
**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**

For the month of July 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 July 5, 6, and 7, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1, Exhibit 99.2, Exhibit 99.3 and are incorporated herein by reference.

Exhibits

[99.1](#) [Press release dated July 5, 2021](#)

[99.2](#) [Press release dated July 6, 2021](#)

[99.3](#) [Press release dated July 7, 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: July 8, 2021

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

Valneva to Host Symposium on COVID-19 and Chikungunya Vaccine Candidates at 31st European Congress of Clinical Microbiology & Infectious Diseases

Saint Herblain (France), July 5, 2021 –Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, announced today it will host a virtual symposium titled, “Developing new vaccines to protect against infectious diseases at home and abroad” on July 9, 2021 at 14:15 CEST at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID).

The symposium will be chaired by Prof. Thea Kølsen Fischer, Danish epidemiologist and member of the WHO team investigating the origins of SARS-CoV-2, and Katrin Dubischar, VP Program Director Chikungunya Vaccine at Valneva.

Adam Finn, Principal investigator for Valneva’s COVID-19 program, Professor of Paediatrics at the University of Bristol and Consultant at the Bristol Royal Hospital for Children, will discuss Phase 1/2 data of VLA2001, the only whole-virus, inactivated adjuvanted COVID-19 vaccine candidate in clinical trials in Europe.

Prof. Thomas Jelinek, renowned key opinion leader and Medical Director of Berlin Centre for Travel and Tropical Medicine, will present on chikungunya disease and results of the Phase 1 study of Valneva’s single-shot chikungunya vaccine candidate VLA1553.

To attend the ECCMID conference and participate in Valneva’s symposium, you can register at <https://www.eccmid.org/registration/>.

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 ongoing pandemic and potentially later 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[®]. 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. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

About VLA1553

VLA1553 targets the chikungunya virus, which has spread to more than 100 countries. VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease. It has been designed by deleting a part of the chikungunya virus genome.

To Valneva’s knowledge, VLA1553 is currently the only chikungunya vaccine candidate in Phase 3 clinical trials that targets long-term protection with a single administration.

In the Phase 1 clinical trial of VLA1553, Valneva observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants. Antibody titers were sustained after 12 months. Based on these results and Valneva’s discussions with regulators, VLA1553 has advanced directly into Phase 3 clinical development. The Company has also received confirmation for its proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, Valneva plans to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection.

The program was granted Fast Track designation by the FDA in December 2018¹ and PRIME designation by the European Medicines Agency (EMA) in October 2020².

VLA1553 would expand Valneva’s existing travel vaccine portfolio and as such, Valneva intends to commercialize this vaccine, if approved, leveraging its existing manufacturing and commercial operations. The global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032³.

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement for the development, manufacturing and marketing of VLA1553⁴. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to \$23.4 million⁵.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
Global Head of Investor Relations &
Corporate Communications
M +33 (0)6 4516 7099
investors@valneva.com

Teresa Pinzolits
Corporate Communications Specialist
T +43 (0)1 20620 1116
communications@valneva.com

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.

¹ *Valneva PR: Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate*

² *Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation*

³ *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

⁴ *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

⁵ *CEPI awards up to US\$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine*

Valneva Strengthens Management Team; Appoints Vincent Dequenne as SVP Operations and Joshua Drumm as VP Investor Relations

Saint-Herblain (France), July 6, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, announced today it has appointed Vincent Dequenne as Senior Vice President Operations and Joshua Drumm as Vice President Investor Relations.

Vincent Dequenne, engineer by training, has an extensive track record in the pharmaceutical industry with over 20 years of manufacturing and production experience including leadership roles at Eli Lilly, GSK vaccines, Pierre Fabre and most recently Eurogentec. Vincent will take responsibility for Valneva’s industrial operations and work closely with Valneva’s Chief Operating Officer Perry Celentano.

Joshua Drumm has over 12 years of experience in Investor Relations for both public and privately held life sciences companies. He holds a Ph.D. in Microbiology and Immunology from Albert Einstein College of Medicine and certificates in Financial Accounting and Financial Modeling from New York University. Joshua will notably focus on developing the Company’s Investor Relations in the U.S. following the Company’s recent Initial Public Offering on Nasdaq. He will work closely with Laetitia Bachelot-Fontaine who will continue to lead European Investor Relations and Global Communications. Josh will be based in New York.

Commenting, **Thomas Lingelbach, Chief Executive Officer of Valneva**, said, “I’m delighted to welcome Vincent and Joshua on board along with their extensive experience. Valneva is going from strength to strength and it’s important that we continue to build our senior management team to accompany this growth”.

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. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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.

Investor & Media Contacts

Joshua Drumm

VP Global Investor Relations

M +001 347 327 2863

Joshua.drumm@valneva.com

Laëtitia Bachelot-Fontaine

VP Global Communications & European Investor Relations

M +33 (0)6 4516 7099

Laetitia.bachelotfontaine@valneva.com

Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate

This new U.S. Milestone Follows FDA Fast Track and EMA PRIME Designations

Saint Herblain (France), July 7, 2021 – Valneva SE (“Valneva” or “the Company”), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced that it has been awarded Breakthrough Therapy Designation for its single-shot chikungunya vaccine candidate, VLA1553, by the U.S. Food and Drug Administration (FDA). Breakthrough Therapy Designation intends to facilitate and expedite development and review of new drugs for serious or life-threatening conditions where preliminary clinical data demonstrates that the drug may have substantial improvement for at least one endpoint over available therapies¹.

This new U.S. milestone comes in addition to the FDA Fast Track designation and the European Medicines Agency (EMA)’s PRIME designation which the Company received in December 2018 and in October 2020, respectively.

Juan Carlos Jaramillo, Chief Medical Officer of Valneva commented, “We are extremely pleased with FDA’s recognition of VLA1553 as a Breakthrough program. Chikungunya is a major, growing public health threat and VLA1553 targets long lasting protection against the chikungunya virus with a single shot. We will continue to work closely with the FDA to bring a preventative solution to the market as soon as possible.”

Valneva announced recruitment completion for its pivotal Phase 3 trial, VLA1553-301, in April 2021 and expects to report topline data this summer. The primary objective of the trial is to evaluate the immunogenicity and safety of VLA1553 at 28 days following a single immunization.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. Infection leads to symptomatic disease in 72-92% of humans after 4 to 7 days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia. As of September 2020, there were more than 3 million reported cases in the Americas² and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

About VLA1553

VLA1553 targets the chikungunya virus, which has spread to more than 100 countries. VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease. It has been designed by deleting a part of the chikungunya virus genome.

To Valneva’s knowledge, VLA1553 is currently the only chikungunya vaccine candidate in Phase 3 clinical trials that targets long-term protection following the administration of a single dose.

In the Phase 1 clinical trial of VLA1553, Valneva observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants. Antibody titers were sustained after 12 months. Based on these results and Valneva’s discussions with regulators, VLA1553 has advanced directly into Phase 3 clinical development. The Company has also received confirmation for its proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, Valneva plans to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection.

VLA1553 would expand Valneva’s existing travel vaccine portfolio and as such, Valneva intends to commercialize this vaccine, if approved, leveraging its existing manufacturing and commercial operations. The global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032³.

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement for the development, manufacturing and marketing of VLA1553. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to \$23.4 million with support from the European Union’s Horizon 2020 programme.

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Laëtitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm
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1 Breakthrough Therapy Designation | Food and Drug Administration

2 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas.

<https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html>. Last accessed 13 Oct 2020.

3 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020