

**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 7, 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

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 7, 2024, the Registrant announced its results from the nine months ended September 30, 2024 and issued a press release and unaudited interim condensed consolidated financial statements, copies of which are attached hereto as Exhibits 99.1, and 99.2, respectively, and 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

- | | |
|--------------|--|
| Exhibit 99.1 | Press release dated November 7, 2024 |
| Exhibit 99.2 | Unaudited Interim Condensed Consolidated Financial Statements as at September 30, 2024 and for the three months ended September 30, 2024 |

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)

/s/ Thomas Lingelbach

Thomas Lingelbach
Chief Executive Officer and President

Date: November 7, 2024

9M 2024

NINE-MONTH
FINANCIAL REPORT
2024

November 7, 2024

VALNEVA SE
Campus Bio-Ouest
6 rue Alain Bombard
44800 Saint-Herblain, France
www.valneva.com

Unaudited interim condensed consolidated financial statements as at September 30, 2024

Valneva SE

I. Unaudited Interim Consolidated Statement of Profit or Loss
and Comprehensive Income

Unaudited Interim Condensed Consolidated Statement of Profit or Loss

in € thousand
Product sales

Nine months ended September 30,

	2024	2023
	112,475	106,130

Other revenues	4,162	5,684
REVENUES		111,814
Cost of goods and services	(71,306)	(74,810)
Research and development expenses	(48,567)	(42,220)
Marketing and distribution expenses	(35,718)	(33,919)
General and administrative expenses	(32,554)	(35,066)
Gain from sale of Priority Review Voucher, net	90,833	—
Other income and expenses, net	14,890	17,020
OPERATING PROFIT/(LOSS)	34,214	(57,180)
Finance income	1,316	724
Finance expenses	(17,713)	(12,477)
Foreign exchange gain/(loss), net	3,045	(1,441)
PROFIT/(LOSS) BEFORE INCOME TAX	20,862	(70,374)
Income tax benefit/(expense)	3,878	1,103
	24,740	
EARNINGS/(LOSSES) PER SHARE		
for profit/(loss) for the period attributable to the equity holders of the Company (expressed in € per share)		
Basic	0.18	(0.50)
Diluted	0.17	(0.50)

Unaudited Interim Condensed Consolidated Statement of Comprehensive Income

<i>in € thousand</i>	Nine months ended September 30,	
	2024	2023
PROFIT/(LOSS) FOR THE PERIOD	24,740	(69,271)
OTHER COMPREHENSIVE INCOME/(LOSS)		
Items that may be reclassified to profit or loss		
Currency translation differences	612	1,677
Items that will not be reclassified to profit or loss		
Defined benefit plan actuarial gains/(losses)	(10)	(8)
Other comprehensive income/(loss) for the period, net of tax	602	1,669
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD	25,342	(67,602)

Unaudited interim condensed consolidated financial statements as at **September 30, 2024**

Valneva SE

II. Unaudited Interim Condensed Consolidated Statement of Financial Position

<i>in € thousand</i>	December 31, 2023	
ASSETS		
Non-current assets	213,000	197,238
Intangible assets	33,478	25,567
Right of use assets	18,653	20,392
Property, plant and equipment	141,647	136,198
Deferred tax assets	11,667	6,592
Other non-current assets	7,555	8,490
Current assets	303,614	262,824
Inventories	57,829	44,466

Trade receivables	30,359	41,645
Other current assets	59,091	50,633
Cash and cash equivalents	156,335	126,080
	516,614	
EQUITY		
Share capital	24,342	20,837
Share premium	647,640	594,003
Other reserves	72,430	65,088
Retained earnings/(Accumulated deficit)	(551,682)	(450,253)
Profit/(Loss) for the period	24,740	(101,429)
TOTAL EQUITY	217,469	128,247
LIABILITIES		
Non-current liabilities	189,989	172,952
Borrowings	153,126	132,768
Lease liabilities	26,015	29,090
Refund liabilities	6,443	6,303
Provisions	562	1,074
Deferred tax liabilities	3,791	3,638
Other liabilities	52	79
Current liabilities	109,156	158,863
Borrowings	19,452	44,079
Trade payables and accruals	42,897	44,303
Income tax liability	266	632
Tax and Employee-related liabilities	18,319	16,209
Lease liabilities	2,655	2,879
Contract liabilities	956	5,697
Refund liabilities	17,095	33,637
Provisions	7,290	10,835
Other liabilities	226	592
TOTAL LIABILITIES	299,145	331,815
	516,614	

Unaudited interim condensed consolidated financial statements as at September 30, 2024

Valneva SE

III. Unaudited Interim Condensed Consolidated Statement of Cash Flows

	Nine months ended September 30,	
<i>in € thousand</i>		2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Profit/(Loss) for the period	24,740	(69,271)
Gain from sale of Priority Review Voucher, net	(90,833)	—
Adjustments for non-cash transactions	25,672	26,867
Changes in non-current operating assets and liabilities	311	(181)
Changes in working capital	(35,075)	(93,335)
Cash generated/(used) in operations	(75,186)	(135,920)
Income tax paid	(1,558)	(913)
NET CASH GENERATED FROM/(USED IN) OPERATING ACTIVITIES	(76,744)	(136,833)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(10,006)	(8,354)

Proceeds from sale of property, plant and equipment	165	43
Purchases of intangible assets	(10,070)	(39)
Proceeds from assets classified as held for sale	—	3,358
Proceeds from sale of Priority Review Voucher	90,833	—
Interest received	1,316	724
NET CASH GENERATED FROM/(USED IN) INVESTING ACTIVITIES	72,228	(4,269)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds/(payments) from issuance of common stock, net of costs of equity transactions	57,460	(240)
Proceeds from borrowings, net of transaction costs	(944)	39,683
Repayment of borrowings	(3,723)	(2,097)
Payment of lease liabilities	(2,788)	(2,444)
Interest paid	(14,733)	(8,764)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES	35,272	26,137
NET CHANGE IN CASH AND CASH EQUIVALENTS	30,757	(114,964)
Cash and cash equivalents at beginning of the year	126,080	286,532
Exchange gains/(losses) on cash	(502)	(315)
	156,335	

Unaudited interim condensed consolidated financial statements as at September 30, 2024

Valneva SE

IV. Unaudited Interim Condensed Consolidated Statement of Changes in Equity

<i>in € thousand</i>	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2024	20,837	594,003	65,088	(450,253)	(101,429)	128,247
Total comprehensive income/(loss)	—	—	602	—	24,740	25,342
Income appropriation	—	—	—	(101,429)	101,429	—
Share-based compensation expense:						
Value of services	—	—	6,740	—	—	6,740
Exercises	55	(55)	—	—	—	—
Capital Increase	3,450	57,730	—	—	—	61,180
Cost of equity transaction, net of tax	—	(4,039)	—	—	—	(4,039)
BALANCE AS AT SEPTEMBER 30, 2024	24,342	647,640	72,430	(551,682)	24,740	217,469

Capital Increase includes the cost of transactions, net of tax.

<i>in € thousand</i>	Share capital	Share premium	Other reserves	Retained earnings/ (Accumulated deficit)	Profit/ (loss) for the period	Total equity
BALANCE AS AT JANUARY 1, 2023	20,755	594,043	55,252	(306,974)	(143,279)	219,797
Total comprehensive income/(loss)	—	—	1,669	—	(69,271)	(67,602)

Income appropriation	—	—	—	(143,279)	143,279	—
Share-based compensation expense:						
Value of services	—	—	5,284	—	—	5,284
Exercises	82	(39)	—	—	—	42

**A EUROPEAN COMPANY (SOCIETAS
EUROPAEA) WITH A BOARD OF DIRECTORS**

Registered Office;
6 rue Alain Bombard, 44800 Saint-Herblain (France)
Nantes Trade and Companies Registry (R.C.S.)
No. 422 497 560

 valneva



Valneva Reports Nine-Month 2024 Financial Results and Provides Corporate Updates

Nine-Month Key Financial Highlights

- Total revenues of €116.6 million, including product sales of €112.5 million
- Net Profit of €24.7 million, including proceeds from the Priority Review Voucher (PRV)¹ sale
 - Operating profit of €34.2 million compared to an operating loss of €57.2 million in the first nine-months of 2023
- Cash position of €156.3 million
 - Includes €61.2 million in gross proceeds from recent private placement²
 - Lower cash burn expected in the second half of 2024 as cost contributions to the agreed R&D budget for partnered Lyme disease program were completed in the second quarter of the year

Full-year 2024 Financial Guidance Narrowed

- Expected total product sales according to guidance between €160 million to €170 million and currently anticipated total revenues between €170 million and €180 million
- Expected R&D investments between €65 million and €75 million
- Expected Other income between €100 million and €110 million, including €95 million from the PRV sale
- Launch of the world's first chikungunya vaccine in Canada and Europe underway; Further potential approvals expected in Brazil (Q4 2024) and the UK (Q1 2025)

Strategic Pipeline Expansion, Strong Clinical and Regulatory Execution

- Secured exclusive worldwide license for S4V2 *Shigella* vaccine candidate, adding an attractive Phase 2 clinical asset to Valneva's R&D pipeline³ - recently granted FDA Fast Track⁴
- Submitted key label extension(s) for IXCHIQ® in Europe and Canada⁵

¹ [Valneva Announces Sale of Priority Review Voucher for \\$103 Million - Valneva](#)

² [Valneva Announces the Success of its Private Placement Raising approximately €60 Million - Valneva](#)

³ [Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate - Valneva](#)

⁴ [Valneva and LimmaTech Awarded FDA Fast Track Designation for Tetravalent Shigella Vaccine Candidate S4V - Valneva](#)

⁵ [Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva](#)

- Published IXCHIQ® two-year antibody persistence and safety data in the Lancet Infectious Diseases⁶ further demonstrating the vaccine's highly differentiated immunological profile
- Awarded new \$41.3 million CEPI grant⁷ to contribute significantly to IXCHIQ® Phase 4 costs and other studies supporting broader access to the vaccine
- Pfizer completed primary vaccination (three doses) in Phase 3 VALOR Lyme disease trial⁸
- Advancing Phase 1 clinical trial for second-generation Zika vaccine candidate toward expected data readout and further decision on potential development path in 2025⁹

Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	Nine months ended September 30,	
	2024	2023
Total Revenues	116.6	111.8
Product Sales	112.5	106.1
Net profit/(loss)	24.7	-69.3
Adjusted EBITDA ¹⁰	48.6	-46.0
Cash	156.3	171.3

Saint-Herblain (France), November 7, 2024 – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported consolidated financial results for the first nine months of the year, ended September 30, 2024. The condensed consolidated interim financial results are available on the Company's website ([Financial Reports – Valneva](#)).

Valneva will provide a live webcast of its nine-month 2024 results conference call beginning at 3 p.m. CET / 9 a.m. ET today. This webcast will also be available on the Company's website. Please refer to this link: <https://edge.media-server.com/mmc/p/6wzgxkji>.

Peter Bühler, Valneva's Chief Financial Officer, commented, "Our objective is to become sustainably profitable in 2027, based on potential milestone and commercial revenues from our Lyme disease vaccine candidate, if approved. We remain focused on growing sales of our travel vaccines and believe we are sufficiently capitalized, while maintaining the flexibility to continue investing in the future development of the Company by leveraging our proven R&D capabilities. As we approach the conclusion of the Phase 3 Lyme disease trial at the end of next year, we believe we are entering a pivotal time in Valneva's evolution."

⁶ [Antibody persistence and safety of a live-attenuated chikungunya virus vaccine up to 2 years after single-dose administration in adults in the USA: a single-arm, multicentre, phase 3b study - The Lancet Infectious Diseases](#)

⁷ [CEPI Expands Partnership with Valneva with a \\$41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva](#)

⁸ [Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion - Valneva](#)

⁹ [Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva](#)

¹⁰ For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR

Commercial Portfolio

Valneva's commercial portfolio is composed of three travel vaccines, IXIARO®/JESPECT®, DUKORAL® and recently launched IXCHIQ®. The Company also distributes certain third-party products in countries where it operates its own marketing and sales infrastructure.

Valneva's sales in the first nine months of 2024 were €112.5 million compared to €106.1 million (€100.4 million excluding final COVID-19 vaccine sales) in the first nine months of 2023.

JAPANESE ENCEPHALITIS VACCINE IXIARO®/JESPECT®

In the first nine months of 2024, IXIARO®/JESPECT® sales increased by 31% to €66.0 million compared to €50.3 million in the first nine months of 2023. Sales to both travelers and the U.S. military showed double digit growth compared to the first nine months of 2023.

Valneva has been supplying additional doses of IXIARO® to the U.S. Department of Defense (DoD) under the current contract, signed in September 2023¹¹, which allowed the DoD to purchase additional doses during the following twelve months. Valneva expects to receive new orders in 2025.

CHOLERA / ETEC¹²-DIARRHEA VACCINE DUKORAL®

In the first nine months of 2024, DUKORAL® sales were €22.3 million compared to €21.1 million in the first nine months of 2023. At the end of June, DUKORAL® sales remained below prior year but sales in the third quarter grew 85% year-over-year, as marketing investments resumed in the third quarter following successful regulatory inspection of Valneva's new manufacturing site in Sweden.

CHIKUNGUNYA VACCINE IXCHIQ®

IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. The vaccine is now approved in the U.S.¹³, Europe¹⁴, and Canada¹⁵ for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. The U.S. launch is underway while first sales in Canada and Europe are anticipated in the fourth quarter of 2024.

Following adoption of the U.S. Advisory Committee on Immunization Practices (ACIP)'s recommendations by the U.S. Centers for Disease Control and Prevention (CDC)¹⁶ at the beginning of March 2024, Valneva recognized initial sales of €1.8 million in the first nine months of 2024. Valneva is focused on growing IXCHIQ® sales in the U.S., particularly among older adults (6

¹¹ [Valneva Announces New IXIARO® Supply Contract with the U.S. Government Worth a Minimum of \\$32 Million - Valneva](#)

¹² Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

¹³ [Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva](#)

¹⁴ [Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva](#)

¹⁵ [Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva](#)

¹⁶ [ACIP Vaccine Recommendations and Schedules | CDC](#)

5+ years old) who are at high risk for severe chikungunya infection and for whom ACIP recommends vaccination for certain travelers.

Valneva remains confident in the long-term prospects for IXCHIQ[®], and while U.S. sales have started slow, several factors are expected to drive future growth, including expanded access to the retail channel via publication of the ACIP recommendations in the Morbidity and Mortality Weekly Report (MMWR)¹⁷ and anticipated label expansion(s). The U.S. Defense Health Agency – Immunization Healthcare Division (DHA-IHD) also recently published chikungunya and vaccines guidance, which authorizes IXCHIQ[®] as a Department of Defense CHIKV countermeasure. Key launch metrics that are expected to enable future sales growth, including stocking and re-stocking across all sales channels, active customer accounts, as well as reimbursement for IXCHIQ[®] by commercial and MediCare insurance plans, continue to track in line with expectations, providing confidence in future sales growth.

The Company plans to review its mid-term IXCHIQ[®] sales guidance in the coming months, taking into account sales trends in the U.S., early insights into sales performance in Canada and first European Union (EU) countries, as well as demand from existing and potential future Low- and Middle-Income Countries (LMIC) partners.

Regulatory review is ongoing in Brazil and the UK and the Company recently filed¹⁸ and is preparing further filings for label extension to adolescents in markets where IXCHIQ[®] is approved, including key antibody persistence data to further establish IXCHIQ[®] as a differentiated brand. Phase 3 antibody persistence results two years after vaccination with a single dose were recently published in *The Lancet*¹⁹ showing that IXCHIQ[®]'s robust immune response was sustained by 97% of participants and was equally durable in younger and older adults. Valneva now expects to report three-year persistence data later this year. These important label updates, combined with anticipated ex-U.S. and endemic product launches are expected to significantly expand access of IXCHIQ[®] and contribute to its future revenues.

Additionally, Valneva recently expanded its partnership with CEPI²⁰ to support broader access to the vaccine in LMICs, post-marketing trials and potential label extensions in children, adolescents and pregnant women. CEPI will provide Valneva up to \$41.3 million of additional funding over the next five years, with support from the EU's Horizon Europe program.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. During the first nine months of 2024, third-party sales decreased by 23% to €22.5 million compared to €29.1 million in the first nine months of 2023 as a result of external supply constraints in the first half of the year.

¹⁷ The *MMWR Recommendations and Reports* contain in-depth articles that relay policy statements for prevention and treatment on all areas in CDC's scope of responsibility (e.g., recommendations from the Advisory Committee on Immunization Practices).

¹⁸ [Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ[®], to EMA and Health Canada - Valneva](#)

¹⁹ [Antibody persistence and safety of a live-attenuated chikungunya virus vaccine up to 2 years after single-dose administration in adults in the USA: a single-arm, multicentre, phase 3b study - The Lancet Infectious Diseases](#)

²⁰ [CEPI Expands Partnership with Valneva with a \\$41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva](#)

Valneva continues to expect a 20 to 30% reduction in third-party sales in 2024 and to gradually wind down third-party sales to less than 5% of overall product sales by 2026/2027, resulting in overall gross margin improvement.

Clinical Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15

Phase 3 primary vaccination completed

VLA15 is the Lyme disease vaccine candidate which has advanced the furthest along the clinical development timeline, with two Phase 3 trials in progress. It leverages an established mechanism of action against Lyme borreliosis infection by targeting the six most prevalent serotypes of the Borrelia outer surface protein A (OspA).

Pfizer and Valneva are currently executing the Phase 3 field efficacy study for VLA15 called VALOR (Vaccine Against Lyme for Outdoor Recreationists). Enrollment in the trial was completed in December 2023 and primary vaccination series was completed in July 2024²¹. Participants will be monitored for the occurrence of Lyme disease cases until the end of the Lyme disease season in 2025.

Pfizer aims to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2026, subject to positive Phase 3 data. If approved and commercialized, Valneva will be eligible to receive \$143 million in initial sales milestones from Pfizer, plus ongoing sales royalties ranging from 14% to 22% and an additional \$100 million in cumulative sales milestones.

Based on the agreement with Pfizer, Valneva's expected cost contributions for the Lyme disease program were completed in the second quarter of 2024, contributing to a substantially lower expected cash burn in the second half of 2024.

SHIGELLA VACCINE CANDIDATE – S4V2

The World's most clinically advanced tetravalent Shigella vaccine candidate

In August 2024, Valneva entered into a strategic partnership and exclusive licensing agreement with LimmaTech Biologics AG for the development, manufacturing and commercialization of Shigella4V2 (S4V2), a tetravalent bioconjugate vaccine candidate against shigellosis²².

The U.S. Food and Drug Administration (FDA) recently granted Fast Track designation to S4V2, recognizing its potential to address a serious condition and fill an unmet medical need²³.

Shigellosis, caused by Shigella bacteria, is the second leading cause of fatal diarrheal disease worldwide. It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to Shigella each year²⁴, particularly among children in LMICs. No approved Shigella vaccine is currently available and the development of Shigella vaccines has been identified

²¹ [Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion - Valneva](#)

²² [LimmaTech Biologics AG](#)

²³ [Valneva and LimmaTech Awarded FDA Fast Track Designation for Tetravalent Shigella Vaccine Candidate S4V - Valneva](#)

²⁴ [Shigellosis | CDC Yellow Book 2024](#)

d as a priority by the World Health Organization (WHO)²⁵. Shigellosis also affects international travelers from high-income countries and deployed military personnel in endemic regions. The global market for a vaccine against Shigella is estimated to exceed \$500 million annually²⁶.

The anticipated development path follows a staggered and risk-mitigated strategy, allowing for efficient capital allocation. LimmaTech will conduct a Phase 2 Controlled Human Infection Model study (CHIM) in the U.S. and a Phase 2 pediatric study in LMICs expected to begin in the second half of 2024. Valneva will assume all further development, including CMC (chemistry, manufacturing and controls) and regulatory activities, and be responsible for its commercialization worldwide if approved.

Under the terms of the agreement, LimmaTech received an upfront payment of €10 million and is eligible to receive additional regulatory, development and sales-based milestone payments of up to €40 million as well as low double-digit royalties on sales.

ZIKA VACCINE CANDIDATE – VLA1601

Phase 1 ongoing with second-generation vaccine candidate

VLA1601 is a second-generation adjuvanted inactivated vaccine candidate against the mosquito-borne disease caused by the Zika virus (ZIKV). In March 2024, Valneva initiated a Phase 1 clinical trial to investigate the safety and immunogenicity of VLA1601²⁷. The randomized, placebo-controlled, Phase 1 trial, VLA1601-102, is planned to enroll approximately 150 participants aged 18 to 49 years in the United States. Participants will receive a low, medium or high dose of VLA1601. In addition, the low dose of VLA1601 will be evaluated with an additional adjuvant. Sentinel recruitment and vaccinations have been completed and the start of the randomized phase is imminent. Data from the trial are expected in the first half of 2025.

Zika disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. Zika virus transmission persists in several countries in the Americas and in other endemic regions. To date, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection²⁸; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat and is included in the FDA's Tropical Disease Priority Review Voucher Program²⁹.

A vaccine against ZIKV could be a valuable addition to Valneva's portfolio against mosquito-borne diseases, which already includes IXCHIQ[®] and IXIARO[®].

²⁵ [Immunization, Vaccines and Biologicals \(who.int\)](#)

²⁶ [LEK analysis](#)

²⁷ [Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva](#)

²⁸ [Zika virus disease \(who.int\)](#)

²⁹ [Tropical Disease Priority Review Voucher Program | FDA](#)

Nine Months 2024 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €116.6 million in the nine months ended September 30, 2024 compared to €111.8 million in the nine months ended September 30, 2023.

Valneva's total product sales reached €112.5 million in the first nine months of 2024 compared to €106.1 million in the same period of 2023. The impact of currency fluctuations of €0.1 million was minimal.

Excluding COVID-19 vaccine sales in the nine months ended September 30, 2023, travel vaccine sales showed a growth of €12.1 million or 12% year-over-year.

IXIARO[®]/JESPECT[®] sales were €66.0 million in the first nine months of 2024 compared to €50.3 million in the nine months ended September 30, 2023. The 31% increase reflects double digit growth in sales to both travelers (11%) and the US military. The impact of foreign currency movements in IXIARO[®]/JESPECT[®] sales was negligible.

DUKORAL[®] sales were €22.3 million in the first nine months of 2024 compared to €21.1 million in the comparative period of 2023. This 6% increase was due to marketing investments resuming in the third quarter of 2024 following successful regulatory inspection of Valneva's new manufacturing facility in Sweden. Foreign currency fluctuations had an immaterial impact on DUKORAL[®] sales.

Following adoption of the U.S. ACIP's recommendations by the U.S. CDC at the beginning of March 2024, Valneva recognized initial sales for IXCHIQ[®] of €1.8 million in the first nine months of 2024.

Third Party product sales were €22.5 million in the first nine months of 2024 compared to €29.1 million in the same period of 2023. This 23% decrease was mainly driven by lower sales of Rabipur[®]/RabAvert[®] and Encepur[®], under the distribution agreement with Bavarian Nordic, as a result of external supply constraints in the first half of the year.

Other revenues, including revenues from collaborations, licensing and services amounted to €4.2 million in the first nine months of 2024 compared to €5.7 million in the same period of 2023. The reduction mainly resulted from lower revenue recognition related to the R&D collaboration activities for chikungunya with Instituto Butantan.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €71.3 million in the nine months ended September 30, 2024. The gross margin on commercial product sales, excluding IXCHIQ[®], amounted to 48.6% compared to 43.7% in the nine months ended September 30, 2023. COGS of €27.2 million related to IXIARO[®] product sales, yielding a product gross margin of 58.8%. COGS of €14.5 million related to DUKORAL[®] product sales, yielding a product gross margin of 34.8%. Product gross margins continued recovering during the third quarter of 2024 as the supply shortages during the first half were resolved. Of the remaining COGS in the first nine

months of 2024, €15.2 million related to the third-party products distribution business, €4.6 million to IXCHIQ[®], €3.6 million to idle capacity costs and €6.3 million to cost of services. In the first nine months of 2023, overall COGS were €74.8 million, of which €67.6 million related to cost of goods and €7.2 million related to cost of services.

Research and development expenses amounted to €48.6 million in the first nine months of 2024, compared to €42.2 million in the first nine months of 2023. This increase was mainly driven by higher costs related to the ongoing transfer of operations into the new Almeida manufacturing facility. Marketing and distribution expenses in the first nine months of 2024 amounted to €35.7 million compared to €33.9 million in the first nine months of 2023. The increase is mainly related to €16.2 million of expenses associated with launch activities for IXCHIQ[®] (first nine months of 2023: €13.8 million). In the first nine months of 2024, general and administrative expenses reduced to €32.6 million after €35.1 million in the same period of 2023. The largest expense categories were employee-related expenses of €15.0 million and consulting and other services of €13.1 million.

During the first nine months of 2024, a net gain of €90.8 million from the sale of the PRV was recorded. The gross proceeds of \$103 million were reduced by transaction costs as well as contractual payment obligations related to the sale of the PRV.

Other income, net of other expenses decreased to €14.9 million in the nine months ended September 30, 2024 from €17.0 million in the nine months ended September 30, 2023. In the first nine months of 2024 Valneva recorded €6.2 million income from the recently awarded CEPI grant. The first nine months of 2023 included income of €10.3 million awarded by Scottish Enterprise (SE) for non-COVID-19 vaccine development (IXCHIQ[®] and IXIARO[®]).

Valneva recorded an operating income of €34.2 million in the first nine months of 2024 compared to an operating loss of €57.2 million in the comparative period of 2023. The increase was mainly the result of the PRV sale.

Adjusted EBITDA (as defined below) profit in the first nine months of 2024 was €48.6 million, whereas in the first nine months of 2023 an adjusted EBITDA loss of €46.0 million was recorded.

Net Result

In the first nine months of 2024, Valneva generated a net profit of €24.7 million, mainly resulting from the sale of the PRV in February 2024. This compared to a net loss of €69.3 million in the first nine months of 2023.

Finance expense and currency effects in the first nine months of 2024 resulted in a net finance expense of €13.4 million, compared to a net finance expense of €13.2 million in the first nine months of 2023. This increase was mainly due to €5.2 million higher interest expenses on loans resulting from the amendment of the Deerfield Management Company and OrbiMed (D&O) loan facility. Additionally foreign exchange profits of €3.0 million were recorded in the first nine months of 2024 compared to losses of €1.4 million observed in the first nine months of 2023, primarily related to the development of the USD and GBP exchange rates to the EUR.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €76.7 million in the first nine months of 2024 compared to €136.8 million of cash used in operating activities in the same period of 2023. Cash outflows in the first nine months of 2024 were largely derived from the operating loss for the period (excluding gains from PRV sale) amounting to €66.1 million and from working capital in the amount of €35.1 million which includes Valneva's final agreed-upon payments to the Lyme disease clinical program. In the first nine months of 2023, changes in working capital were higher, mainly related to higher payments to Pfizer in conjunction with the Lyme disease program, reducing the refund liability.

Cash inflows from investing activities amounted to €72.2 million in the first nine months of 2024 compared to cash outflows of €4.3 million in the first nine months of 2023. Both years included outflows from construction activities across production sites in Scotland and Sweden and, in addition, 2024 included outflows from the upfront payment to LimmaTech Biologics AG recorded as purchase of an intangible asset. The sale of the PRV positively impacted 2024 by €90.8 million.

Net cash generated in financing activities increased to €35.3 million in the first nine months of 2024 from €26.1 million in the first nine months of 2023. This increase was primarily due to €57.5 million net proceeds from the recent private placement completed in the third quarter of 2024, while the first nine months of 2023 included proceeds from the increase of the loan facility provided by Deerfield Management Company and OrbiMed.

Cash and cash equivalents were €156.3 million as at September 30, 2024, compared to €126.1 million at December 31, 2023.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Valneva's current performance, performance trends, and financial condition.

Adjusted EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. Adjusted EBITDA is defined as net profit / (loss) for the period before income tax, finance income/expense, foreign exchange (gain)/loss, amortization, depreciation, and impairment (excluding impairment loss of disposal).

A reconciliation of Adjusted EBITDA net profit / (loss), which is the most directly comparable IFRS measure, is set forth below:

€ in million (unaudited results, consolidated per IFRS)	Nine months ended September 30,	
	2024	2023
Net profit / (loss)	24.7	-69.3
Add:		
Income tax (benefits)/expense	-3.9	-1.1
Total finance income	-1.3	-0.7
Total finance expense	17.7	12.5
Foreign currency (gain)/loss - net	-3.0	1.4
Amortization	3.7	4.7
Depreciation	10.7	8.4
Impairment, excluding impairment loss of disposal	0.0	-1.9
Adjusted EBITDA	48.6	-46.0

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, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

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 financial results for 2024; mid-term revenue and cash outlook; the progress, timing, results and completion of research, development and clinical trials for product candidates; regulatory approval of product candidates and requested label extensions; 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 in this press release will in fact be realized. Valneva is providing this information as of the date of this press release 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.