

---

---

**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: October 26, 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 [  ]    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 October 26 and 27, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1, Exhibit 99.2 and are incorporated herein by reference.

**Exhibit**

[99.1](#) [Press release dated October 26, 2021](#)

[99.2](#) [Press release dated October 27, 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.

Valneva SE  
(Registrant)

Date: October 27, 2021

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

## Valneva Announces Launch of Proposed Global Offering of American Depository Shares and Ordinary Shares

**Saint Herblain (France), October 26, 2021** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) (the “Company”), a specialty vaccine company, today announced its intention to issue and sell, subject to market conditions, 5,500,000 of its ordinary shares in a global offering to specified categories of investors comprised of (i) a public offering of its American Depository Shares (“ADSs”), each representing two ordinary shares, in the United States (the “U.S. Offering”) and (ii) a concurrent private placement of its ordinary shares in certain jurisdictions outside of the United States (the “European Private Placement” and together with the U.S. Offering, the “Global Offering”).

Goldman Sachs, Jefferies, Guggenheim Securities and Bryan, Garnier & Co. are acting as joint bookrunners for the Global Offering.

The Company intends to grant the underwriters for the Global Offering (the “Underwriters”) a 30-day option to purchase additional ADSs (each representing two ordinary shares) in an aggregate amount of up to 15% of the total number of ordinary shares (including in the form of ADSs) proposed to be sold in the Global Offering.

All securities to be sold in the Global Offering will be offered by the Company. The ADSs are listed on the Nasdaq Global Select Market under the ticker symbol “VALN,” and the Company’s ordinary shares are listed on the regulated market of Euronext in Paris (“Euronext”) under the symbol “VLA.”

The offering price per ADS in U.S. dollars and the corresponding offering price per ordinary share in euros, as well as the final number of ADSs and ordinary shares sold in the Global Offering, will be determined following a book building process commencing immediately. The price per ordinary share (and corresponding offering price per ADS) will be at least equal to the weighted average price of the Company’s ordinary shares on Euronext over a period, chosen by the Management Board, of between three (3) and ninety (90) consecutive trading days preceding the determination of the offering price, reduced by a maximum discount of 15%, if applicable.

The ADSs and/or ordinary shares will be issued through a capital increase without shareholders’ preferential subscription rights and for the benefit of a specified category of persons within the meaning of Article L.225-138 of the French Commercial Code (*Code de commerce*) and pursuant to the 17<sup>th</sup> and 18<sup>th</sup> resolutions of the Company’s annual combined general meeting held on June 23, 2021. Under the authority granted by the shareholders in the 17<sup>th</sup> resolution, the ordinary shares and ADSs may only be purchased initially by (i) natural persons and legal entities, including companies, trusts or investment funds, organized under French or foreign law, that routinely invest in the pharmaceutical, biotechnological or medical technology sector; and/or (ii) companies, institutions or entities of any type, French or foreign, that do a significant part of their business in the pharmaceutical, cosmetic, chemical or medical devices and/or technologies or research in these sectors. In order to purchase ordinary shares and/or ADSs in the Global Offering, potential investors will be required to execute and provide to the Underwriters an investor letter representing that they satisfy the foregoing investor criteria.

The European Private Placement will be open only to qualified investors as such term is defined in article 2(e) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of June 14, 2017.

The closings of the U.S. Offering and the European Private Placement will occur simultaneously, will be conditioned on each other and are expected to occur on the third trading day after the final pricing and allocation of the Global Offering. The underwriting agreement to be entered into among the Company and the Underwriters will not constitute a performance guarantee (*garantie de bonne fin*) within the meaning of Article L225-145 of the French Commercial Code.

The Global Offering will commence immediately and the Company plans to announce the result of the Global Offering as soon as practicable after pricing thereof in a subsequent press release. The Company expects to use the net proceeds from the Global Offering, together with its existing cash and cash equivalents, as follows (assuming an exchange rate of €1.00 = \$1.1603, the exchange rate on October 25, 2021, as reported by the European Central Bank):

- Approximately \$50 million to fund further development of its Lyme VLA15 vaccine candidate through completion of Phase 2 clinical trials including handover to Pfizer;
- Approximately \$60 million to complete development of its chikungunya VLA1553 vaccine candidate through BLA approval;
- Approximately \$100 million to fund further development of its COVID-19 VLA2001 vaccine candidate through conditional licensure and commercial launch, including capital expenditure into production facilities;
- Approximately \$20 million to fund advancement of preclinical vaccine candidates towards clinical development; and
- The remainder, if any, for working capital and general corporate purposes.

A registration statement on Form F-1 relating to the securities referred to herein has been filed with the U.S. Securities and Exchange Commission (“SEC”) but has not yet become effective. These securities may not be sold, nor may offers to buy be accepted, prior to the time the registration statement becomes effective. This press release does not constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities

laws of that jurisdiction. The securities sold will not be part of a public offering in France. The registration statement can be accessed by the public on the website of the SEC.

The securities referred to in this press release will be offered in the United States only by means of a prospectus approved by the SEC. When available, copies of the preliminary prospectus relating to and describing the terms of the Global Offering may be obtained from: Goldman Sachs & Co. LLC, Attn: Prospectus Department, 200 West Street, New York, New York 10282, telephone: 866-471-2526, facsimile: 212-902-9316, e-mail: prospectus-ny@ny.email.gs.com or Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, or by telephone at +1 877 821 7388 or by email at Prospectus\_Department@Jefferies.com.

Application will be made to list the new ordinary shares to be issued pursuant to the Global Offering on the regulated market of Euronext in Paris.

The Global Offering was not subject to a prospectus to be approved by the French financial markets authority (*Autorité des marchés financiers* - the “AMF”). The Company draws the public’s attention to the risk factors related to the Company and its activities set forth in section 1.5 of the universal registration document of the Company registered with the AMF under number D.21-0286 on April 9, 2021, as completed by the risk factors set forth in the Company’s half year financial report published on August 10, 2021 and the risk factors set forth in section 1.5 of the amendment to the universal registration document of the Company registered with the AMF under number D.21-0286-A01 on October 26, 2021. Copies of the Company’s 2020 universal registration document, as amended, will be available free of charge on the Company’s website ([www.valneva.com](http://www.valneva.com)) and on the AMF’s website ([www.amf-france.org](http://www.amf-france.org)).

### **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**

Laëtitia Bachelot-Fontaine

VP Global Communications & European Investor Relations

M +33 (0)6 4516 7099

[laetitia.bachelot-fontaine@valneva.com](mailto:laetitia.bachelot-fontaine@valneva.com)

Joshua Drumm, Ph.D.

VP Global Investor Relations

M +001 917 815 4520

[joshua.drumm@valneva.com](mailto:joshua.drumm@valneva.com)

### **Disclaimer**

This press release contains certain forward-looking statements concerning the Global Offering as well as the Company and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that the Company considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in section 1.5 of the universal registration document of the Company registered with the AMF under number D.21-0286 on April 9, 2021 (copies of which are available on the Company’s website) and to the development of economic conditions, financial markets and the markets in which the Company operates. The forward-looking statements contained in this press release are also subject to risks not yet known to the Company or not currently considered material by the Company. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of the Company to be materially different from such forward-looking statements.

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction. The registration statement can be accessed by the public on the website of the SEC.

This announcement is an advertisement and not a prospectus within the meaning of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017, as amended (the “Prospectus Regulation”).

In France, the European Private Placement described above will take place solely as a placement to the benefit of categories of persons, in accordance with Article L. 225-138 of the “Code de commerce” and applicable regulations. The European Private Placement is reserved, in Europe (including in France), to “qualified investors”, as that term is defined in Article 2(e) of the Prospectus Regulation.

In relation to each member state of the European Economic Area other than France (each, a “Relevant Member State”), an offer of the securities referred to herein is not being made and will not be made to the public in that Relevant Member State, other than: (i) to any legal entity which is a qualified investor as defined in the Prospectus Regulation; (ii) to fewer than 150 natural or legal persons per relevant member state; or (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation; provided that no such offer of the securities referred to herein shall require the Company to publish a prospectus pursuant to Article 3 of the Prospectus Regulation. For the purposes of the above, the expression an “offer to the public” in any Relevant Member State shall have the meaning ascribed to it in article 2(d) of the Prospectus Regulation.

This communication is being distributed only to, and is directed only at (a) persons outside the United Kingdom, (b) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”), and (c) high net worth entities, and other persons to whom it may otherwise lawfully be communicated, falling within Article 49(2) of the Order (all such persons together being referred to as “relevant persons”). Any investment or investment activity to which this communication relates is available only to relevant persons and will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this communication or any of its contents.

Solely for the purposes of each manufacturer’s product approval process, the target market assessment in respect of ordinary shares has led to the conclusion that: (i) the target market for the ordinary shares is eligible counterparties, professional clients and retail clients, each as defined in Directive 2014/65/EU, as amended (“MiFID II”); and (ii) all channels for distribution of the ordinary shares to eligible counterparties, professional clients and retail clients are appropriate. Any person subsequently offering, selling or recommending the ordinary shares (a “distributor”) should take into consideration the manufacturers’ target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the ordinary shares (by either adopting or refining the manufacturers’ target market assessment) and determining appropriate distribution channels. For the avoidance of doubt, even if the target market includes retail clients, the Underwriters have decided that they will only procure investors for the ordinary shares who meet the criteria of eligible counterparties and professional clients.

This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

## Valneva Publishes Amendment to 2020 Universal Registration Document

**Saint Herblain (France), October 27, 2021** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced the publication of an amendment filed with the French Financial Markets Authority (“AMF”) on October 26, 2021 under the filing number D.21-0286-A01 (the “URD Amendment”) to its 2020 Universal Registration Document (“URD”), filed with the AMF on April 9, 2021 under the filing number D.21-0286. The key amendments made to the URD, including certain information updates, are discussed below.

In October 2021, the Company announced positive Phase 3 initial results for VLA2001, a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus that causes COVID-19.<sup>1</sup> In anticipation of these results, the Company commenced its rolling submission and review process with the UK’s Medicines & Healthcare products Regulatory Agency (“MHRA”), in August 2021.<sup>2</sup> The Company expects to incorporate its positive Phase 3 initial results into this submission in November 2021 and believes that it could receive MHRA approval by the end of 2021. The Company is also preparing to commence a rolling review process with the European Medicines Agency, (“EMA”). Further submissions to other regulatory agencies may take place in 2022.

In September 2021, Valneva and Pfizer Inc. announced positive new Phase 2 results, including data after a booster dose, for Valneva’s Lyme disease vaccine candidate, VLA15.<sup>3</sup> The two companies are working closely together on the next development steps and are planning for a placebo-controlled pivotal Phase 3 trial in 2022. The dosing of the first subject in the Phase 3 clinical trial will trigger a milestone payment from Pfizer of \$25 million.

In relation to VLA1553, the Company’s chikungunya vaccine candidate, the Company has received confirmation from the EMA of its acceptance of the surrogate of protection Valneva had previously agreed with the US Food & Drug Administration (“FDA”) to use as a base for licensure of VLA1553. The Company announced in August 2021 that the seroprotection rate observed in the pivotal Phase 3 trial of VLA1553 was 98.5%, exceeding the 70% surrogate of protection threshold agreed with the FDA.<sup>4</sup>

The URD Amendment includes an explanation of i) changes to the Company’s segment reporting structure effective as of January 1, 2021 and ii) events after the reporting period, which describes the circumstances of the termination of the agreement to supply VLA2001, the Company’s COVID-19 vaccine candidate, to the United Kingdom (the “UK Supply Agreement”)<sup>5</sup> and the potential impact of this termination.

The URD Amendment explains that the UK government (the “UK Authority”) provided notice of its decision to terminate the UK Supply Agreement following the close of business on September 10, 2021. This included an allegation that Valneva would be in future breach of the UK Supply Agreement which claim could give rise to a liability for damages (the contractual cap on which would not exceed the amounts received). As detailed in the URD Amendment, Valneva strongly disputes any claims relating to breach of the UK Supply Agreement (and believes that it is very unlikely that any such claim by the UK Authority would ultimately be successful) but has acknowledged termination of the UK Supply Agreement for convenience by the UK Authority effective as of October 10, 2021 (and associated obligations on the part of Valneva and the UK Authority arising from or surviving termination of the Agreement). Valneva is not obligated to refund or repay any amount paid by the UK Authority in case of termination for convenience. Further details are available in the URD Amendment.

Valneva is continuing to discuss the final terms of the termination of the UK Supply Agreement with the UK Authority, and those final terms as well as other commercial opportunities and receipt of regulatory approval of VLA2001 may impact the Company’s financial position. The potential impact of the termination of the UK Supply Agreement on the Company’s financial position is presented in the note on events after the reporting period included in the URD Amendment. The note discusses potential impact on the Company’s inventories and advance payments for inventories, property, plant and equipment, refund liabilities, and contract liabilities.

Additionally, the Company has received a request for information from a directorate within Health Canada, the agency supervising pharmaceutical products in Canada, regarding the data supporting the indication and labeling of the Company’s product DUKORAL<sup>®</sup>. This remains an ongoing matter, and if the indications or labeling of DUKORAL<sup>®</sup> were to change significantly in Canada, this could have a significant negative impact on the Company’s sales which could in turn result in the product no longer being economically viable.

Finally, the Company had planned to communicate its third quarter results on November 18, 2021. Given the difficulty of assessing the impact of a number of post-closing events at this time, the Company will communicate, on November 18, 2021, only its cash position for the quarter ended September 30, 2021 and its revenues for the nine months ended September 30, 2021. The year-end closing on December 31, 2021 will allow for the integration of all necessary elements.

The URD Amendment is available on the Company’s corporate website (<https://valneva.com/investors/financial-reports/>) and on the AMF’s website ([www.amf-france.org](http://www.amf-france.org)) and should be read together with the URD. A hard copy of the document may be obtained from the Company, free of charge and upon request, at the following address: 6 rue Alain Bombard, 44800 Saint-Herblain, France.

Valneva has publicly filed a registration statement on Form F-1 with the Securities and Exchange Commission (SEC) in the United States. This document refers to a potential public offering of American Depositary Shares in the United States and a

concurrent private placement of ordinary shares in Europe (together, the “Global Offering”), and discloses the potential use of proceeds in the event of the completion of such offering.

## **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 & Investors Contacts**

Laëtitia Bachelot-Fontaine

VP Global Communications & European Investor Relations

M +33 (0)6 4516 7099

laetitia.bachelot-fontaine@valneva.com

Joshua Drumm

VP Global Investor Relations

M +001 917 815 4520

joshua.drumm@valneva.com

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the potential consequences of termination of the UK Supply Agreement, relating to the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and review of existing products, and to 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.

---

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

*2 Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine*

*3 Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate*

*4 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate*

*5 Valneva Receives Notice of Termination of COVID-19 Vaccine Supply Agreement by UK Government*