
**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 23, 2021

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 []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

On August 23, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit

[99.1](#) [Press release dated August 23, 2021](#)

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 23, 2021

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

Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine

Saint-Herblain (France), August 23, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on prophylactic vaccines for infectious diseases, today commenced rolling submission, for initial approval of its COVID-19 vaccine candidate, VLA2001, with the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK). VLA2001 is a whole virus, inactivated, adjuvanted vaccine candidate and is the only vaccine candidate of this type currently in clinical trials in Europe.

VLA2001 is currently being studied in the UK in a pivotal Phase 3 trial, “Cov-Compare” (VLA2001-301), for which topline results are currently expected early in the fourth quarter 2021. Subject to positive Cov-Compare data and MHRA review, Valneva believes that initial approval could be granted before the end of 2021.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025. So far, the UK Government has ordered 100 million doses for supply in 2021 and 2022.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “We are pleased to begin the regulatory review process for our COVID-19 vaccine with the MHRA. Valneva believes that everyone should have access to technology best suited to protect them against this virus. We are working hard to make our vaccine candidate available as soon as possible. We are grateful to the National Institute for Health Research (NIHR), Public Health England (PHE), and other partners for their unstinting support and hard work.”

Valneva recently initiated a further Phase 3 clinical trial, VLA2001-304, to generate data in the elderly and as part of the Company’s strategy to evaluate variant-based vaccines. Data from VLA2001-304 will complement Cov-Compare and other clinical trials. In parallel, the UK Government is funding a clinical trial, “COV-Boost”, which is evaluating different COVID-19 vaccines, including VLA2001, as potential boosters.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines. VLA2001 is produced on Valneva’s established Vero-cell platform, leveraging the manufacturing technology for Valneva’s licensed Japanese encephalitis vaccine, IXIARO[®]. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. This adjuvant combination has consistently induced higher antibody levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. CpG 1018 adjuvant, supplied by Dynavax Technologies Corporation (Nasdaq: DVAX), is a component of the US FDA- and EMA-approved HEPLISAV-B[®] vaccine. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes chemical inactivation to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

About Valneva SE

Valneva is a specialty vaccine company focused on the development 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, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. The Company has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

Media & Investor 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, design, data read-outs, anticipated results and completion of clinical trials for VLA2001. 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. In particular, the expectations of Valneva could be affected by, among other things, uncertainties 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, the ability to obtain or maintain patent or other proprietary intellectual property protection and the impact of the COVID-19 pandemic. 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.