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 13, 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 13, 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 13, 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 13, 2024

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

EXHIBIT 99.1

Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine

Results Intended to Support Filing for Potential Label Extension for Use in Adolescents

Saint-Herblain (France), May 13, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported further positive pivotal Phase 3 data in adolescents for its single-shot chikungunya virus (CHIKV) vaccine. Following the initial analysis up to Day 29 post-vaccination, the most recent analysis of study VLA1553-321 evaluated the safety and immunogenicity six months (Day 180) after vaccination with a single dose of the vaccine. The Day 180 results confirm the initial positive immunogenicity and safety data Valneva reported previously[1,2], and are intended to support filing for potential label extension for use in adolescents aged 12 to 17 years. The data are also expected to support licensure of IXCHIQ® in Brazil, which would be the first potential approval for use in endemic populations.

The latest VLA1553-321 data confirmed that a single-dose vaccination with VLA1553 induced a high, sustained immune response with a seroresponse rate of 99.1% (232 out of 234 participants) at Day 180 compared to 98.8% (248 out of 251 participants) at Day 29 in an immunogenicity subset of individuals who were CHIKV negative at baseline.

Geometric mean antibody titers (GMTs) consistently surpassed the seroresponse threshold defined with the U.S. Food and Drug Administration (FDA)[3] as the surrogate of protection in baseline seronegative participants who received a single dose of VLA1553.

Additionally, the Day 180 data confirmed that a single dose of the vaccine was generally safe and well tolerated in adolescents receiving VLA1553, irrespective of previous infection with the chikungunya virus. Throughout the trial, an Independent Data Safety Monitoring Board (IDSMB) consistently assessed safety data and found no safety issues. The majority of solicited adverse events observed following VLA1553 administration were mild or moderate and resolved within three days post vaccination.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "We are highly encouraged by these data, as they reinforce the strong immunity and safety observed in adults and the elderly, upon which FDA approval was granted. Given the substantial risk that chikungunya presents to individuals residing in or traveling to endemic regions, it's imperative to ensure the vaccine is available to all age groups. This broader accessibility can help provide protection and mitigate the burden of this debilitating illness."

Conducted in collaboration with Instituto Butantan in Brazil and funded by the Coalition for Epidemic Preparedness Innovations (CEPI) with support from the European Union's Horizon 2020 program, the VLA1553-321 trial represents the first clinical trial conducted in an endemic area and with individuals previously infected with CHIKV.

Valneva's vaccine IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. It was approved by the U.S. FDA in November 2023[4], and the Centers for Disease Control and Prevention (CDC) recently adopted the Advisory Committee on Immunization Practices' (ACIP) recommendations on use of the vaccine in the U.S.[5]. Three marketing applications are currently under review by the European Medicines Agency, Health Canada and the Brazilian Health Regulatory Agency (ANVISA) with potential approvals in 2024. IXCHIQ®'s final pivotal Phase 3 data were published in The Lancet, the world's leading peer-reviewed medical journal, in June 2023[6].

About Phase 3 Study VLA1553-321

VLA1553-321 is a prospective, double-blinded, multicenter, randomized, placebo-controlled pivotal Phase 3 trial conducted in 754 adolescents aged 12 to 17 years old in Brazil. The VLA1553-321 clinical trial was initiated in January 2022 and Valneva reported initial immunogenicity and safety data in November[7] and August 2023[8], respectively. VLA1553 or placebo was administered as a single intramuscular immunization to participants who were randomized into two study groups at a 2:1 ratio. The primary objective is to evaluate the immunogenicity and safety of the adult dose of VLA1553 in adolescents 28 days following a single vaccination. Secondary objectives of the trial include assessment of safety and immunogenicity up to twelve months following a single vaccination with VLA1553. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04650399).

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[9]. 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. 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[11]. Between 2013 and 2023, more than 3.7 million cases were 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. 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 VLA1553[13]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[14], 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 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 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 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 Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate
2 Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate
3 Defined as $\mu PRNT_{50}$ antibody titer ≥ 150 agreed with the FDA as surrogate of protection to support accelerated approval
4 Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
5 ACIP Vaccine Recommendations and Schedules | CDC
6 Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicentre, randomised, placebo-controlled, phase 3 trial - The Lancet
7 Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate
8 Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate

9 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
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 2018-2023 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.
13 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries
14 CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine