
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 15, 2024

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 February 15, 2024, 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 February 15, 2024](#)

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: February 15, 2024

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

Valneva Reports Full Year 2023 Revenue and Cash, Provides First 2024 Guidance

**Valneva Reports Full Year 2023 Revenue and Cash,
Provides First 2024 Guidance**

Total revenues of €153.7 million, including product sales of €144.6 million

- Product sales surpassed pre-pandemic (2019) sales by 12% and 2022 sales by 26%
- Excluding COVID-19 vaccine sales, product sales grew by 63% compared to 2022

Cash position of €126.1 million at December 31, 2023

- Excludes recent sale of the Priority Review Voucher (PRV) for \$103 million (€95 million)¹
- Reflects significant payments related to the Phase 3 Lyme disease study, for which Valneva's cost contributions are expected to be completed in the first half 2024²

First full year 2024 guidance

- Product sales expected between €150 million and €180 million, reflecting continued revenue growth for proprietary products and IXCHIQ[®]'s launch-year sales, despite anticipated supply constraints for third-party products and IXIARO[®]
- Other income anticipated between €95 million and €105 million, including the PRV sold in early 2024 for €95 million
- Expected R&D expenses between €65 million and €90 million

Saint-Herblain (France), February 15, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today reported its revenue and cash balance for the full year 2023 and provided first full year 2024 sales and R&D expense guidance. The Company will publish its 2023 audited consolidated financial statements on March 20, 2024.

Peter Bühler, Valneva's Chief Financial Officer, commented, "In 2023, Valneva successfully executed on key strategic objectives despite a difficult economic environment. Our chikungunya vaccine IXCHIQ[®] became the world's first licensed chikungunya vaccine available to address this unmet medical need and we also managed to surpass our pre-pandemic product sales. Our objective for 2024 is to continue capitalizing on the travel industry recovery to deliver further commercial growth for our existing proprietary products and generate first sales from our chikungunya vaccine IXCHIQ[®]. With the recent successful sale of our PRV, we are entering 2024 in a good financial position to support our commercial and R&D objectives."

Revenues

Valneva's total revenues were €153.7 million in 2023 compared to €361.3 million in 2022. Total revenues in 2022 included €280.0 million of revenue recognition mainly related to the COVID-19 supply agreements in the prior year.

Valneva's total product sales reached €144.6 million in 2023 compared to €114.8 million in 2022. Currency fluctuations of €2.8 million adversely impacted product sales. COVID-19 vaccine sales in 2023 amounted to €5.7 million compared to €29.6 million in 2022. Excluding COVID-19, product sales reached €138.9 million in 2023 compared to €85.2 million during the comparator period of 2022, an increase of 63%.

IXIARO[®]/JESPECT[®] sales were €73.5 million in 2023 compared to €41.3 million in 2022. The 78% increase in sales is primarily the result of the continued travel market recovery, as well as price increases. The increase in IXIARO[®]/JESPECT[®] product sales included an adverse €1.5 million foreign currency impact.

DUKORAL[®] sales were €29.8 million in 2023 compared to €17.3 million in 2022. This 72% increase is also a result of the significant recovery in the private travel markets and price increases. Foreign currency fluctuations reduced DUKORAL[®] sales by €0.9 million.

Third Party product sales were €35.7 million in 2023 compared to €26.5 million in 2022, a 34% increase which was mainly driven by sales of Rabipur[®]/RabAvert[®] and Encepur[®] under the distribution agreement with Bavarian Nordic.

Other revenues, including revenues from collaborations, licensing and services amounted to €9.1 million in 2023 compared to €246.5 million in 2022. Other revenues in 2022 included COVID-related one-time effects of €280.0 million consisting of released refund liability as a result of the settlement with the UK government, as well as released non-refundable advance payments from European Member States, partially offset by €45.9 million of negative revenue resulting from an increase in the refund liability linked to the amended VLA15 collaboration and license agreement with Pfizer.

Liquidity

Cash and cash equivalents were €126.1 million as of December 31, 2023, compared to €289.4 million as of December 31, 2022. Cash and Cash equivalents in 2023 included the drawing of a total of \$100 million from the Deerfield & OrbiMed loan agreement as well as significant payments made to Pfizer related to the companies' Phase 3 Lyme disease study "VALOR". They, however, excluded \$103 million of proceeds from the PRV which Valneva sold in February 2024.

2024 Guidance

Product sales in 2024 are expected between €150 million and €180 million, subject to availability of IXIARO[®] and third-party products, as well as IXCHIQ[®]'s launch-year sales performance in the United States. 2024 product sales are expected to reflect further growth of the Company's existing proprietary product sales (IXIARO[®], DUKORAL[®]), lower third-party product sales due to supply constraints as well as first IXCHIQ[®] sales. Other revenues are expected at similar levels as compared to 2023. Other income is anticipated between €95 million and €105 million, including the PRV sold in early 2024 for €95 million. The Company expects R&D expenses between €65 million and €90 million, mainly driven by investments in earlier stage R&D pipeline programs and ongoing clinical development activities for the Company's chikungunya vaccine.

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 three proprietary travel vaccines, including the world's first and only chikungunya vaccine, as well as certain third-party vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes 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[®].

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
VP, Global Communications and European Investor Relations
M +33 (0)6 4516 7099
investors@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 expected total revenues and product sales for full fiscal year 2023 and guidance for certain financial results in fiscal year 2024. 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 indicative of future results. 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 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 other global events, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, and the impact of a 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.

1 Valneva Announces Sale of Priority Review Voucher for \$103 Million - Valneva

2 Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15