
**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: December 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 Form 40-F

On December 29, 2023, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information contained in this Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-266839).

Exhibit

[99.1](#) [Press release dated December 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: December 29, 2023

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

Valneva Provides Updated 2023 Financial Guidance

Saint-Herblain (France), December 29, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Company is modifying its financial guidance for 2023. Product sales guidance remains unchanged, as do anticipated R&D expenses. The €90 million to €110 million of other income related to proceeds from potential sale of the Company’s priority review voucher (PRV), which was previously expected before year-end, is now expected in early 2024.

The Company’s previous guidance included expected total revenues and other income between €220 million and €260 million¹. The modified 2023 guidance now includes the previously stated product sales revenue of €130 million to €150 million, which the Company remains on track to achieve, as well as R&D expenses between €60 million and €70 million, which were recently reduced², primarily driven by lower than anticipated costs related to the closeout of the Company’s COVID-19 activities.

Peter Bühler, Chief Financial Officer of Valneva, said, “We remain confident in our ability to sell our priority review voucher successfully at a price within the previously suggested range. As we continue to work actively toward a potential sale agreement, we look forward to providing an update in the new year.”

The Company was awarded a tropical disease PRV in November 2023³ following U.S. FDA approval of IXCHIQ[®], Valneva’s single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. With this approval, IXCHIQ[®] became the world’s first licensed chikungunya vaccine available to address this unmet medical need. Valneva expects to launch the vaccine in the U.S. in early 2024.

The Company has also drawn down the remaining \$50 million made available under its debt financing agreement with funds managed by U.S. investment firms Deerfield Management Company and OrbiMed⁴.

About Valneva SE

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the world’s first vaccine against the chikungunya virus and the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

About IXCHIQ[®]

In the U.S., IXCHIQ[®] is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA’s accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.

Please click here for full Prescribing Information for IXCHIQ[®].

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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 its financial results for 2023 and the sale of its priority review voucher. 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 Valneva Reports Nine-Month 2023 Financial Results and Provides Corporate Updates

2 Valneva Reports Nine-Month 2023 Financial Results and Provides Corporate Updates

3 Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ[®] - Valneva

4 Valneva Reports Nine-Month 2023 Financial Results and Provides Corporate Updates - Valneva