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 8, 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 6, 2022 and September 8, 2022, the Registrant issued press releases, a copy of each of which is attached hereto as Exhibits 99.1 and 99.2, respectively, and is incorporated herein by reference. The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, 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 6, 2022
99.2	Press release dated September 8, 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 8, 2022

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

EXHIBIT 99.1

Valneva Announces Publication of its COVID-19 Vaccine Phase 3 Data in The Lancet Infectious Diseases

Saint-Herblain (France), September 6, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces that *The Lancet Infectious Diseases ("The Lancet ID")*, a peer-reviewed medical journal, has published the Company's pivotal Phase 3 clinical data for its inactivated, whole-virus COVID-19 vaccine, VLA2001.

The paper, entitled "Immunogenicity and safety of an inactivated whole-virus COVID-19 vaccine (VLA2001) compared with the adenoviral vector vaccine ChAdOx1 in adults in the UK (COV-COMPARE): interim analysis of a randomised, controlled, phase 3, immunobridging trial" provides a detailed analysis of the Phase 3 results, showing that VLA2001 demonstrated superior neutralizing antibody titer levels versus the comparator vaccine, as well as broad T-cell responses against the S- (spike), M- (membrane), and N- (neucleocapsid) proteins, and a significantly better tolerability profile versus the comparator vaccine. It can be accessed via the following link: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00502-3/fulltext.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "This Lancet publication is a strong scientific and developmental validation of the work that has been accomplished at Valneva. We are pleased that more detailed results on our inactivated COVID-19 vaccine are now available to the scientific and broader public health communities."

Valneva reported positive topline Phase 3 results for VLA2001 in October 2021[1].

In August 2022, the World Health Organization issued recommendations for use of Valneva's inactivated COVID-19 vaccine[2].

The Company published safety and immunogenicity data from the Phase 1/2 trial of VLA2001 in the *Journal of Infection*[3] in June 2022.

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 HEPLISAV-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 is the first COVID-19 vaccine to receive a standard marketing authorization in Europe[4] 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[5] and emergency use authorization in the United Arab Emirates[6] and Kingdom of Bahrain[7]. Valneva currently has agreements to supply VLA2001 to certain EU Member States[8] and the Kingdom of Bahrain[9]. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001[10]. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine[11]. Valneva is retaining inventory for potential additional supply to these EU Member States should demand increase. In parallel, the Company is continuing discussions with various other governments around the world, with the aim to deploy approximately eight to ten million doses of remaining inventory into international markets in the next six to twelve months.

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.

Media & Investor Contacts

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1 Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001
2 Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine

3 https://pubmed.ncbi.nlm.nih.gov/35718205/
4 Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001
5 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine
6 Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine
7 Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001
8 European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine
9 Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001
10 Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine
11 European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine

EXHIBIT 99.2

Valneva and VBI Vaccines Announce European Partnership for Marketing and Distribution of PreHevbri®

SAINT-HERBLAIN, France and CAMBRIDGE, Mass. (September 8, 2022) – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) (Valneva) and VBI Vaccines Inc. (Nasdaq: VBIV) (VBI) today announced a partnership in select European markets for the marketing and distribution of PreHevbri® [Hepatitis B vaccine (recombinant, adsorbed)], the only 3-antigen hepatitis B vaccine approved in Europe.

Under the terms of the agreement, specialty vaccine company Valneva will promote and distribute PreHevbri throughout select European countries, which initially include the United Kingdom, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands. Valneva and VBI expect PreHevbri to be available in these countries in early 2023.

Thomas Lingelbach, President and CEO of Valneva, commented: "We welcome this partnership with VBI which underlines Valneva's expertise in vaccine commercialization. Among the past years, we have continued to develop our third-party vaccine marketing and distribution activities further, notably with the signing of a distribution agreement with Bavarian Nordic in 2020, and we are extremely pleased to add VBI's Hepatitis B vaccine to this portfolio today. Our objective is to continue leveraging our commercial infrastructure to combat as many infectious diseases as we can."

Jeff Baxter, President and CEO of VBI, commented: "This partnership is a significant milestone for PreHevbri, enabling us to hit the ground running in Europe. Valneva has substantial local knowledge, experience, and relationships in each of these European countries where we expect to launch, which will be of critical value as we work, collectively, to provide broad access to this differentiated 3-antigen HBV vaccine in Europe. Strategically, VBI and Valneva are two companies aligned by a shared mission to reduce the burden of infectious disease, and this new collaboration will build upon that meaningful synergy."

PreHevbri was approved by the European Commission (EC) and the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) in the second quarter of 2022 for active immunization against infection caused by all known subtypes of the hepatitis B virus (HBV) in adults.

About Hepatitis B

Hepatitis B is one of the world's most significant infectious disease threats with more than 290 million people infected globally. HBV infection is the leading cause of liver disease and, with current treatments, it is very difficult to cure, with many patients going on to develop liver cancers. An estimated 900,000 people die each year from complications of chronic HBV such as liver decompensation, cirrhosis, and hepatocellular carcinoma.

About PreHevbri® [Hepatitis B vaccine (recombinant, adsorbed)]

PreHevbri is the only 3-antigen hepatitis B vaccine, comprised of the three hepatitis B surface antigens of the hepatitis B virus – S, pre-S1, and pre-S2. It is approved for use in the European Union/European Economic Area, the United Kingdom, the United States, and Israel. The brand names for this vaccine are: PreHevbri™ (EU/EEA/UK), PreHevbrio™ (US), and Sci-B-Vac® (Israel).

Full European Summary of Product Characteristics for PreHevbri are available from the EMA website at www.ema.europa.eu.

Please visit www.PreHevbrio.com for U.S. Important Safety Information for PreHevbrio™ [Hepatitis B Vaccine (Recombinant)], or please see U.S. Full Prescribing Information.

U.S. Indication

PreHevbrio is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. PreHevbrio is approved for use in adults 18 years of age and older.

U.S. Important Safety Information (ISI)

Do not administer PreHevbrio to individuals with a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of PreHevbrio.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of PreHevbrio.

Immunocompromised persons, including those on immunosuppressant therapy, may have a diminished immune response to PreHevbrio.

PreHevbrio may not prevent hepatitis B infection, which has a long incubation period, in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common side effects (> 10%) in adults age 18-44, adults age 45-64, and adults age 65+ were pain and tenderness at the injection site, myalgia, fatigue, and headache.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women who received PreHevbrio during pregnancy. Women who receive PreHevbrio during pregnancy are encouraged to contact 1-888-421-8808 (toll-free).

To report SUSPECTED ADVERSE REACTIONS, contact VBI Vaccines at 1-888-421-8808 (toll-free) or VAERS at 1-800-822-7967 or www.vaers.hhs.gov**.**

Please see Full Prescribing Information.

About Valneva SE

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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, its manufacturing and commercialization capabilities, 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.

About VBI Vaccines Inc.

VBI Vaccines Inc. (“VBI”) is a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease. Through its innovative approach to virus-like particles (“VLPs”), including a proprietary enveloped VLP (“eVLP”) platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B, coronaviruses, and cytomegalovirus (CMV), as well as aggressive cancers including glioblastoma (GBM). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Website Home: http://www.vbivaccines.com/
News and Resources: http://www.vbivaccines.com/news-and-resources/
Investors: http://www.vbivaccines.com/investors/

VBI Cautionary Statement on Forward-looking Information

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively, “forward-looking statements”). The Company cautions that such statements involve risks and uncertainties that may materially affect the Company’s results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to, the impact of general economic, industry or political conditions in the United States or internationally; the impact of the ongoing COVID-19 pandemic on our clinical studies, manufacturing, business plan, and the global economy; the ability to successfully manufacture and commercialize PreHevbrio/PreHevbri; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of pipeline candidates and the commercialization of PreHevbrio/PreHevbri; the ability to obtain appropriate or necessary regulatory approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company’s ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company’s products. A discussion of these and other factors, including risks and uncertainties

with respect to the Company, is set forth in the Company's filings with the SEC and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the SEC on March 7, 2022, and filed with the Canadian security authorities at sedar.com on March 7, 2022, as may be supplemented or amended by the Company's Quarterly Reports on Form 10-Q. Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. All such forward-looking statements made herein are based on our current expectations and we undertake no duty or obligation to update or revise any forward-looking statements for any reason, except as required by law.

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