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: September 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 [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 September 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 September 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: September 24, 2021

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

EXHIBIT 99.1

Valneva Continues Expansion of Clinical Trials of its Inactivated COVID-19 Vaccine Candidate VLA2001

- **Commences recruitment of Adolescents into Phase 3 trial "Cov-Compare"**
- **Enrolls participants in the Phase 1/2 Booster Trial**

Saint-Herblain (France), September 23, 2021 – Valneva SE, (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today announced that it has commenced recruitment of adolescents in its pivotal Phase 3 Clinical Trial (VLA2001-301, "Cov-Compare") for its inactivated COVID-19 vaccine candidate VLA2001 in the United Kingdom. Topline results from the pivotal Cov-Compare trial are expected early in the fourth quarter of 2021 and are intended to form the basis for potential regulatory approval in adults. The Company has also started to provide boosters to volunteers in its Phase 1/2 VLA2001-201 trial. This planned expansion of VLA2001 clinical trials will support future approval in further age groups, in addition to adults.

Recruitment of adolescents, aged 12 to 17 years, has commenced in the United Kingdom as part of Valneva's pivotal Cov-Compare Phase 3 trial (VLA2001-301). An initial cohort of adolescents will be enrolled in an open label, non-randomized format. Subject to safety review, remaining participants will be randomized to receive two doses of either VLA2001 or a placebo 28 days apart, followed by a booster dose seven months after enrolling into the study. Approximately 660 participants will be recruited for this trial. Participants randomized to the placebo arm will have the opportunity to receive a course of VLA2001 following the initial safety assessment. A further expansion of the study to include volunteers younger than 12 years old is also envisaged, subject to data from the adolescent group.

Valneva has also commenced booster vaccinations as a continuation of the Phase 1/2 VLA2001-201 trial for which the Company reported positive topline data in April 2021[1]. The booster shot will be provided to each volunteer six months after initial vaccination.

Valneva is conducting several clinical trials of VLA2001. In addition to Cov-Compare and VLA2001-201, VLA2001 is being evaluated in elderly volunteers in study VLA2001-304 in New Zealand as well as in a small, policy-led trial sponsored by University Hospital Southampton NHS Foundation Trust which is not part of Valneva's regulatory package.

Valneva continues discussions with the European Commission regarding a potential VLA2001 supply contract. The Company is also actively pursuing opportunities to make VLA2001 available to other customers, subject to positive Cov-Compare data and regulatory approval.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "*Our teams at Valneva remain fully committed to carry out VLA2001's development plan and bring our inactivated vaccine to all patient groups who could benefit. We continue to receive messages on a daily basis from people across the world who are waiting for an inactivated vaccine so we continue to believe that our differentiated vaccine candidate could contribute to the ongoing fight against the COVID-19 pandemic. We're confident that many countries, and regulators, will want to have the opportunity to consider our inactivated COVID-19 vaccine.*"

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 using 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

Laëtitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com

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, the cancellation of existing contracts, including but not limited to the HMG Supply Agreement, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. 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 Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001*