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: August 5, 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 [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 August 5, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit

99.1	Press release dated August 5, 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: August 5, 2021

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

EXHIBIT 99.1

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

- **Pivotal study VLA1553-301 met its primary endpoint**
- **Vaccine candidate induced protective CHIKV neutralizing antibody titers in 98.5% of subjects after a single vaccination**
- **VLA1553 was well tolerated across all age groups**
- **Final trial results expected within the next six months**

Saint Herblain (France), August 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, today announced positive topline results from the Phase 3 pivotal trial of its single-shot chikungunya vaccine candidate, VLA1553. VLA1553 was recently awarded Breakthrough Designation status by the Food and Drug Administration (FDA).

The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the U.S., met its primary endpoint inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95%CI: 96.2-99.6). The seroprotection rate result of 98.5% exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission of VLA1553 under the accelerated approval pathway. The vaccine candidate was highly immunogenic with a GMT of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 trial.

Additionally, VLA1553 was also highly immunogenic in elderly study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

Juan Carlos Jaramillo, M.D, Chief Medical Officer of Valneva commented, "We are delighted with these Phase 3 results confirming the compelling profile of our vaccine candidate across all age groups. These first-ever Phase 3 trial results for a chikungunya vaccine mean that we are a step closer to addressing this major, growing and unmet public health threat. I would like to thank everyone who participated in the trial and who continued to advance the trial during the pandemic. We will continue to work with regulators to bring VLA1553 to market as soon as possible."

The trial will continue towards final analysis including the 6-month safety data. Final trial results are expected within the next six months. The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

The program was awarded Breakthrough Therapy Designation by the FDA in July 2021. This new milestone came 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.

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 Americas[1] 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 is a live-attenuated, single dose vaccine candidate targeting the chikungunya virus, which has spread to more than 100 countries. 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, 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 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 2032[2].
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 program.

About Phase 3 trial VLA1553-301
VLA1553-301 Phase 3 trial was initiated in September 2020. It is a prospective, double-blinded, multicenter, randomized, pivotal Phase 3 trial evaluating 4,115 participants aged 18 years or above. Lyophilized VLA1553 or placebo were administered as a single intramuscular immunization. The primary objective of the trial was to evaluate the immunogenicity and safety of VLA1553 28 days following a single immunization. Safety data and immunogenicity will continue to be assessed until Month 6; further long-term follow up is ongoing. Additional information, including a detailed description of the trial design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04546724).

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, 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. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. Valneva has leveraged its expertise and capabilities to successfully commercialize two wholly owned vaccines and rapidly advance multiple vaccine candidates into late-stage clinical development, including candidates against Lyme disease (partnered with Pfizer), the chikungunya virus and COVID-19.

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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 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.

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1 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.
2 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020