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 29, 2023

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 [ ]

The Registrant issued press releases on August 28 and August 29, 2023, copies of which are attached hereto as Exhibits 99.1 and 99.2 and are 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).

Exhibits

99.1	Press release dated August 28, 2023
99.2	Press release dated August 29, 2023

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 29, 2023

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

EXHIBIT 99.1

Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate

Saint-Herblain (France), August 28, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported positive initial Phase 3 safety data in adolescents for its single-dose chikungunya virus (CHIKV) vaccine candidate VLA1553. Immunogenicity data for the trial are expected in November 2023.

Funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and conducted in collaboration with Instituto Butantan, the VLA1553-321 adolescent trial is intended to support label extension in this age group following a potential initial regulatory approval in adults from the Food and Drug Administration (FDA) in the United States (U.S). The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. The present safety analysis is also expected to enable regulatory submission to the European Medicines Agency (EMA) later this year.

Initial safety data generated in the ongoing trial VLA1553-321, Valneva's first clinical trial in an endemic area and with individuals previously infected with CHIKV, showed that VLA1553 was generally safe and well tolerated in adolescents aged 12 to 17 years, regardless of previous CHIKV infection.

754 individuals were vaccinated in trial VLA1553-321, and the present analysis includes safety data up to Day 29. An independent DSMB has continuously evaluated safety data during the trial and has not identified any safety concerns. Overall, the adverse event profile is consistent with the profile observed in Valneva's pivotal Phase 3 trial in adults. The majority of solicited adverse events observed following VLA1553 administration were mild or moderate and resolved within three days. Importantly, the initial data suggest a favorable safety profile in seropositive participants, confirming the observations following re-vaccination of individuals in Phase 1 trial VLA1553-101[1].

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "These new safety data in a younger population and in individuals previously infected with the chikungunya virus confirm the safety profile we previously observed in adults and the elderly. Chikungunya represents a major threat for people traveling to or living in areas where chikungunya virus is endemic, it is therefore our objective to make this vaccine available to all age groups, especially as no vaccine or specific treatments are currently available for this debilitating disease."

Valneva reported final pivotal Phase 3 data in 4,115 adults aged 18 years and above in March 2022[2] and the *Lancet* subsequently published these results in June 2023[3]. Final lot-to-lot consistency results were published in May 2022[4] and positive twelve-month persistence data in December 2022[5].

A Biologic License Application (BLA) for VLA1553 is currently under priority review by the U.S. FDA with a Prescription Drug User Fee Act (PDUFA) action date planned for end of November 2023[6].

Additionally, a regulatory application has also been filed with Health Canada[7]. If approved, VLA1553 could become the first licensed chikungunya vaccine available to address this unmet medical need.

About Phase 3 study VLA1553-321
VLA1553-321 is a prospective, double-blinded, multicenter, randomized, placebo-controlled pivotal Phase 3 trial conducted in 754 adolescents aged 12 to 17 years old in Brazil. The VLA1553-321 clinical trial was initiated in January 2022 and Valneva reported enrollment and vaccination completion in February 2023. VLA1553 or placebo was administered as a single intramuscular immunization to participants who were 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 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 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 up to 97% of humans after four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[8]. 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, and the virus has spread to more than 110 countries[9]. As of July 2022, more than three million cases have been reported in the Americas[10] 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 investigational vaccine candidate targeting the chikungunya virus, which has spread to

over 110 countries[11]. It has been designed by deleting a part of the chikungunya virus genome.

Valneva reported final data from the pivotal Phase 3 trial of VLA1553 in March 2022[12], final lot-to-lot consistency results in May 2022[13] and positive twelve-month persistence data in December 2022[14].

If approved, VLA1553 would expand Valneva's existing commercial vaccines portfolio and as such, Valneva intends to commercialize this vaccine, leveraging its existing manufacturing and commercial operations.

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[15]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[16], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program.

VLA1553 received FDA Fast Track, Breakthrough Therapy designations and Priority Review in 2018, 2021 and 2023, respectively. VLA1553 was also granted PRIority MEdicine (PRIME) designation by the European Medicines Agency (EMA) in 2020.

About Valneva SE

We are a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet medical needs to ensure we can make a difference to peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today, we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

Valneva Investor and Media Contacts

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

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@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, to regulatory approval of product candidates and review of existing products. 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 and delays 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 Chikungunya vaccine: a single shot for a long protection? - The Lancet Infectious Diseases
2 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
3 Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet
4 Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate
5 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate
6 Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva
7 Valneva Files for Chikungunya Vaccine Authorization with Health Canada - Valneva
8 *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
9 https://www.who.int/news-room/fact-sheets/detail/chikungunya
10 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2022 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 25 Jul 2022.
11 https://www.who.int/news-room/fact-sheets/detail/chikungunya
12 *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
13 *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
14 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
15 *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income*

EXHIBIT 99.2

Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review

Saint-Herblain (France), August 29, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that Health Canada has completed screening validation of the Company's regulatory application for marketing approval of its single-shot chikungunya vaccine candidate VLA1553 in persons aged 18 years and above, and has determined that the New Drug Submission (NDS) application is sufficiently complete to permit a substantive review. Based on Health Canada's performance standard to process an NDS application, the Company believes the regulatory review could be completed by mid-2024.

This is the second regulatory application for VLA1553 filed by Valneva, and the Company intends to make additional regulatory submissions in 2023. A Biologic License Application (BLA) is currently under priority review[1] by the U.S. Food and Drug Administration (FDA)[2].

VLA1553 is currently the only chikungunya vaccine candidate worldwide for which regulatory review processes are underway and, if approved, it could become the first licensed chikungunya vaccine available to address this unmet medical need. It would also represent the third vaccine Valneva[3] has brought from early R&D to approval.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "Chikungunya represents a major threat for people traveling to or living in areas where chikungunya virus and the mosquitos that transmit it are present, including popular destinations for U.S. and Canadian travelers. This threat continues to grow as shown by the recent epidemiological alert issued by the Pan American Health Organization (PAHO)[4]. No vaccine or specific treatments are currently available for this debilitating disease, and we will continue to work diligently to make VLA1553 available in different territories as quickly as possible."

The regulatory submissions with Health Canada and the FDA follow final pivotal Phase 3 data in March 2022[5], final lot-to-lot consistency results in May 2022[6] and positive twelve-month persistence data in December 2022[7]. The Company's pivotal Phase 3 results were published in the Lancet in June 2023.

A clinical study of VLA1553 in adolescents aged 12 to 17 years is ongoing in Brazil[8], for which Valneva reported initial Phase 3 safety data in adolescents yesterday[9]. This study, conducted by Valneva's partner Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is intended to support label extension in this age group following a potential initial regulatory approval in adults from the FDA. The study is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations, as well as regulatory submission in Europe.

The vaccine was granted PRIority MEdicine (PRIME) designation by the European Medicines Agency (EMA) in 2020 and also received FDA Fast Track, Breakthrough Therapy and Priority Review designations in 2018, 2021 and 2023 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 up to 97% of humans after four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[10]. 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, and the virus has spread to more than 110 countries[11]. As of July 2022, more than three million cases have been reported in the Americas[12] 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 investigational vaccine candidate targeting the chikungunya virus, which has spread to over 110 countries[13]. It has been designed by deleting a part of the chikungunya virus genome.

Valneva reported final data from the pivotal Phase 3 trial of VLA1553 in March 2022[14], final lot-to-lot consistency results in May 2022[15] and positive twelve-month persistence data in December 2022[16].

If approved, VLA1553 would expand Valneva's existing commercial vaccines portfolio and as such, Valneva intends to commercialize this vaccine, leveraging its existing manufacturing and commercial operations.

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[17]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[18], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program.

VLA1553 received FDA Fast Track, Breakthrough Therapy designations and Priority Review in 2018, 2021 and 2023, respectively. VLA1553 was also granted PRIority MEdicine (PRIME) designation by the European Medicines Agency (EMA) in 2020.

About Valneva SE
Valneva is a specialty vaccine company focused on the development, manufacturing 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 the chikungunya virus and Lyme disease.

Valneva Investor and Media Contacts

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

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@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, to regulatory approval of product candidates and review of existing products. 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 and delays 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 FDA Accepts Valneva’s Chikungunya Vaccine License Application for Priority Review - Valneva
2 Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva
3 This statement refers to Valneva and its predecessor Intercell
4https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas
5 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
6 Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate
7 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
8 Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva
9 Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
10 *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
11 https://www.who.int/news-room/fact-sheets/detail/chikungunya
12 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2022 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 25 Jul 2022.
13 https://www.who.int/news-room/fact-sheets/detail/chikungunya
14 *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
15 *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
16 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
17 *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
18 *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*