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: November 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 November 27, 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 November 27, 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: November 27, 2023

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

EXHIBIT 99.1

EMA Accepts Valneva's Chikungunya Vaccine Marketing Authorization Application for Accelerated Assessment

Saint-Herblain (France), November 27, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Medicines Agency (EMA) has performed a technical validation of the Marketing Authorization Application (MAA) for Valneva's single-shot chikungunya vaccine candidate VLA1553 and has determined that all essential regulatory elements required for scientific assessment were included in the application. The MAA was granted accelerated assessment[1] last month 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"[2].

Accelerated assessment reduces the timeframe for EMA's CHMP to review a MAA once it is accepted for review from 210 days under the standard review procedure to 150 days. This does not, however, include clock stops when applicants must provide additional information during the review process, which is common in review procedures.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "We welcome EMA's MAA review acceptance and will work closely with them to bring VLA1553 to market. Chikungunya virus, or CHIKV, has already spread to over 110 countries and the risk of chikungunya spreading in Europe is relatively high due to the possibility of infected travelers[3]. No vaccine or specific treatments are currently available for this debilitating disease which therefore constitutes an unmet medical need. Following approval of VLA1553 in the United States[4], we will continue to work diligently to bring VLA1553 to other territories as soon as possible."

VLA1553 received approval from the U.S. Food and Drug Administration (FDA)[5] at the beginning of the month under the brand name IXCHIQ®. In the U.S., the vaccine is indicated for the prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV.

Mid-November, Valneva also reported positive pivotal Phase 3 immunogenicity data in adolescents for VLA1553 which are intended to support label extension in this age group[6]. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations.

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[7]. 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[8]. 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[9]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[10] 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. In Europe, there is no preventive vaccines or effective treatments available and, as such, chikungunya is considered 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[11]. 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[12], final lot-to-lot consistency results in May 2022[13], positive twelve-month persistence data in December 2022[14] and positive pivotal Phase 3 data in adolescents in November 2023[15].

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[16]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[17], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program.

VLA1553 received FDA approval in November 2023 under the brand name IXCHIQ® and is indicated for the prevention of disease caused by CHIKV in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. Continued approval of IXCHIQ® in the United States is contingent upon verification of clinical benefit in confirmatory studies.

VLA1553 was also granted PRIority MEdicine (PRIME) designation and accelerated assessment by the European Medicines Agency (EMA) in 2020 and 2023 respectively.

The Company intends to commercialize this vaccine by leveraging its existing manufacturing and commercial operations.

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.

Valneva 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, to regulatory approval of product candidates and review of existing products. 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 and delays 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 Accelerated assessment | European Medicines Agency (europa.eu)
2 Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment
3 https://www.ecdc.europa.eu/en/chikungunya/threats-and-outbreaks/risk-assessment-chikungunya-eu
4 Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
5 Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
6 Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
7 Staples, J.E. Hills, S.L. Powers, A.M. "Chikungunya." In CDC Yellow Book 2020: Health Information for International Travel, by Centers for Disease Control and Prevention. New York: Oxford University Press, 2020
8 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020
9 https://www.who.int/news-room/fact-sheets/detail/chikungunya
10 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2023 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 01 Aug 2023.
11 https://www.who.int/news-room/fact-sheets/detail/chikungunya
12 *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
13 *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
14 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
15 Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
16 *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
17 *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*