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: May 31, 2024

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 May 31, 2024, 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 May 31, 2024

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: May 31, 2024

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

EXHIBIT 99.1

Valneva Receives EMA's Positive CHMP Opinion for its Chikungunya Vaccine

- **If approved, IXCHIQ® will become the first vaccine available in the EU against the chikungunya virus (CHIKV)**
- **Decision on EU marketing authorization expected in the third quarter of 2024**

Saint Herblain (France), May 31, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending authorization of Valneva's single-dose vaccine for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older.

The European Commission (EC) will review the CHMP recommendation, and a decision on the marketing authorization application of IXCHIQ® in the European Union (EU), Norway, Liechtenstein and Iceland is expected in the third quarter of 2024. If approved, it will become the first chikungunya vaccine available in Europe to address this unmet medical need. In accordance with the International Recognition Procedure (IRP)[1], Valneva is also preparing a Marketing Authorization Application (MAA) for submission to the UK Medicines and Healthcare products Regulatory Agency (MHRA).

The CHMP opinion follows the November 2023 approval of IXCHIQ® by the US Food and Drug Administration (FDA)[2]. Two additional marketing authorization applications are currently under review by Health Canada and the Brazilian Health Regulatory Agency (ANVISA) with potential approvals in 2024.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This positive CHMP opinion marks a crucial milestone toward introducing a preventative solution against chikungunya in the EU. In recent years, climate change has caused the Aedes mosquito, a known carrier of chikungunya and dengue viruses, to spread to areas in Europe that were previously unaffected. It is critical to provide a vaccine solution not only to European travelers going to endemic chikungunya areas, such as South America or Africa, but also to the local European populations experiencing invasive mosquito attacks. The broader we can make this vaccine accessible, the better we will mitigate the burden of this debilitating illness, and we would like to thank our partner, CEPI, for supporting us in this endeavor."

Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), commented, "Over one billion people live in areas where Chikungunya is endemic, and recent large outbreaks underline the urgent need for safe and effective vaccines against this debilitating disease. Valneva's single-dose vaccine is well-suited for use in outbreak response and in low-resource settings, and CEPI's partnership with Valneva and Instituto Butantan – supported by the EU – will help to make this vaccine accessible to the people most affected by the virus in low- and middle-income countries. Today's positive opinion from the EMA is an important step towards making the vaccine more widely available."

The positive CHMP opinion is supported by data from the pivotal Phase 3 study which were published in The Lancet, the world's leading peer-reviewed medical journal, and showed a 98.9% seroresponse rate at 28 days with a single vaccination. This robust immune response was sustained for 24 months by 97% of participants and was equally durable in younger and older adults[3]. Earlier this month, Valneva reported further positive pivotal data in adolescents six months after a single vaccination, which are intended to support filing for potential label extension for use in adolescents aged 12 to 17 years[4]. The data are also expected to support licensure of IXCHIQ® in Brazil, which would be the first potential approval for use in an endemic population.

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[5]. 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[6]. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. The 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[7]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[8] 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. Before IXCHIQ®, there were no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

To make the vaccine 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 IXCHIQ®[9]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[10], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program. Regulatory review by the Brazilian authority ANVISA is ongoing.

About IXCHIQ®

In the U.S., IXCHIQ® is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV)

in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA's accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.

Please **click here** for full U.S. Prescribing Information for IXCHIQ®.

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 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 three 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, 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 International Recognition Procedure - GOV.UK (www.gov.uk)
2 Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
3 Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva
4 Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva
5 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
6 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020
7 https://www.who.int/news-room/fact-sheets/detail/chikungunya
8 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.
9 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries
10 CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine