

**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: January 3, 2023

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 December 30, 2022, 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).

Exhibits

[99.1](#) [Press release dated December 30, 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.

Valveva SE
(Registrant)

Date: January 3, 2023

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

Valneva Reports Further Heterologous Booster Data for its inactivated COVID-19 vaccine

Saint-Herblain (France), December 30, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported further heterologous booster data from an exploratory, small clinical study for its inactivated COVID-19 vaccine, VLA2001.

In study VLA2001-307¹, a subset of participants (three out of nine groups) received VLA2001 following two or three doses of mRNA COVID-19 vaccine, with or without break-through infection (25-50 participants per group).

The data show that a booster dose of VLA2001 was well tolerated in previously BNT162b2 (Pfizer/BioNTech)- or mRNA 1273 (Moderna)-vaccinated participants, confirming the favorable safety profile of VLA2001 seen across all studies – including in homologous or heterologous booster settings². However, in this study, an additional booster dose of VLA2001 elicited only a marginally increased neutralizing antibody response. The Company previously reported positive heterologous booster results following primary vaccination with ChAdOx1-S (AstraZeneca) in August 2022³ and positive homologous booster results at the end of December 2021⁴.

Valneva is currently seeking regulatory approval for VLA2001 as a homologous booster as well as heterologous booster in ChAdOx1-S (AstraZeneca) primed individuals which may support the Company in deploying its inventory in international markets⁵.

Juan Carlos Jaramillo, M.D., Valneva's Chief Medical Officer, commented, "While these latest booster results are not aligned with the encouraging homologous and heterologous booster results seen previously, we are pleased to once again confirm the favorable safety and tolerability profile of VLA2001, which was important for EMA and MHRA approval."

About Trial VLA2001-307

VLA2001-307 is a multicenter, open-label clinical study investigating the safety, tolerability and immunogenicity of a VLA2001 booster vaccination in participants aged 18 years and older. Approximately 275 participants, either generally healthy or with a stable medical condition, were planned to be enrolled in the trial. The VLA2001 booster will be given to adults at least 6 months after vaccination with an mRNA COVID-19 vaccine, with or without confirmed SARS-CoV-2 infection, or to unvaccinated adults at least four months after confirmation of natural SARS-CoV-2 infection.

About VLA2001

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 HEP LISAV-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).

VLA2001 was the first COVID-19 vaccine to receive a standard marketing authorization in Europe⁶ and the only whole virus, inactivated, COVID-19 vaccine to receive marketing authorization in Europe for use as primary vaccination in people from 18 to 50 years of age. The vaccine was also granted conditional marketing authorization in the United Kingdom⁷ and emergency use authorization in the United Arab Emirates⁸ and Kingdom of Bahrain⁹. Valneva signed agreements to supply VLA2001 to certain EU Member States² and the Kingdom of Bahrain¹⁰. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001¹¹. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine and is continuing discussions on potential additional supply agreements with various other governments around the world to deploy remaining inventory. VLA2001's shelf life is expected to be extended to up to 24 months, compared to 18 months currently.

About Valneva SE

Valneva is a specialty vaccine company focused on the development, manufacturing 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 commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease and the chikungunya virus.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine

VP, Global Communications and European Investor Relations

M +33 (0)6 4516 7099

investors@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 development and commercialization plans for VLA2001 and agreements with potential partners and purchasers. 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, expectations regarding entering into an agreement with third parties for the continued development of a second-generation COVID program, 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 <https://valneva.com/press-release/valneva-initiates-heterologous-booster-trial-of-inactivated-covid-19-vaccine-candidate/>

² Munro APS et al. COV-BOOST study group. *Lancet*. 2021 Dec 18;398(10318):2258-2276. doi: 10.1016/S0140-6736(21)0271

³ Valneva Announces Positive Homologous Booster Data for Inactivated Adjuvanted Covid-19 Vaccine Candidate (December 16, 2021)

⁴ Valneva Reports Further Positive Phase 3 Immunogenicity and the First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001 - Valneva

⁵ Valneva Reports Nine-Month 2022 Results and Provides Corporate Updates - Valneva

⁶ Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001

⁷ Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine

⁸ Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine

⁹ Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001

¹⁰ Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001

¹¹ Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine