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: October 16, 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 October 16, 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 October 16, 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: October 16, 2024

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

EXHIBIT 99.1

Valneva and LimmaTech Awarded FDA Fast Track Designation for Tetravalent Shigella Vaccine Candidate S4V

Saint Herblain (France) and Schlieren (Zurich), October 16, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and LimmaTech Biologics AG, a clinical-stage biotech company developing vaccines for the prevention of life-threatening diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Shigella4V (S4V), the world's most clinically advanced tetravalent bioconjugate shigellosis vaccine candidate, for which Valneva obtained an exclusive worldwide license from LimmaTech.

Fast Track designation is granted by the FDA to products under development that have the potential to treat serious conditions and fill an unmet medical need. It is designed to facilitate the clinical development and expedite the review of important new products with the intention to get them to the people who need them earlier[1].

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "Shigellosis is the second leading cause of fatal diarrheal disease worldwide. However, there is currently no approved *Shigella* vaccine and the development of *Shigella* vaccines has been identified as a priority by the World Health Organization (WHO). Fast Track designation allows us to work closely with the FDA to accelerate our efforts to deliver a preventative solution against this deadly disease."

Dr. Franz-Werner Haas, Chief Executive Officer of LimmaTech, stated, "We are highly encouraged by the FDA's Fast Track designation, which reinforces our efforts and underscores the significant potential of the S4V *Shigella* vaccine candidate to address a serious global health threat."

It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to *Shigella* each year, particularly among children in Low- and Middle-Income Countries (LMICs). Shigellosis also affects international travelers from high-income countries and deployed military personnel in endemic regions.
In August 2024, Valneva entered into a strategic partnership and exclusive licensing agreement with LimmaTech[2] for the development, manufacturing and commercialization of S4V. Following positive Phase 1/2 results[3] earlier this year, LimmaTech will conduct a Phase 2 Controlled Human Infection Model study (CHIM) in the U.S. and a Phase 2 pediatric study in LMICs, both expected to begin before the end of 2024. Valneva will assume all further development, including CMC (chemistry, manufacturing and controls) and regulatory activities, and be responsible for its commercialization worldwide, if approved.

The anticipated regulatory pathway for S4V will leverage a combination of CHIM studies to support potential initial approval in adults followed by field efficacy studies to potentially expand the indication to children.

About Shigellosis
Shigellosis is a global health threat caused by the Gram-negative *Shigella* bacteria. It is estimated that up to 165 million infections[4] are due to *Shigella* of which 62.3 million occur in children younger than five years. Diarrheal infection is one of the major causes of morbidity and mortality in numerous countries as well as in travelers and deployed military personnel in endemic regions. There are an estimated 600,000 deaths attributed to *Shigella* each year and it is the second leading cause for diarrheal deaths[5]. The standard treatment for shigellosis is oral rehydration and antibiotic therapy, however, the bacteria have acquired resistance to many antibiotics with numerous reports of outbreaks of multidrug-resistant strains, making treatment extremely difficult. Currently, no licensed *Shigella* vaccine is available.

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, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

About LimmaTech Biologics AG
LimmaTech Biologics is at the forefront of combating the global antimicrobial resistance epidemic based on its unparalleled track record in vaccine technology and clinical candidate development. The company is leveraging its proprietary self-adjuvanting and multi-antigen vaccine platform alongside additional disease-specific vaccine approaches to prevent increasingly untreatable microbial infections. With decades of expertise and an expanding, robust pipeline, the LimmaTech team is dedicated to generating protective solutions to deliver transformative value worldwide. LimmaTech Biologics is backed by specialist healthcare investors, including Adjuvant Capital, AXA IM Alts, Novo Holdings REPAIR Impact Fund, and Tenmile.
For more information, please visit www.lmtbio.com.

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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 financial results for 2024; mid-term revenue and cash outlook; the progress, timing, results and completion of research, development and clinical trials for product candidates; regulatory approval of product candidates and requested label extensions; 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 Fast Track | FDA
2 2024_08_01_VLA_LMTB_S4V_PR_EN_Final.pdf (lmtbio.com)
3 20240221_LimmaTech_Shigella-Interim-Data-PR_Final.pdf (lmtbio.com)
4 Shigellosis | CDC Yellow Book 2024
5 Shigellosis | CDC Yellow Book 2024