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: June 10, 2022

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 [ ]

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 June 10, 2022, 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 June 10, 2022

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: June 10, 2022

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

Valneva Provides Update on European Inactivated, Whole-Virus COVID-19 Vaccine Program VLA2001

Saint-Herblain (France), June 10, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today provides an update on its European inactivated whole-virus COVID-19 vaccine candidate VLA2001.

Following receipt of the European Commission (EC)'s notice of intent to terminate the Advance Purchase Agreement (APA)[1], Valneva proposed a remediation plan, which is now subject to further discussion within the EC and among the participating member states.

Some member states have confirmed their interest in having an inactivated, adjuvanted whole-virus vaccine solution in their portfolio. However, the preliminary, unofficial volume indications received from the EC would not be sufficient to ensure the sustainability of Valneva's COVID-19 vaccine program. This would also impede the future development of the program beyond the current product profile.

If such indications are confirmed, Valneva will not be able to enter into an amendment to the APA that could allow for a reduced order, and the EC is thus likely to terminate the agreement. As a result, Europeans would not have access to Valneva's inactivated vaccine VLA2001.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We hope that the EC and its member states will continue to evaluate the potential advantages of an inactivated vaccine. There is emerging evidence that hybrid immunity – from a combination of vaccination and natural infection – increases protection against development of severe COVID-19 caused by different variants of concern, and our inactivated vaccine closely mimics natural infection by exposing vaccinees to the entire inactivated SARS-CoV-2 virus. Additionally, market research studies in six European countries indicated material interest in an inactivated COVID-19 vaccine for primary or booster vaccination. We continue to receive messages from people looking for a more traditional vaccine technology and we hope to receive a meaningful order size to further support public health in Europe".

In parallel, the regulatory process with the European Medicine Agency (EMA) continues as planned. EMA accepted the filing of Marketing Authorization Application on May 19, 2022[2] and the Committee for Medicinal Products for Human Use (CHMP) is expected to take a final vote during the week of June 21, 2022. Valneva also continues to work with agencies outside of the European Union for potential future approvals and additional purchase agreements.

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. VLA2001's manufacturing process, 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 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 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 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 possible purchase agreements and regulatory approval of 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.

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1 Valneva Receives Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement – Valneva
2 EMA accepts filing of marketing authorization application for Valneva's inactivated COVID-19 Vaccine Candidate – Valneva