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**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 23, 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 [  ]    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.

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On June 20 and June 23, 2022, the Registrant issued press releases, a copy of each of which is attached hereto as Exhibits 99.1, 99.2, 99.3, and 99.4, respectively, and is incorporated herein by reference.

**Exhibits**

[99.1](#) [Press release dated June 20, 2022](#)

[99.2](#) [Press release dated June 23, 2022](#)

[99.3](#) [Press release dated June 23, 2022](#)

[99.4](#) [Press release dated June 23, 2022](#)

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## 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 23, 2022

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

## Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15

- *Pfizer will invest €90.5 million in Valneva*
- *Planned Phase 3 study confirmed to initiate in Q3 2022*

**Saint-Herblain (France) and New York, June 20, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today announced that they have entered into an Equity Subscription Agreement and have updated the terms of their Collaboration and License Agreement for Lyme disease vaccine candidate VLA15. As previously announced on April 26, 2022, Pfizer plans to initiate the Phase 3 study of VLA15 in the third quarter of 2022.

As part of the Equity Subscription Agreement, Pfizer will invest €90.5 (\$95) million in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase to further support the strategic Lyme partnership between the two companies. The per share purchase price was determined based on the average closing price of the Company's shares on Euronext Paris during the 10 trading days preceding the date of the Equity Subscription Agreement. The equity investment is due to close on June 22, 2022. Valneva is planning to use the proceeds from Pfizer's equity investment to support its Phase 3 development contribution to the Lyme disease program.

In addition, Valneva and Pfizer updated the terms of their collaboration and license agreement which they announced on April 30, 2020<sup>1</sup>. Valneva will now fund 40% of the remaining shared development costs compared to 30% in the initial agreement. Pfizer will pay Valneva tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement. In addition, the royalties will be complemented by up to \$100 million in milestones payable to Valneva based on cumulative sales. Other development and early commercialization milestones are unchanged, of which \$168 million remain, including a \$25 million payment to Valneva upon Pfizer's initiation of the Phase 3 study.

**Thomas Lingelbach, Chief Executive Officer of Valneva**, commented "Pfizer's investment in Valneva highlights the quality of the work that we've done together over the past two years and is a strong recognition of Valneva's vaccine expertise. This subscription agreement will contribute to our investment in the Phase 3 study while limiting the impact on our cash position. Lyme disease is spreading and represents a high unmet medical need which impacts the lives of millions of people in the Northern Hemisphere. We are looking forward to further investigating our VLA15 candidate in Phase 3, which will take us a step closer to potentially help protect both adults and children from this devastating disease."

"Lyme disease continues to place a heavy burden on countries in North America and Europe, with an estimated 600,000 cases each year across both regions," said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer**. "As the geographic footprint of Lyme disease widens, the medical need for vaccination becomes even more imperative. We are excited to continue partnering with Valneva on the development of VLA15 and look forward to working together to progress the program with the goal of bringing forward a vaccine that could help prevent this debilitating disease."

Pending successful initiation and completion of the planned Phase 3 study for VLA15, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration as early as 2025.

### Dilution

The 9,549,761 new ordinary shares to be issued to Pfizer pursuant to the Equity Subscription Agreement will represent a dilution of approximately 8.1% of the share capital of the Company. On an illustrative basis, a shareholder holding 1% of Valneva's capital before this capital increase will now hold a stake of 0.919%.

### About VLA15

VLA15 is the only Lyme disease vaccine candidate currently in clinical development. This investigational multivalent protein subunit vaccine uses an established mechanism of action for a Lyme disease vaccine that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. Blocking OspA inhibits the bacterium's ability to leave the tick and infect humans. The vaccine covers the six most common OspA serotypes expressed by *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe. VLA15 has demonstrated a strong immunogenicity and safety profile in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017<sup>2</sup>. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15<sup>1</sup>.

### About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by infected *Ixodes* (aka deer or blacklegged) ticks<sup>3</sup>. It is considered the most common vector-borne illness in the Northern Hemisphere and according to a study published on June 13, 2022 in BMJ Global Health, Lyme disease has likely infected 14.5% of the world's population<sup>4</sup>. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens<sup>5</sup>.

## **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.

## **About Pfizer: Breakthroughs That Change Patients' Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.Pfizer.com](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

### **Valneva**

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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 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.

## **Pfizer Disclosure Notice**

The information contained in this release is as of June 20, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and an Equity Subscription Agreement and a Collaboration and License Agreement between Pfizer and Valneva for VLA15, including their potential benefits and a planned Phase 3 clinical trial, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement

and/or completion dates or enrollment targets for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, including uncertainties relating to the time needed to accrue cases in the planned Phase 3 trial, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; whether our collaboration with Valneva will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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- 1 *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15 – Valneva*
  - 2 <https://valneva.com/press-release/valneva-receives-fda-fast-track-designation-for-its-lyme-disease-vaccine-candidate-vla15/>
  - 3 Stanek et al. 2012, *The Lancet* 379:461–473
  - 4 [https://gh.bmj.com/content/7/6/e007744?utm\\_source=STAT%20Newsletters&utm\\_campaign=c7e76c7c4eMR\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-c7e76c7c4e-150175797](https://gh.bmj.com/content/7/6/e007744?utm_source=STAT%20Newsletters&utm_campaign=c7e76c7c4eMR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-c7e76c7c4e-150175797)
  - 5 *New Scientist*, *Lyme disease is set to explode and we still don't have a vaccine*; March 29, 2017.  
<https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/>

## Valneva Receives Positive CHMP Opinion for Marketing Authorization of its Inactivated COVID-19 Vaccine Candidate in Europe

**Saint Herblain (France), June 23, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended marketing authorization in Europe for Valneva’s inactivated whole-virus COVID-19 vaccine candidate, VLA2001, for use as primary vaccination in people from 18 to 50 years of age.

The European Commission (EC) will review the CHMP recommendation, and a decision on the marketing authorization application for VLA2001 is expected shortly. If granted, this will be the first COVID-19 vaccine to receive a standard marketing authorization in Europe.

The CHMP concluded by consensus after a thorough evaluation that, “the data on the vaccine were robust and met the EU criteria for efficacy, safety and quality.”

**Thomas Lingelbach, Chief Executive Officer of Valneva**, commented, “We are pleased that the CHMP has recommended VLA2001, the only inactivated COVID-19 vaccine candidate in Europe, for full marketing authorization and are now looking forward to receiving marketing authorization from the EC. I would like to personally thank all those who have supported us in this endeavor, as well as everyone at Valneva for all their hard work. We hope that the EC and its member states will recognize the potential advantages of an inactivated vaccine and make a meaningful order, since we have clear evidence that Europeans are seeking a more traditional vaccine technology. Our aim is to further support public health in Europe by providing a new option for the 15% of Europeans over 18 who are not yet vaccinated<sup>1</sup>.”

Once granted by the EC, the marketing authorization would be valid in all European Union Member States as well as in Iceland, Liechtenstein, and Norway.

The EMA’s CHMP opinion 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 in May 2022 and in Bahrain in March 2022.

### 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 pandemic and 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<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).

### About Valneva SE

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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.

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*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*



**Valneva announces resumption of trading of its ordinary shares on Euronext Paris**

**Saint-Herblain (France), June 23, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announces the resumption of trading of its ordinary shares on the regulated market of Euronext in Paris, starting at 4:30pm CEST today.

At the request of the Company, trading of Valneva's ordinary shares was suspended on June 23, 2022 from 9:00 AM CEST to allow for the publication of a press release by the European Medicines Agency regarding the Committee for Medicinal Products for Human Use (CHMP) opinion on marketing authorization in Europe for Valneva's COVID-19 vaccine candidate, VLA2001.

**About Valneva SE**

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## Valneva and Pfizer Announce Closing of Equity Investment

**Saint-Herblain (France) and New York, June 23, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today announced the closing of the equity investment announced on June 20, 2022.<sup>1</sup>

Pursuant to an Equity Subscription Agreement, Pfizer has invested €90.5 (\$95) million in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase. Valneva is planning to use the proceeds to support its contribution to the planned Phase 3 development program for Lyme disease vaccine candidate VLA15. Pfizer plans to initiate the Phase 3 study of VLA15 in the third quarter of 2022.

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### Valneva

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### Valneva Forward-Looking Statements

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### **Pfizer Disclosure Notice**

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This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and an Equity Subscription Agreement and a Collaboration and License Agreement between Pfizer and Valneva for VLA15, including their potential benefits and a planned Phase 3 clinical trial, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates or enrollment targets for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, including uncertainties relating to the time needed to accrue cases in the planned Phase 3 trial, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; whether our collaboration with Valneva will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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*1 Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15*