
**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: October 11, 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 [] 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 October 10, 2022, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information contained in this Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-266839).

Exhibit

[99.1](#) [Press release dated October 10, 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: October 11, 2022

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

Valneva to Present on its Single-Shot Chikungunya Vaccine Candidate at Leading Scientific Conferences

Saint-Herblain (France), October 10, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announces today it will present on its single-shot chikungunya vaccine candidate at several leading scientific conferences during the fourth quarter of 2022.

At the **World Vaccine Congress Europe** in Barcelona, Valneva will present “One step closer to a chikungunya vaccine: update on Valneva’s live-attenuated vaccine candidate,” on October 13, 2022 at 2:45pm CEST. The Company will also have a display in the exhibit area at booth #46 for the duration of the Congress, from October 11 through 14, 2022.

On October 27, 2022 at 10:30am ICT, Valneva will present “Progress of Clinical Development of a Live-Attenuated Single Shot Chikungunya Vaccine Candidate” as part of the Vaccines for Tropical Diseases symposium at the **20th International Congress for Tropical Medicine and Malaria (ICTMM2020)** in Bangkok.

Valneva will also present on the Phase 3 clinical development of its single-shot chikungunya vaccine candidate at the **American Society of Tropical Medicine and Hygiene (ASTMH) 2022 Annual Meeting**, taking place October 30 through November 3, 2022 in Seattle. The Company will present an abstract on November 1, 2022 at 10:15am PST during an in-person scientific session.

At the **International Society for Pharmacoeconomics and Outcomes Research (ISPOR) European Congress** taking place November 6 through 9, 2022 in Vienna and online, two posters will be presented: “Burden of Illness and Paucity of Treatment of the Mosquito-Borne Chikungunya Virus (CHIKV)” and “The Economic Burden of the Globally Spreading Chikungunya Virus: A Systematic and Targeted Review.”

Finally, the Company will present at the **Joint International Tropical Medicine Meeting (JITMM) 2022** in Bangkok from December 7 through 9, 2022.

Presentations will be made by Valneva’s senior scientific leadership, including Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva; Katrin Dubischar, VP Program Director – Chikungunya Vaccine; and Susanne Eder-Lingelbach, VP Clinical Development, among others.

Valneva initiated rolling submission with the U.S. Food and Drug Administration (FDA) of a Biologics License Application (BLA) for licensure of its single-shot chikungunya vaccine candidate in individuals aged 18 years and above in August 2022.

This BLA submission follows final pivotal Phase 3 data reported in March 2022¹ and final lot-to-lot consistency results reported in May 2022². A clinical study of VLA1553 in adolescents is ongoing in Brazil³, which may support future regulatory submissions in this group if VLA1553 is approved in adults.

The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted PRiority MEDicine (PRIME) designation by the European Medicines Agency (EMA) in 2020, and Valneva plans to make regulatory submissions for VLA1553 in Europe in the first half of 2023.

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 four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032⁴. 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, and the virus has spread to more than 120 countries. As of July 2022, more than three million cases have been reported in the Americas⁵ 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 investigational vaccine candidate targeting the chikungunya virus, which has spread to over 120 countries. It has been designed by deleting a part of the chikungunya virus genome.

Valneva reported final data from the pivotal Phase 3 trial of VLA1553 in March 2022⁶ and final lot-to-lot consistency results in May 2022⁷.

If approved, VLA1553 would expand Valneva’s existing commercial vaccines portfolio and as such, Valneva intends to commercialize this vaccine leveraging its existing manufacturing and commercial operations.

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 VLA1553⁸. The collaboration falls

within the framework of the agreement signed between the Coalition for Epidemic Preparedness Innovations and Valneva in July 2019⁹, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

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 three vaccines and to rapidly advance a broad range of vaccine candidates into the clinic, including candidates against Lyme disease and the chikungunya virus.

Media & Investor Contacts

Laëtitia Bachelot-Fontaine

VP Global Communications & European Investor Relations

M +33 (0)6 4516 7099

laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.

VP Global Investor Relations

M +001 917 815 4520

joshua.drumm@valneva.com

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to regulatory approval of VLA1553, timing and plans for clinical programs and product candidates and revenue forecasts. 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 in this press release 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 Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

2 [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

3 [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

4 [VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020](#)

5 [PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas \(Cumulative Cases 2018-2022 and Cases per year 2013-2017\). <https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html>. Last accessed 25 Jul 2022.](#)

6 [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

7 [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

8 [Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries](#)

9 [CEPI awards up to \\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine](#)