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: February 1, 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 January 31, 2022, 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 January 31, 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: February 1, 2022

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

EXHIBIT 99.1

Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate

CEPI-funded trial intended to support potential label expansion in this age group

Saint-Herblain (France), January 31, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced the initiation of a Phase 3 trial in adolescents for its single-shot chikungunya vaccine candidate, VLA1553.

Funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the trial is intended to support the label extension in this age group following a potential initial regulatory approval in adults from the US Food and Drugs Administration (FDA). It is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations.

Conducted in Brazil by Instituto Butantan, VLA1553-321 is a double-blinded, multi-center, randomized and placebo-controlled Phase 3 trial. 750 adolescents aged 12 to 17 years will be randomized at a 2:1 ratio to receive either VLA1553 or placebo. The primary objective of the trial is to evaluate safety and immunogenicity following a single vaccination with VLA1553. Participants will be evaluated after 28 days and followed up to twelve months. The study will also provide safety and immunogenicity data in participants previously exposed to chikungunya.

Juan Carlos Jaramillo, M.D, Chief Medical Officer of Valneva commented, "We are delighted to work with Instituto Butantan and CEPI on this new trial, which represents another major step in the development of this exciting product. We reported compelling pivotal Phase 3 results in adults and in the elderly, and we are looking forward to obtaining results in adolescents. The dreadful impact of the COVID-19 pandemic has underlined the importance of vaccines to combat public health crises. Chikungunya outbreaks have impacted over 120 countries and affected millions, yet no vaccine or specific treatment is currently available to prevent this debilitating disease."

Prof. Dimas Tadeu Covas, President of Instituto Butantan which sponsors the VLA1553-321 trial, commented, "VLA1553 is currently the most clinically advanced chikungunya vaccine candidate worldwide having successfully completed Phase 3 in adults. Through developing, producing and commercializing Valneva's chikungunya vaccine, Butantan reinforces even more its engagement to improve public health in developing countries."

Dr. Melanie Saville, Director of Vaccine Research & Development at CEPI, **added,** "Today, well over a billion people live in areas where chikungunya outbreaks occur – and climate change could further amplify the threat posed by this debilitating virus. Tremendous progress has been made by our partner, Valneva, to advance its chikungunya vaccine candidate in recent years and I am pleased to see these additional developments, announced today with Instituto Butantan, to evaluate the performance of its vaccine candidate in the adolescent population."

At the beginning of August 2021, Valneva announced positive topline results for the pivotal Phase 3 trial VLA1553-301 in adults aged 18 years and above. The vaccine candidate induced protective chikungunya-virus neutralizing antibody titers in 98.5% of trial participants after a single vaccination and was well tolerated across all age groups[1]. Valneva expects to report final results from VLA1553-301 in the first quarter of 2022. The Company also reported positive primary endpoint data from its ongoing lot-to-lot manufacturing consistency trial VLA1553-302 in December 2021.These data should allow pre-submission discussions with regulators which the Company plans to start in 2022.

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing and marketing of VLA1553[2]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[3], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program.

Brazil had an exponential increase of chikungunya cases in 2021 in comparison to 2020, according to data from the Brazilian Vigilance Health Secretary (SVS). At the beginning of December 2021, 90,147 chikungunya cases had been registered compared to 78,808 over the same period last year. The southeast of the country, where São Paulo and Rio de Janeiro are located, presented a higher incidence with 29,700 cases of chikungunya, including 14,300 cases in São Paulo compared to 281 last year.

About VLA1553

VLA1553 is a live-attenuated, single dose vaccine candidate targeting the chikungunya virus, which has spread to over 120 countries. It has been designed by deleting a part of the chikungunya virus genome.

In August 2021, Valneva reported positive topline results for pivotal Phase 3 clinical trial, VLA1553-301. In this double-blind, multi-center, randomized Phase 3 clinical trial, 4,115 participants aged 18 years and above were randomized 3:1 into two groups to receive either 0.5mL of VLA1553 or a placebo. The trial 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 seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission for approval of VLA1553 under the accelerated approval pathway. VLA1553 was highly immunogenic, with a GMT of approximately 3,270.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. The majority of solicited adverse events were mild or moderate and resolved within 3 days.

Additionally, VLA1553 was 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.
VLA1553-301 will continue towards final analysis including the 6-month safety data. The Company expects to report final trial results in early 2022.
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[4].

About Phase 3 study VLA1553-321
VLA1553-321 is a prospective, double-blinded, multicenter, randomized, placebo-controlled pivotal Phase 3 trial conducted in 750 adolescents aged 12 to 17 years old in Brazil. VLA1553 or placebo will be administered as a single intramuscular immunization to participants who will be randomized into two study groups at a 2:1 ratio. The primary objective is to evaluate the immunogenicity and safety of the adult dose of VLA1553 28 days following a single vaccination. Secondary objectives of the trial will include assessment of safety and immunogenicity up to twelve months following a single vaccination with VLA1553. The study will also provide safety and immunogenicity data in participants previously exposed to chikungunya.
Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04650399).

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.

About Instituto Butantan
Instituto Butantan is the main producer of immunobiological products and vaccines in Brazil. Instituto Butantan carries out scientific missions domestically and abroad through the Pan American Health Organization, the World Health Organization, UNICEF and the United Nations. The Institute collaborates with other agencies of the São Paulo State Secretariat of Health and the Brazilian Ministry of Health for the improvement of overall health in Brazil. It acts in partnership with various universities and entities such as the Bill & Melinda Gates Foundation for the achievement of its institutional objectives. For more information please visit the Institute website at www.butantan.gov.br or contact the press office at (+55 11) 2627-9606 / 9428 or email to imprensa@butantan.gov.br

About CEPI
CEPI is an innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).
CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 9 partnerships to develop vaccines against the novel coronavirus. The programmes will leverage rapid response platforms already supported by CEPI as well as new partnerships. The aim is to advance COVID-19 vaccine candidates into clinical testing as quickly as possible.
CEPI, alongside Gavi and the World Health Organisation, co-leads the vaccines pillar of the ACT Accelerator – known as COVAX – which is working to develop, distribute and deploy COVID-19 vaccines to the world. Learn more at **http://www.cepi.net**. Follow CEPI at **@CEPIvaccines**.

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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, 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.

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1 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate
2 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries
[3] CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine
4 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

Attachment

- 2022_31_01_VLA1553_Adolescents_Study_Initiation_PR_EN_Final (https://ml-eu.globenewswire.com/Resource/Download/3d6dc2d6-1ea3-4797-ba0e-d0af63916c6b)