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 24, 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 June 24, 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 June 24, 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: June 24, 2024

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

EXHIBIT 99.1

Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ®

Saint-Herblain (France), June 24, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that Health Canada has approved IXCHIQ®, Valneva's single-dose vaccine for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. This decision marks the second approval the Company has received for IXCHIQ® following approval from the U.S. Food and Drug Administration (FDA) in November 2023. The European Medicines Agency (EMA) also recently recommended marketing authorization of the vaccine in Europe, and a formal decision is expected in the third quarter of 2024.

IXCHIQ® is the world's only licensed chikungunya vaccine available to address this unmet medical need. Every year, over 50 million North Americans, of which approximately 7 million Canadians[1], travel to countries where chikungunya is endemic. Valneva began commercializing the vaccine in the U.S. this year and plans to sell first doses in Canada in the fourth quarter of 2024.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This second approval marks another significant milestone toward introducing a preventative solution against chikungunya disease worldwide. In recent years, climate change has caused the Aedes mosquito, a known carrier of chikungunya and dengue viruses, to spread to areas that were previously unaffected. 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."

In addition to U.S., Canada and Europe, Valneva partnered with the Coalition for Epidemic Preparedness Innovations (CEPI) [2] and Instituto Butantan in Brazil[3] to make the vaccine more accessible to Low- and Middle-Income Countries (LMIC). The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[4], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program. A marketing authorization application is currently under review by the Brazilian Health Regulatory Agency (ANVISA) with potential approval in 2024.

Dr. Richard Hatchett, Chief Executive Officer of CEPI, commented: "Health Canada's approval of IXCHIQ® represents another significant advance in the fight against the debilitating chikungunya virus. Accelerated by climate change, the size and frequency of chikungunya outbreaks are increasing, with hundreds of thousands of cases already reported so far this year in the Americas, South Asia, and Africa. This is why CEPI, with its partners Valneva and the European Commission, are working to expand access to the vaccine for everyone, including the world's most vulnerable populations."

Health Canada's approval was based on data from the pivotal Phase 3 study which were published in The Lancet, one of the world's leading peer-reviewed medical journal, and showed a 98.9% seroresponse rate at 28 days with a single vaccination. This immune response was sustained for six months by 96.3% of participants and was equally durable in younger and older adults[5].

About Chikungunya

Chikungunya virus (CHIKV) is a mosquito-borne viral disease spread by the bites of infected female *Aedes* mosquitoes which causes fever, severe joint pain, muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years.[6]

In 2004, the disease began to spread quickly, causing large-scale outbreaks around the world. Since the re-emergence of the virus, CHIKV has now been identified in over 110 countries in Asia, Africa, Europe and the Americas.[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 with climate change as the mosquito vectors that transmit the disease continue to spread geographically. As such, the World Health Organization (WHO) has highlighted chikungunya as a major public health problem.[9]

About IXCHIQ®

In Canada, IXCHIQ™ (chikungunya vaccine, live, attenuated) Powder for Solution for Intramuscular Injection is intended for active immunization in individuals 18 years and older for the prevention of disease caused by the chikungunya virus (CHIKV), as a single-dose immunization.

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 three proprietary travel vaccines, including the world's first and only chikungunya vaccine, as well as certain third-party vaccines.

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.

More information is available at www.valneva.com.

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 in this press release will in fact be realized. Valneva is providing this information as of the date 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.

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1 Data accessed March 2024 from International Air Transport Association (IATA)

[2] CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

3 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

[4] CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

5 Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva

6 https://jvi.asm.org/content/jvi/88/20/11644.full.pdf

7 https://cmr.asm.org/content/31/1/e00104-16

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 Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)