

**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: November 8, 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 November 8, 2021 and November 10, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1 and Exhibit 99.2 and are incorporated herein by reference.

Exhibit

[99.1](#) [Press release dated November 8, 2021](#)

[99.2](#) [Press release dated November 10, 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.

Valveva SE
(Registrant)

Date: November 10, 2021

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

Valneva to Present and Hold Investor Meetings at the Jefferies London Healthcare Conference

Saint-Herblain (France), November 8, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that its senior management will present and participate in 1-on-1 meetings with institutional investors at the Jefferies London Healthcare Conference on November 16 and 17, 2021.

Valneva's Chief Executive Officer Thomas Lingelbach and acting Chief Financial Officer David Lawrence will notably discuss the Company's late stage vaccine candidates against Lyme disease (VLA15), chikungunya (VLA1553) and COVID-19 (VLA2001).

Valneva recently reported positive Phase 3 results for VLA2001¹, currently the only whole virus, inactivated, adjuvanted vaccine candidate against COVID-19 in clinical trials in Europe. The Company also announced last week the closing of a \$102.0 million Global Offering².

Valneva's presentation will take place on November 16, 2021 at 4:20pm GMT and can be accessed via the following link: <https://wsw.com/webcast/jeff201/vla.pa/2050524>. To request a meeting at the event, please contact your representative at Jefferies.

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.

Valneva Investor and Media Contacts

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¹ Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

² Valneva Announces Closing of Approximately \$102.0 Million Global Offering

Valneva Announces European Commission Approval of Advance Purchase Agreement for up to 60 Million Doses of Inactivated COVID-19 Vaccine VLA2001

Saint-Herblain (France), November 10, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Commission (“EC”) has approved an agreement pursuant to which Valneva would supply up to 60 million doses of VLA2001, its inactivated COVID-19 vaccine candidate, over two years including approximately 27 million doses in 2022.

Under the current terms of the agreement, the EC has the option to increase its initial purchase, in 2022, of VLA2001 up to a total of 60 million doses by the end of 2023. The agreement will be completed following final review, including volumes required, by each of the European Union Member States. Today’s announcement follows the conclusion of advanced exploratory talks with the European Commission that began in January 2021. Delivery of the vaccine is currently expected to begin in April 2022, subject to approval by the European Medicines Agency (EMA) human medicines committee (CHMP), which is expected to start a rolling review of VLA2001 shortly.

Thomas Lingelbach, Chief Executive Officer of Valneva, said, “We are grateful to the European Commission for its support and are eager to help address the ongoing pandemic. We continue to receive messages from people across the world who are waiting for an inactivated vaccine. We are deeply committed to bringing an alternative vaccine solution to the market as quickly as possible and continue to work tirelessly to achieve that. Our Phase 3 results confirmed the advantages often associated with inactivated vaccines and we continue to believe that our differentiated vaccine candidate could make an important contribution to the global fight against the COVID-19 pandemic.”

Franck Grimaud, Chief Business Officer of Valneva, commented, “I would like to express my thanks to the respective teams in the EC and across Valneva who have worked assiduously on this agreement. We are looking forward to completing the agreement and getting the rolling review with EMA underway. Our recent Phase 3 data have allowed us to showcase the value of VLA2001 and we believe that other supply deals could follow this one.”

Valneva reported positive Phase 3 results for VLA2001 in October 2021¹. VLA2001 demonstrated superiority in terms of neutralizing antibody titer levels against the active comparator vaccine, AstraZeneca’s AZD1222, as well as non-inferiority in terms of seroconversion rates and a significantly better tolerability profile.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate against COVID-19 in clinical trials 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).

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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 and regulatory review processes 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.

¹ Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001