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 27, 2023

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 [ ]

On October 25, 2023, 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 25, 2023

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 27, 2023

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

EXHIBIT 99.1

Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment

Saint-Herblain (France), October 25, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces the submission of a marketing application with the European Medicines Agency (EMA) for approval of the Company's single-shot chikungunya vaccine candidate, VLA1553. Valneva was also granted accelerated assessment[1] for the application by EMA's Committee for Medicinal Products for Human Use (CHMP) based on the vaccine candidate's "major interest for public health and therapeutic innovation".

VLA1553 is currently the first and only chikungunya vaccine candidate worldwide for which regulatory review processes are underway. A Biologic License Application (BLA) is currently under priority review by the U.S. Food and Drug Administration (FDA)[2] with a Prescription Drug User Fee Act (PDUFA) action date planned for the end of November 2023[3]. Additionally, a marketing application is under review by Health Canada[4].

If approved, VLA1553 could become the first licensed chikungunya vaccine available to address this unmet medical need.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "We welcome EMA's accelerated assessment and will work closely with them to bring this vaccine to market. Chikungunya virus, or CHIKV, is a serious and debilitating mosquito-borne viral infection that poses a significant unmet need and the risk of chikungunya spreading in Europe is relatively high due to the possibility of infected travelers[5]. No vaccine or specific treatments are currently available for this debilitating disease. We will continue to work diligently to bring VLA1553 to different territories as soon as possible."

The regulatory submissions with the EMA, FDA and Health Canada follow final pivotal Phase 3 data in March 2022[6] (Lancet article), final lot-to-lot consistency results in May 2022[7], twelve-month persistence data in December 2022[8] and positive initial Phase 3 safety data in adolescents[9].

VLA1553 was granted PRIority MEdicine (PRIME) designation by EMA in 2020 and received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively.

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 up to 97% 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 2032[10]. 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 110 countries[11]. As of July 2022, more than three million cases have been reported in the Americas[12] 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 110 countries[13]. 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 2022[14], final lot-to-lot consistency results in May 2022[15], positive twelve-month persistence data in December 2022[16] and positive initial Phase 3 safety data in Adolescents[17]. The pivotal Phase 3 data were published in *The Lancet*[18](article link), the world's leading peer-reviewed medical journal, in June 2023.

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 VLA1553[19]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[20], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program.

About Valneva SE

We are a specialty vaccine company that develops, manufactures and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, potentially the world's

first vaccine against the chikungunya virus, as well as vaccine candidates against the Zika virus and other global public health threats.

Media & Investor 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 regulatory approval of VLA1553 and timing and plans for clinical programs and clinical trials. 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.

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1 Accelerated assessment | European Medicines Agency (europa.eu)
2 FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva
3 Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva
4 Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review - Valneva
5 https://www.ecdc.europa.eu/en/chikungunya/threats-and-outbreaks/risk-assessment-chikungunya-eu
6 *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
7 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
8 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
9 Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
10 *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
11 https://www.who.int/news-room/fact-sheets/detail/chikungunya
12 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.
13 https://www.who.int/news-room/fact-sheets/detail/chikungunya
14 *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
15 *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
16 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
17 Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
18 Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet - Valneva
19 *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
20 *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*