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: August 14, 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 [X] Form 40-F [ ]

On August 14, 2023, 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 August 14, 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.

Valneva SE
(Registrant)

Date: August 14, 2023

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

EXHIBIT 99.1

Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate

Saint-Herblain (France), August 14, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the U.S. Food and Drug Administration (FDA) has revised the Prescription Drug User Fee Act (PDUFA) action date for the Biologics License Application (BLA) for VLA1553, Valneva's chikungunya virus vaccine candidate, from the previously communicated end of August to the end of November.

The FDA extended the PDUFA date to allow sufficient time to align and agree on the phase 4 program necessary under the accelerated approval pathway. No additional clinical data have been requested for the approval process.

Valneva is committed to working with the FDA in its ongoing review of the BLA, and to potentially delivering the world's first chikungunya vaccine. The Company reconfirms its previous guidance for potential BLA approval, initial launch, and potential award of a priority review voucher (PRV) still in 2023. This PDUFA extension does not impact Valneva's current regulatory submission in Canada or its planned submission with the European Medicines Agency (EMA).

Juan Carlos Jaramillo, Chief Medical Officer of Valneva, said, "We appreciate and take pride in the fact that our BLA for VLA1553, if approved, will represent the first vaccine candidate to be approved under the accelerated approval pathway in an outbreak disease, and hence the necessary Phase 4 activities will set a future standard. We are continuing to work closely and collaboratively with the FDA, and we believe it may be possible to obtain an approval before the new PDUFA date."

About Valneva SE

We are a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet medical needs to ensure we can make a difference to peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today, we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against Lyme disease, the chikungunya virus.

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.