
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 31, 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 Form 40-F

The Registrant issued press releases on March 30, 2023 and March 31, 2023, copies of which are attached hereto as Exhibit 99.1 and Exhibit 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).

Exhibits

[99.1](#) [Press release dated March 30, 2023](#)
[99.2](#) [Press release dated March 31, 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.

Valveva SE
(Registrant)

Date: March 31, 2023

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

Valneva to Present on its Chikungunya Vaccine Candidate and Host a Roundtable at the 23rd World Vaccine Congress in Washington D.C.

Saint Herblain (France), March 30, 2023 –[Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announced today it will present on its single-shot chikungunya vaccine candidate, VLA1553, and host a roundtable on Zika vaccines next week at the 23rd World Vaccine Congress in Washington, D.C.

On April 4, 2023, at 11.40am EDT, Valneva’s Chief Medical Officer, Juan Carlos Jaramillo, MD, will host a roundtable discussion on the opportunities and challenges for a Zika vaccine. Valneva successfully developed an inactivated whole-virus Zika vaccine candidate though Phase 1 prior to the COVID-19 pandemic and is currently evaluating potential re-entry into clinical development later this year or early next year.

In addition, on April 5, 2023, at 9.40am EDT, Susanne Eder-Lingelbach, Vice President, Clinical Development at Valneva, will review the clinical results of the Company’s single-shot chikungunya vaccine candidate, for which a regulatory review process is underway with the U.S. Food and Drug Administration (FDA)¹. If approved, it could become the first vaccine in the world to address the unmet medical need of chikungunya.

Juan Carlos Jaramillo and Valneva’s Chief Executive Officer, Thomas Lingelbach, will be available during the conference for one-on-one meetings. Interested parties may request a meeting at communications@valneva.com.

Valneva will also display a poster on the clinical results of its chikungunya vaccine candidate in the exhibition foyer of the congress and will have a display in the exhibit area at booth #503.

About VLA1553

VLA1553 is a live-attenuated, single dose investigational vaccine candidate targeting the chikungunya virus, which has spread to over 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

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 VLA1553². The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019³, which provides funding of up to \$24.6 million with support from the European Union’s Horizon 2020 program.

Valneva reported final data from the pivotal Phase 3 trial of VLA1553 in March 2022⁴, final lot-to-lot consistency results in May 2022⁵ and positive twelve-month persistence data in December 2022⁶.

VLA1553 received FDA Fast Track, Breakthrough Therapy designations and Priority Review in 2018, 2021 and 2023, respectively. VLA1553 was also granted PRIority MEDicine (PRIME) designation by the European Medicines Agency (EMA) in 2020.

If approved, VLA1553 would expand Valneva’s existing commercial vaccines portfolio and as such, Valneva intends to commercialize this vaccine, leveraging its existing manufacturing and commercial operations.

About Valneva SE

Valneva is a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

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.

¹ [Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

² [Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries](#)

³ [CEPI awards up to \\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine](#)

⁴ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

⁵ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

⁶ [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

Valneva Announces Filing of 2022 Universal Registration Document and US Form 20-F

Saint-Herblain (France), March 31, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announced today the filing, on March 30 2023, of its 2022 Universal Registration Document (URD) with the French Financial Markets Authority (AMF) under the filing number D.23-0199 and its Form 20-F with the U.S. Securities and Exchange Commission (SEC).

Valneva's 2022 Universal Registration Document includes the Company's 2022 audited Annual Financial Report, the Management Board Report, the Supervisory Board's report on Corporate Governance and the Group's Corporate Social Responsibility Report.

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

Valneva is a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

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