**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: March 26, 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 [ ]

The Registrant issued press releases on March 25 and March 26, 2024, copies of which are attached hereto as Exhibits 99.1 and 99.2 and are incorporated herein by reference. The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, 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 March 25, 2024 |
| 99.2 | Press release dated March 26, 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: March 26, 2024

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

**EXHIBIT 99.1**

**Valneva Announces Filing of 2023 Universal Registration Document and US Form 20-F**

**Saint-Herblain (France), March 25, 2024** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announced today the filing, on March 22, 2024, of its 2023 Universal Registration Document (URD) with the French Financial Markets Authority (AMF) under the filing number D.24-0157 and its Form 20-F with the U.S. Securities and Exchange Commission (SEC).

Valneva's 2023 Universal Registration Document – available in its entirety in French – includes the Company's 2023 Annual Financial Report, the Company's Annual Management Report, the Board of Directors' Corporate Governance Report and the Company's Sustainability Report. The Sustainability Report is available in both English and French.

These documents are available on Valneva's website (https://valneva.com/investors/financial-reports/) and will also be available on the AMF (www.amf-france.org/) and SEC (www.sec.gov/) websites, respectively. Hard copies of these documents may be obtained from the Company, free of charge, upon request at the following address: 6 rue Alain Bombard, 44800 Saint-Herblain, France.

**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.

**Valneva Investor and Media Contacts**

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**Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate**

**Saint-Herblain (France), March 26, 2024** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced the initiation of a Phase 1 clinical trial to investigate the

the safety and immunogenicity of VLA1601, its second-generation adjuvanted inactivated vaccine candidate against the Zika virus (ZIKV). There are currently no preventive vaccines or effective treatments available against ZIKV. As such, this mosquito-borne disease remains a public health threat and is included in the Food and Drug Administration's Tropical Disease Priority Review Voucher Program[1].

The randomized, placebo-controlled, Phase 1 trial, VLA1601-102, is planned to enroll approximately 150 participants aged 18 to 49 years in the United States. Participants will receive a low, medium or high dose of VLA1601. In addition, the low dose of VLA1601 will be evaluated with an additional adjuvant, either the CpG 1018® adjuvant from Dynavax Technologies Corporation or 3M-052-AF adjuvant from the Access to Advanced Health Institute (AAHI). Topline data from the trial are expected in the first half of 2025.

VLA1601 is being developed on the original manufacturing platform of Valneva's licensed Japanese encephalitis (JE) vaccine IXIARO®, which was further optimized to develop the Company's inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. Phase 1 results from Valneva's first-generation Zika vaccine candidate were reported in 2018 showing a favorable safety profile and immunogenicity in all tested doses and schedules[2].

**Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said**, "Valneva's commitment to our vision – to live in a world in which no one dies or suffers from a vaccine-preventable disease – fuels our pursuit for preparedness solutions against the Zika virus. As global temperatures rise and rainfall increases, the habitat for disease-carrying mosquitoes expands, presenting an ongoing public health challenge."

A vaccine against ZIKV would nicely complement Valneva's portfolio of travel vaccines against mosquito-borne diseases. The Company received U.S. approval for its chikungunya vaccine IXCHIQ®, the world first and only chikungunya vaccine to address this unmet medical need, in November 2023, and has been commercializing its JE vaccine IXIARO®, for over ten years. Some health authorities and scientific leaders in the field have indicated a preference for a purified inactivated vaccine method compared to other vaccine technologies. This preference stems from the understanding that the primary recipients of a Zika vaccine are anticipated to be women of childbearing age, potentially including those who are pregnant.

**About the Zika Virus**
The Zika virus (ZIKV) is a mosquito-borne flavivirus that was first discovered in 1947. The first human cases were detected in 1952. Since then, disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, in 2015, in the Americas. Zika virus is currently circulating in Mexico, Central and South America, many countries and territories in the Caribbean region, and in a small number of geographically limited areas of the continental United States. To date, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection; however, surveillance remains limited globally.
According to the World Health Organization, there is scientific consensus that ZIKV is a cause of microcephaly and Guillain-Barré syndrome. Since 2013, 31 countries and territories have reported cases of microcephaly and other central nervous system malformations associated with ZIKV infection.

**About VLA1601**
VLA1601 is a highly purified inactivated vaccine candidate against the Zika virus (ZIKV), developed on the original manufacturing platform of Valneva's licensed Japanese encephalitis vaccine IXIARO®, which was further optimized to develop the Company's inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. Valneva reported positive Phase 1 results for VLA1601 in 2018[3]. The vaccine candidate was immunogenic and showed a favorable safety profile in all tested doses and schedules that was comparable to IXIARO® and other clinical stage ZIKV vaccines.

**About IXIARO®/JESPECT®**

Valneva's Japanese encephalitis vaccine is indicated for active immunization for the prevention of the disease for people who travel to, or live in, endemic areas. It received marketing approval in the U.S., Europe, Canada, Hong Kong, Singapore, and Israel under the trade name IXIARO® and in Australia and New Zealand where it is marketed as JESPECT®. It is the only vaccine available to the U.S. military for Japanese Encephalitis. IXIARO® is approved for use in individuals two months of age and older in the U.S. and EU member states, Canada, Norway, Liechtenstein, Iceland, Singapore, Hong Kong, Japan, the Republic of Korea and Israel. In all other licensed territories, IXIARO®/JESPECT® is indicated for use in persons aged 18 years or more.

**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®.**

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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 guidance for certain financial results in fiscal year 2024 and mid-term outlook on financial results, cash position, and other business developments, including results of ongoing clinical trials, the timing and possible occurrence of further or initial regulatory approvals of its product candidates, the anticipated size of markets for its approved products and sales of those products, receipt of funding from external sources, supply of products sold by Valneva, and relationships with current business partners. 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. These risks and uncertainties include those developed or identified in any public documents filed with the French financial markets authority (*Autorité des marchés financiers*) and the U.S. Securities and Exchange Commission made or to be made by Valneva. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines (including in relation to organic or strategic expansion of Valneva's clinical pipeline), unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis and other global economic or political events, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, the impact of a pandemic, and changes in the regulatory environment in which Valneva operates. The occurrence of any of these risks and uncertainties could substantially harm Valneva's business, financial condition, prospects and results of operations. 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 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 Tropical Disease Priority Review Voucher Program | FDA*
*2 A randomized, placebo-controlled, blinded phase 1 study investigating a novel inactivated, Vero cell-culture derived Zika virus vaccine - PubMed (nih.gov) and Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva*
*3 A randomized, placebo-controlled, blinded phase 1 study investigating a novel inactivated, Vero cell-culture derived Zika virus vaccine - PubMed (nih.gov) and Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva*