# 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 24, 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 24, 2022, the Registrant issued two press releases, a copy of each of which is attached hereto as Exhibits 99.1 and 99.2 and is incorporated herein by reference.

### <u>Exhibit</u>

- Press release dated June 24, 2022 Press release dated June 24, 2022 <u>99.1</u>
- <u>99.2</u>

### **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 24, 2022

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

#### Valneva Announces Successful Outcome of its AGM and Appointment of two New Supervisory Board Members

**Saint-Herblain (France), June 24, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that all the resolutions recommended by the Management Board were approved by the shareholders at its Annual General Meeting (AGM) held yesterday in Paris.

Among the adopted resolutions were approval of the 2021 financial statements, delegations for the management board to increase Valneva's share capital and/or issue financial instruments, and the appointment, for a three-year term, of two new Supervisory Board members.

Bpifrance Participations was appointed to Valneva's Supervisor Board and will be represented by Maïlys Ferrère. Ms. Ferrère, a French national, is Director of Large Venture Investments at Bpifrance, France's state-owned investment bank. In her role at Bpifrance, she sits on various boards of Euronext-listed companies. Before joining Bpifrance Large Venture in 2013, Ms. Ferrère was an Investment Director at the Fonds Stratégique d'Investissement. Prior to this, Ms. Ferrère had a career in the banking industry, focusing on equity capital markets in various financial institutions. She graduated from Institut d'Etudes Politiques de Paris.

James Edward Connolly, an American national, was also appointed to Valneva's Supervisory Board. Mr. Connolly is a seasoned business executive with more than three decades of experience in the life sciences industry. Since 2013, Mr. Connolly has been serving on a number of boards for a variety of vaccine, biopharmaceutical and investment organizations. From 2010 to 2013, Mr. Connolly was President and CEO of Aeras (now IAVI.) Prior to this, he had a long and successful 24-year career at Wyeth (now Pfizer), where he held a series of senior roles, the last two of which were Executive Vice President and General Manager, Wyeth Vaccines and President, Wyeth Canada. During his tenure leading Wyeth Vaccines, Mr. Connolly played a leading role building the company's vaccines business into one of the top four global manufacturers and creating the first true blockbuster vaccine, Prevnar, with sales in excess of \$3 billion.

Additionally, the term of office of Supervisory Board members Frédéric Grimaud, James Sulat, and Anne-Marie Graffin was renewed until June 2025. In a separate meeting, Frédéric Grimaud was re-elected as Chairman of Valneva's Supervisory Board.

Valneva also confirmed during the AGM that initiation of the Phase 3 study of Lyme disease vaccine candidate VLA15 is planned in the third quarter of 2022 and that it is expecting to submit the Biologics License Application (BLA) for its chikungunya vaccine candidate VLA1553 to the Food and Drug Administration (FDA) in the second half of 2022.

The AGM's voting results will be made available in the "Investors & Media" section of Valneva's corporate website in the coming days.

#### 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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#### Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates and estimates for future performance. 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 sustained in the future. 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 largely 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, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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 these materials as of this press release and disclaim

any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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

### VLA2001 becomes the first COVID-19 vaccine to receive a standard marketing authorization in Europe

Saint Herblain (France), June 24, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Commission (EC) has granted marketing authorization in Europe for Valneva's inactivated whole-virus COVID-19 vaccine, VLA2001, for use as primary vaccination in people from 18 to 50 years of age.

With this approval, VLA2001 becomes the first COVID-19 vaccine to receive a standard marketing authorization in Europe. The marketing authorization will cover all 28 European Union Member States as well as Iceland, Liechtenstein, and Norway.

**Thomas Lingelbach, Chief Executive Officer of Valneva**, commented, "We are extremely pleased that the EC granted full marketing authorization for VLA2001, the only inactivated whole-virus COVID-19 vaccine available in Europe. Once again, we have shown that Valneva has the expertise to bring a vaccine all the way from bench to market. Since we began working on VLA2001, we have continued to receive messages from Europeans who are waiting for a more traditional vaccine technology. Now that we have received this full marketing authorization, we hope that the EC and its member states will place orders that reflect this demand. 15% of Europeans over 18 are not yet vaccinated<sup>1</sup>, and we believe that making our inactivated vaccine available could increase vaccination coverage and have a meaningful impact on public health."

The EC's approval follows recommendations yesterday from the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) to grant marketing authorization. This new marketing authorization in Europe follows conditional marketing authorization in the United Kingdom, which was granted in April 2022<sup>2</sup>, and emergency use authorization granted in the United Arab Emirates and Bahrain in May 2022 and March 2022, respectively.

#### About VLA2001

VLA2001 is the only whole virus, inactivated, adjuvanted COVID-19 vaccine which has received marketing authorization in Europe for use as primary vaccination in people from 18 to 50 years of age. VLA2001 is produced on Valneva's established Verocell 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).

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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 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.

1 EMA Press Briefing May 5, 2022: https://www.youtube.com/watch?v=C5DL66-Fb0Q 2 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva