our top line data this summer”.

The lot-to-lot consistency Phase 3 trial runs in parallel to the ongoing, pivotal Phase 3 trial, VLA1553-301, for which the Company already announced recruitment completion in April 2021¹. 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)².

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 Americas³ 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 for protection against the chikungunya which has spread to more than 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

In the Phase 1 clinical trial of VLA1553, Valneva observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants. Antibody titers were sustained after 12 months. Based on these results and Valneva’s discussions with regulators, VLA1553 has advanced directly into Phase 3 clinical development. The Company has also received confirmation for its proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, Valneva plans to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection.

The program was granted Fast Track designation by the FDA in December 2018 and PRIME designation by the European Medicines Agency (EMA) in October 2020.

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 vaccines against chikungunya is estimated to exceed \$500 million annually by 2032⁴.

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement for the development, manufacturing and marketing of VLA1553. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to \$23.4 million.

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 410 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 a total of six months and overall, the study is expected to last approximately eight months. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, will be published on ClinicalTrials.gov.

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. We take 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. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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.

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 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 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 Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial*

2 <https://priorityreviewvoucher.org/>

3 *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.

4 *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

Valneva Announces Termination of Liquidity Contract with Oddo BHF and Natixis and Publishes End of Contract Statement

Saint-Herblain (France), June 11, 2021 – Valneva SE (“Valneva” or “the Company”), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, announces today that it has terminated the liquidity agreement relating to its ordinary shares concluded with Oddo BHF and Natixis on June 25, 2018, as the liquidity of the Company’s securities has improved. The termination is effective as of today.

The following assets were booked on the liquidity account on the termination date:

- 4 025 Valneva shares
- €556,103.17 in cash

From January 1, 2021 to June 11, 2021 the following transactions were executed:

- 297 buy-side transactions
- 408 sell-side transactions

During the same period, the traded volume represented:

- Buy-side traded volume: 102,749 shares for €954,024.57
- Sell-side traded volume: 120,724 shares for €1,162,906.31

As a reminder, for the previous half-year statement at December 31 2020, the following assets appeared on the liquidity account:

- 22,000 shares
- €347,221.43 euros

Moreover, the following resources were allocated to the liquidity account when the liquidity contract was implemented beginning July 2, 2018:

- 78,992 Valneva shares
- €70,609.98 in cash

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