

VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, France

Valneva Reports Half Year 2025 Financial Results and Provides Corporate Updates

- Total revenues of €97.6 million compared to €70.8 million in the first half of 2024
- Cash and cash equivalents of €161.3 million at end of June 2025
- Further clinical and regulatory progress
- 2025 financial outlook confirmed

Saint-Herblain (France), August 12, 2025 – <u>Valneva SE</u> (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its condensed consolidated financial results for the first half of the year, ended June 30, 2025, and confirmed its 2025 financial guidance. The half year financial report, including the condensed consolidated interim financial report and the half year management report, is available on the Company's website (Financial Reports – Valneva).

Valneva will provide a live webcast of its first half 2025 results conference call beginning at 3 p.m. CEST/9 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/kkyrijxj

First Half 2025 Financial Update

- Total revenues were €97.6 million compared to €70.8 million for the first half of 2024, an increase of 37.8%
- Product sales reached €91.0 million compared to €68.3 million in the first half of 2024, an increase of 33.3%
- Net loss of €20.8 million compared to a net profit of €34.0 million in the first half of 2024, which
 included one-time net proceeds of €90.8 million from the sale of a Priority Review Voucher
 (PRV)¹
- Significant reduction in operating cash burn (€10.9 million in the first half of 2025 compared to €66.3 million in the first half of 2024)
- Cash and cash equivalents were €161.3 million as at June 30, 2025, compared to €168.3 million as at December 31, 2024
 - Cash at June 30, 2025 included €20.1 million of net proceeds from two At The Market (ATM) transactions with leading U.S. institutional healthcare investors Novo Holdings A/S and Frazier Life Sciences in Q2 2025²

VALNEVA SE

August 12, 2025

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

² https://valneva.com/investors/regulated-information/



Financial Outlook

The Company confirms the following guidance for fiscal year 2025:

- Product sales expected to grow to €170-180 million, driving positive cash flow for the commercial business
- Total revenues expected to reach €180-190 million
- Total R&D investments expected between €90-100 million, partially offset by grant funding and anticipated R&D tax credits
- Continued stringent focus on cash management supporting sufficient cash runway to reach key inflection points; targeting more than 50% lower operating cash burn compared to the prior year

Peter Bühler, Valneva's Chief Financial Officer, commented, "As we approach the potentially transformative Phase 3 data readout for our Lyme disease vaccine candidate, we remain strategically focused on two key objectives - growing our commercial sales and effectively managing our cash. In the first half of the year, we again delivered double-digit sales growth while continuing to expand access to our vaccines. We also substantially reduced our spending and successfully leveraged our ATM program to welcome two new leading healthcare investors among our main shareholders, strengthening our financial position ahead of this important clinical catalyst."

Key R&D, Regulatory, and Commercial Updates

- Finalized new \$32.8 million IXIARO® supply contract with the U.S. Department of Defense (DoD) in January 2025³
- Signed exclusive agreement with CSL Seqirus to market and distribute Valneva's three proprietary vaccines in Germany⁴
- VALOR Lyme disease study on track; Pfizer confirmed all vaccinations have been completed⁵
- Responded to French government's call for vaccine supply of IXCHIQ[®] to combat chikungunya outbreak in La Réunion⁶
- Announced European Medicines Agency (EMA) and Food and Drug Administration (FDA)'s
 decisions to lift temporary restrictions on use of IXCHIQ[®] in elderly following their thorough
 review of the vaccine on reported serious adverse events (SAE's) in that age group
- Secured additional marketing authorizations for IXCHIQ® in the United Kingdom (UK) and Brazil⁷, marking the world's first approval of a chikungunya vaccine in an endemic country⁸
- Received label extension for IXCHIQ[®] in Europe for individuals 12 years of age and older⁹ and submitted additional adolescent label extension applications in other countries

³ Valneva Announces New IXIARO® Supply Contract with the U.S. Government Worth a Minimum of \$32.8 Million - Valneva

⁴ <u>Valneva Announces Exclusive Vaccine Marketing and Distribution Agreement for Germany with CSL Segirus - Valneva</u>

⁵ https://s206.q4cdn.com/795948973/files/doc_financials/2025/q2/PFE-USQ_Transcript_2025-08-05.pdf

⁶ Valneva Responds to French Government's Call for Vaccine Supply of IXCHIQ® against Chikungunya Outbreak in La Réunion - Valneva

⁷ Valneva Receives Marketing Authorization in the UK for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva

⁸ Valneva Receives First Marketing Authorization for IXCHIQ® in a Chikungunya Endemic Country - Valneva

⁹ Valneva's Chikungunya Vaccine IXCHIQ® Now Authorized in EU for Adolescents Aged 12 and Above - Valneva



- Reported positive Phase 2 six-month antibody persistence and safety results in children¹⁰ vaccinated with IXCHIQ[®], as well as high sustained immune response in adolescents one year after a single vaccination¹¹
- Announced first vaccination in Phase 2 infant study of tetravalent Shigella vaccine candidate S4V2¹²

Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	6 months ended June 30,	
	2025	2024
Total revenues	97.6	70.8
Product sales	91.0	68.3
Net profit / (loss)	(20.8)	34.0
Adjusted EBITDA ¹³	(6.0)	56.2
Cash	161.3	131.4

Commercial Portfolio

Valneva's commercial portfolio is composed of three travel vaccines, IXIARO®/JESPECT®, DUKORAL® and 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 half of 2025 were €91.0 million compared to €68.3 million in the first half of 2024, which had been impacted by supply constraints. First half 2025 sales included €11.4 million of third-party sales. Valneva expects that third-party sales will gradually wind down to less than 5% of its total sales by 2026/2027, allowing the Company to improve gross margins.

In June 2025, Valneva announced an exclusive agreement with CSL Seqirus¹⁴, one of the world's largest influenza vaccine companies, for the marketing and distribution of Valneva's three proprietary vaccines in Germany. Under the agreed terms, CSL Seqirus recently launched Valneva's single-dose chikungunya vaccine IXCHIQ® and will begin commercializing Valneva's Japanese encephalitis vaccine IXIARO® and cholera/ETEC vaccine DUKORAL® from January 2026. This agreement has an initial three-year term and includes minimum annual purchasing quantities and standard termination clauses based on change of control and non-performance.

¹⁰ Valneva Reports Positive Six-Month Antibody Persistence and Safety Phase 2 Results in Children for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva

¹¹ Valneva Reports High Sustained Immune Response in Adolescents One Year After Single Vaccination with its Chikungunya Vaccine - Valneva

¹² Valneva and LimmaTech Announce First Vaccination in Phase 2 Infant Study of Tetravalent Shigella Vaccine Candidate S4V2 - Valneva

¹³ For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR

¹⁴ Valneva Announces Exclusive Vaccine Marketing and Distribution Agreement for Germany with CSL Seqirus - Valneva



JAPANESE ENCEPHALITIS VACCINE IXIARO®/JESPECT®

In the first half of 2025, IXIARO®/JESPECT® sales increased by 30.6% to €54.7 million compared to €41.9 million in the first half of 2024. Sales to both travelers and the DoD showed double-digit growth compared to the first half of 2024, when sales were impacted by IXIARO® supply constraints.

In January 2025, Valneva secured a new \$32.8 million contract with the DoD¹⁵. Similar to previous DoD contracts, it includes the possibility to purchase additional doses during the twelve months following the signing date.

CHOLERA / ETEC16-DIARRHEA VACCINE DUKORAL®

In the first half of 2025, DUKORAL[®] sales were €17.4 million compared to €14.9 million in the first half of 2024. This 16.4% growth was notably supported by the supply of doses to combat an outbreak on the French island of Mayotte for €1.1 million in the first quarter of 2025.

CHIKUNGUNYA VACCINE IXCHIQ®

In the first half of 2025, Valneva reported IXCHIQ[®] sales of €7.5 million compared to sales of €1.0 million in the first half of 2024, when the vaccine had just been launched in the U.S. First half IXCHIQ[®] sales benefited from the supply of vaccine doses to the French island La Réunion, primarily in the second quarter of the year, as the island experienced a major chikungunya outbreak.

In addition to ramping up sales and launching the vaccine in additional countries, Valneva is focused on expanding the vaccine's label and access. In April 2025, IXCHIQ® was granted marketing authorization in Brazil, marking the world's first approval of a chikungunya vaccine in an endemic country. In April 2025, IXCHIQ® was also granted label extension in adolescents 12 years of age and older in the European Union, and additional label extension applications are under review in the U.S., Canada, Brazil, and the UK.

In the second quarter of 2025, Valneva reported changes to recommendations for use of IXCHIQ® in the U.S., France and Europe based on reports of serious adverse events (SAEs) mainly in elderly people with several underlying medical conditions. As a temporary measure, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and France's Haute Autorité de Santé suspended the use of the vaccine for individuals in this age group. Both the EMA and FDA announced the lifting of these temporary restrictions in July¹⁷ and August¹⁸ 2025, respectively. The two agencies underlined that IXCHIQ® should only be given when there is a significant risk of chikungunya infection and after careful consideration of the benefits and risks. The FDA noted that for most U.S. travelers the risk of exposure to CHIKV is low. Both agencies also reminded healthcare professionals that IXCHIQ® is contraindicated in individuals with a weakened immune system due

¹⁵ Valneva Announces New IXIARO® Supply Contract with the U.S. Government Worth a Minimum of \$32.8 Million - Valneva

¹⁶ 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.

¹⁷ Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted | European Medicines Agency (EMA)

¹⁸ https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-update-safety-ixchiq-chikungunya-vaccine-live



to disease or immunosuppressive treatments, as stated in IXCHIQ[®]'s product label in the U.S., Europe and other territories. Additionally, the U.S. Prescribing information (PI) and European Summary of Product Characteristics (SmPC) were updated to reflect the SAE profile observed, especially in people above 65 years of age and older with one or more chronic medical condition.

Clinical Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15 Phase 3 vaccination completed

Valneva and Pfizer are developing VLA15, a Phase 3 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common serotypes found in the United States and Europe. VLA15 is the only Lyme disease program in late-stage clinical development today and has received Fast Track designation from the FDA.

Pfizer is currently executing the randomized, placebo-controlled Phase 3 field efficacy study, VALOR (Vaccine Against Lyme for Outdoor Recreationists). Phase 3 vaccinations have now been completed.

Participants will be monitored for the occurrence of Lyme disease cases until the end of the 2025 Lyme disease season (end of October), with topline data expected as soon as all Lyme disease cases are confirmed.

Pfizer aims to submit a Biologics License Application (BLA) to the U.S. FDA and a Marketing Authorization Application (MAA) to EMA in 2026, subject to positive Phase 3 data. If VLA15 is approved and commercialized in the United States and Europe, Valneva will be eligible to receive \$143 million in milestones from Pfizer, plus ongoing sales royalties ranging from 14% to 22% and an additional \$100 million in cumulative sales-based milestones.

SHIGELLA VACCINE CANDIDATE - S4V2

Two Phase 2 trials ongoing

S4V2 is the world's most clinically advanced tetravalent vaccine candidate against shigellosis, a diarrheal infection caused by Shigella bacteria, under development in collaboration with LimmaTech Biologics AG.

Shigellosis is the second leading cause of fatal diarrhea worldwide. It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to Shigella each year¹⁹, particularly among children in Low Middle-Income Countries.

In April 2025, Valneva and LimmaTech announced vaccination of the first participant in a Phase 2 infant safety and immunogenicity study of S4V2. This followed the launch of a Phase 2b Human Challenge Study (CHIM) in the United States²⁰, sponsored and conducted by LimmaTech. Results

¹⁹ Shigellosis | CDC Yellow Book 2024

²⁰ Valneva and LimmaTech Announce First Vaccination in Phase 2b Human Challenge Study of Tetravalent Shigella Vaccine Candidate S4V2



for the infant and CHIM studies are expected in the second half of 2025 and first half of 2026, respectively. Subject to positive results for both Phase 2 studies, Valneva will assume responsibility for all further development²¹.

No approved multivalent Shigella vaccine is currently available outside of Russia or China, and the development of Shigella vaccines has been identified as a priority by the World Health Organization (WHO)²². In October 2024, the U.S. FDA granted Fast Track designation to S4V2, recognizing its potential to address a serious condition and fill an unmet medical need²³. The global market for a vaccine against Shigella is estimated to exceed \$500 million annually²⁴.

ZIKA VACCINE CANDIDATE – VLA1601 Phase 1 ongoing with optimized vaccine candidate

VLA1601 is a novel 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 VLA1601²⁵. Sentinel recruitment and vaccinations have been completed and results from the trial are expected this year.

Zika virus transmission persists in several countries in the Americas and in other endemic regions, such as India and Africa. To date, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection²⁶; 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 Program²⁷.

First Half 2025 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €97.6 million in the first half of 2025 compared to €70.8 million in the first half of 2024.

Valneva's total product sales reached €91.0 million in the first half of 2025 compared to €68.3 million in the first half of 2024. Foreign currency fluctuations of €0.5 million adversely impacted product sales during the first half of 2025.

Other revenues, including revenues from collaborations, licensing and services increased to €6.5 million in the first half of 2025, compared to €2.5 million in the first half of 2024. The increase

²¹ <u>Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate - Valneva</u>

²² Immunization, Vaccines and Biologicals (who.int)

²³ Valneva and LimmaTech Awarded FDA Fast Track Designation for Tetravalent Shigella Vaccine Candidate S4V - Valneva

²⁴ LEK analysis

²⁵ Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva

²⁶ Zika virus disease (who.int)

²⁷ <u>Tropical Disease Priority Review Voucher Program | FDA</u>



was related to revenues recognized under the exclusive license agreement with the Serum Institute of India for Valneva's single-shot chikungunya vaccine.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €47.2 million in the first half of 2025. The gross margin on commercial product sales, excluding IXCHIQ[®], amounted to 59.2% in the first half of 2025 compared to 47.7% in the first half of 2024. The improvement in gross margin was driven primarily by better manufacturing performance.

COGS of €18.9 million related to IXIARO[®] product sales yielded a product gross margin of 65.5%, while COGS of €8.2 million related to DUKORAL[®] product sales yielded a product gross margin of 52.9%. Of the remaining COGS in the first half of 2025, €7.0 million related to the third-party products distribution business, €2.5 million to IXCHIQ[®], €5.9 million to idle capacity costs and €4.6 million to cost of services. In the first half of 2024, overall COGS were €45.6 million, of which €41.1 million related to cost of goods and €4.6 million related to cost of services.

Research and development expenses were €32.4 million in the first half of 2025, compared to €29.7 million in the first half of 2024. This increase was mainly driven by higher costs related to the Shigella vaccine candidate following the R&D collaboration agreement with LimmaTech Biologics AG.

Marketing and distribution expenses in the first half of 2025 were €20.3 million compared to €23.2 million in the first half of 2024. The decrease was mainly related to a planned reduction in advertising, promotional and consultancy spending, which was partly offset by higher costs for warehousing and distribution.

In the first half of 2025, general and administrative expenses were reduced to €19.0 million compared to €22.8 million in the first half of 2024. The reductions were primarily related to lower recruitment spending and insurance charges as well as savings in advisory and professional services.

During the first half 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. This one-time net gain did not recur in 2025.

Other income, net of other expenses decreased to €4.6 million in the first half of 2025, from €6.4 million in the first half of 2024. The reduction was mainly related to lower R&D tax credits during the first half of 2025.

Valneva recorded an operating loss of €16.8 million in the first half of 2025 compared to an operating profit of €46.7 million in the first half of 2024. The decrease was mainly the result of the PRV sale in 2024, partly offset by higher product sales resulting in higher gross profit, as well as reduced SG&A spending in the first half of 2025.



Adjusted EBITDA (as defined below) loss in the first half of 2025 was €6.0 million, whereas in the first half of 2024, an adjusted EBITDA profit of €56.2 million, benefiting from the PRV sale, was recorded.

Net Result

In the first half of 2025, Valneva generated a net loss of €20.8 million. This compared to a net profit of €34.0 million in the first half of 2024, mainly resulting from the sale of the PRV in February 2024.

Finance expense and currency effects in the first half of 2025 resulted in a net finance expense of €2.7 million, compared to a net finance expense of €12.8 million in the first half of 2024. This is mainly related to the development of USD exchange rate versus EUR, which generated a foreign currency profit of €7.8 million in the first half of 2025 compared to a foreign currency loss of €1.7 million in the first half of 2024.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €10.9 million in the first half of 2025 compared to €66.3 million cash used in operating activities in the first half of 2024. The significant reduction in cash used in operating activities compared to last year is driven by the significant increase in sales and efficient cost management.

Cash outflows from investing activities amounted to €1.6 million in the first half of 2025 compared to cash inflows of €87.6 million in the first half of 2024. Cash inflows in the first half of 2024 resulted from €90.8 million net proceeds from the sale of the PRV.

Net cash generated from financing activities amounted to €9.3 million in the first half of 2025 compared to a net cash outflow of €16.6 million in the first half of 2024. Cash inflows from the first half of 2025 included €20.1 million net proceeds from two ATM transactions partly offset by interest payments. Cash outflows for the first half of 2024 mainly consisted of interest and lease payments.

Cash and cash equivalents were €161.3 million as at June 30, 2025, compared to €168.3 million at December 31, 2024.

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 provides 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.



A reconciliation of Adjusted EBITDA to operating loss, which is the most directly comparable IFRS measure, is set forth below:

€ in million	6 months ended June 30	
(unaudited results, consolidated per IFRS)	2025	2024
Net profit/(loss)	(20.8)	34.0
Add:		
Income tax benefit/expense	1.3	(0.2)
Total Finance income	(1.1)	(0.8)
Total Finance expense	11.6	12.0
Foreign exchange (gain)/loss – net	(7.8)	1.7
Amortization	2.4	2.5
Depreciation	8.4	7.0
Impairment	-	-
Adjusted EBITDA	(6.0)	56.2

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.

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 tetravalent 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 Laetitia.bachelotfontaine@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 business partnerships, clinical trials, technology transfer, regulatory approvals, product indications, sales and spending. 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 forwardlooking 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 (including in connection with changes in leadership at the national or agency level), reports of adverse events following vaccination with a Valneva product, competition in general, currency fluctuations, the impact of global economic and political events, 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.