

**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 26, 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 September 26, 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).

**Exhibit**

[99.1](#) [Press release dated September 26, 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: September 26, 2022

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

## Valneva Provides Further Update on its COVID-19 Activities

**Saint-Herblain (France), September 26, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced a further update on its COVID-19 vaccine activities.

The Company had previously communicated that it would invest in further development of a potential second-generation COVID-19 vaccine only if it received the necessary funding or commitments to such funding during the third quarter of 2022<sup>1</sup>. The Company is in active discussions with a prospective partner for potentially funding the development of a second-generation COVID-19 vaccine. These ongoing discussions may continue for several months and may not lead to an agreement.

In parallel, Valneva is continuing discussions with various governments and has initiated regulatory processes with additional regulatory authorities, with the aim to deploy remaining inventory into international markets in the next twelve months. The Company also expects to report additional clinical data in the fourth quarter of 2022, notably heterologous booster data, which may potentially support the positioning of its inventory.

**Thomas Lingelbach, Valneva's Chief Executive Officer**, commented, "As we are near the end of the third quarter 2022, we are engaged in active discussions that are likely to continue into the coming months. We therefore plan to continue exploring these potential funding opportunities and will provide future updates if and when we enter into an agreement for further development of our COVID-19 vaccine program."

### About VLA2001

VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO<sup>®</sup>. 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<sup>®</sup> 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 is the first COVID-19 vaccine to receive a standard marketing authorization in Europe<sup>2</sup> and the only whole virus, inactivated, adjuvanted 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 Kingdom<sup>3</sup> and emergency use authorization in the United Arab Emirates<sup>4</sup> and Kingdom of Bahrain<sup>5</sup>. Valneva currently has agreements to supply VLA2001 to certain EU Member States<sup>2</sup> and the Kingdom of Bahrain<sup>6</sup>. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001<sup>7</sup>. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine. Valneva is retaining inventory for potential additional supply to these EU Member States should demand increase.

### 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 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.

<sup>1</sup> [Valneva Reports H1 2022 Results and Provides Corporate Updates](#)

<sup>2</sup> [Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001](#)

<sup>3</sup> [Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine](#)

<sup>4</sup> [Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine](#)

<sup>5</sup> [Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001](#)

<sup>6</sup> [Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001](#)

<sup>7</sup> [Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine](#)