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 20, 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 16, 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 16, 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 20, 2022

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

Valneva and IDT Biologika Agree on Termination of their COVID-19 Collaboration

Saint-Herblain (France) and Dessau-Roßlau (Germany), September 16, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and IDT Biologika today announced they have agreed to terminate their collaboration following the delivery of inactivated COVID-19 bulk vaccine to Valneva, and considering the current order levels and existing inventories.

As per the commercial manufacturing services agreement signed in November 2021^1 , IDT Biologika produced VLA2001 bulk vaccine at its Biosafety Level 3 facilities in Germany, and Valneva bought the batches that were manufactured so far by IDT. In light of the reduced European Commission order², Valneva has suspended manufacturing of the vaccine and, as compensation, will pay IDT up to 636.2 million in cash and the equivalent of 64.5 million in kind, in the form of specified equipment purchased by Valneva.

Valneva has started to deliver doses of VLA2001 to the European Member States who ordered the vaccine and is retaining inventory for potential additional supply to these 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.

A bout VI A 2001

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 Europe³ 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 of Bahrain⁶. Valneva currently has agreements to supply VLA2001 to certain EU Member States⁷ and the Kingdom of Bahrain⁸. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001⁹.

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.

About IDT Biologika

IDT Biologika is an innovative biotech company with a successful history dating back 100 years. On the basis of modern technologies and high levels of expertise, we support customers in the development and manufacture of innovative virus vaccines, gene and immune therapy products as well as biologics employed worldwide as protection against diseases. German sites are the BioPharmaPark in Dessau-Roßlau and Magdeburg. In the US, the IDT Corporation has a manufacturing site for clinical test samples in Rockville, Maryland.

Valneva Investor and Media Contacts

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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 the manufacturing and commercialization plans for 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," "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, 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 sta

- 1 Valneva and IDT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001 Valneva
- 2 Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine Valneva
- 3 Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001
- $4\ \textit{Valneva Receives Conditional Marketing Authorization from UK\ \textit{MHRA for its Inactivated COVID-19 Vaccine}}$
- 5 Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine
- 6 Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001
- 7 European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine
- 8 Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001
- 9 Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine