

**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: November 18, 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 November 15 and November 18, 2021, the Registrant issued press releases, copies of which are attached hereto as Exhibit 99.1 and 99.2 and are incorporated herein by reference.

Exhibit

[99.1](#) [Press release dated November 15, 2021](#)

[99.2](#) [Press release dated November 18, 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.

Valveva SE
(Registrant)

Date: November 18, 2021

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

Valneva to Present its Chikungunya Vaccine Candidate at the ASTMH 2021 Annual Meeting

Saint-Herblain (France), November 15, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced it will present its Chikungunya vaccine candidate, VLA1553, on November 18 and 19, 2021 during the American Society of Tropical Medicine & Hygiene (ASTMH) 2021 Annual Meeting.

Valneva's Chief Medical Officer, Juan Carlos Jaramillo, MD, will present on Friday, November 19 at 2:15pm ET, "Chikungunya: Phase 3 Clinical Development of a Single-shot Live-attenuated Vaccine" and Martina Schneider, PhD, Clinical Strategy Manager at Valneva, will present a poster abstract entitled "Chikungunya: Safety up to Day 29 of Phase 3 Clinical Development of a Single-shot Live-attenuated Vaccine" on Thursday, November 18 from 11:00 to 12:30pm ET.

At the beginning of August 2021, Valneva announced positive topline results for the Phase 3 pivotal trial of VLA1553. The vaccine candidate induced protective CHIKV neutralizing antibody titers in 98.5% of trial participants after a single vaccination and was well tolerated across all age groups¹.

TropMed21, the ASTMH 2021 Annual Meeting, is the premier international forum for the exchange of scientific advances in tropical medicine, hygiene and global health and will be 100% virtual this year. For more information and to register for the conference, please visit <https://www.astmh.org/annual-meeting>.

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.

In September 2020, Valneva initiated the pivotal Phase 3 clinical trial, VLA1553-301, in the United States. 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. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of trial 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.

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 2032².

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 VLA1553³. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019⁴, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

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.

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 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.

¹ Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate

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

³ Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

⁴ CEPI awards up to \$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

Valneva Reports Nine-Month 2021 Revenue and Cash

Strong financial position

- **Cash and cash equivalents of €247.9 million at the end of September 2021**
 - Reflects \$107.6 million of gross proceeds raised in a US IPO and placement in Europe in the second quarter of 2021
 - Does not include \$102.0 million of gross proceeds raised in a follow-on offering in the US and Europe in the fourth quarter of 2021

Total revenue (excluding COVID) of €69.8 million in the first nine months of 2021 compared to €58.8 million in the first nine months of 2020

- Product sales of €45.5 million in the first nine months of 2021 (€45.9 million in the first nine months of 2020)
- €24.3 million of Other Revenues (revenues from collaborations, licensing and services) in the first nine months of 2021 (€12.9 million in the first nine months of 2020)

Updated 2021 financial guidance (excluding COVID)

- Total revenues, excluding VLA2001, now expected between €85 million and €100 million (compared to €80 million to €105 million previously)
- R&D expenses, excluding VLA2001, now expected between €60 million to €70 million (compared to €65 million to €75 million previously)

Valneva confirms that Peter Bühler will join the Company as Chief Financial Officer on January 1, 2022 and has appointed Vincent Dequenne, formerly Senior Vice President Operations, as Chief Operating Officer.

Key Milestones Achieved in 2021 include:

Lyme Disease Vaccine Candidate VLA15

- Further positive Phase 2 results reported, including booster response

Inactivated COVID-19 Vaccine Candidate VLA2001

- Positive pivotal Phase 3 Results reported
 - Superiority in terms of neutralizing antibody titer levels compared to comparator vaccine, AstraZeneca's AZD1222
 - Non-inferiority in terms of seroconversion rates
 - Significantly better tolerability profile than comparator
 - Advance Purchase Agreement approved by European Commission (EC) for up to 60 million doses

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Positive pivotal Phase 3 results reported

Raised approximately \$210 million

- Successful Nasdaq Initial Public Offering (IPO) and concurrent placement in Europe
- Successful follow-on offering in the US and Europe

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, *"Valneva is continuing to deliver on its R&D objectives. This year, we successfully advanced our clinical programs and reported positive Phase 3 results for two vaccine candidates. If approved, we expect both vaccines to make a positive change to people's lives. Based on the strong tolerability and immunogenicity of our differentiated COVID-19 vaccine candidate, we have been able to get a deal approved by the EC and are grateful for the trust and confidence the EU has put in us and VLA2001. Our team has delivered phenomenally well this year and I would like to thank them for their continued commitment and dedication. I would also like to thank our long term shareholders for their support."*

Saint Herblain (France), November 18, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today reported its revenue and cash balance for the first nine months of the year 2021.

Revenues

Valneva's total revenues were €69.8 million in the first nine months of 2021 compared to €58.8 million in the first nine months of 2020.

Product sales slightly declined by 0.9% to €45.5 million in the first nine months of 2021 compared to €45.9 million in the first nine months of 2020 as the travel industry continued to be impacted by the COVID-19 pandemic. On a constant exchange rate (CER) basis, product sales increased by 1.8% in the first nine months of 2021 compared to the first nine months of 2020.

IXIARO®/JESPECT® sales increased by 9.5% (14.9% at CER) to €33.7 million in the first nine months of 2021 compared to €30.8 million in the first nine months of 2020 as the impact of the COVID-19 pandemic on the vaccine sales was mitigated by sales to the U.S. Government's Department of Defense (DoD) during the period.

DUKORAL® sales declined by 95.9% (equally 95.9% at CER) to €0.5 million in the first nine months of 2021 compared to €13.2 million in the first nine months of 2020.

Third Party product sales grew by almost 500% to €11.2 million in the first nine months of 2021 from €1.9 million in the first nine months of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur®/RabAvert® and Encepur® that commenced in certain territories in 2021.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €24.4 million in the first nine months of 2021 compared to €13.0 million in the first nine months of 2020. This increase was attributable to higher revenues related to the Lyme R&D collaboration agreement with Pfizer, incremental revenues related to the collaboration with Instituto Butantan for providing VLA1553 in LMICs as well as higher revenues generated in the CTM Manufacturing unit in Sweden.

Liquidity

Liquid funds increased to €247.9 million as of September 30, 2021 compared to €156.2 million as of December 31, 2020. Liquids funds at the end of September 2021 do not include approximately \$102.0 million of gross proceeds raised in a follow-on offering in the US and Europe in the fourth quarter of 2021.

About Valneva SE

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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 statements, whether as a result of new information, future events, or otherwise.