VALNEVA SE
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Valneva Reports First Quarter 2024 Financial Results and Provides Corporate Updates

Q1 financial highlights

- Total revenues of €32.8 million, including sales of €32.1 million, on track to meet anticipated full year guidance

- Cash position of €176.6 million, including €95 million from sale of Priority Review Voucher (PRV)[1].
    - Significantly extended cash runway with recent update of debt financing agreement[2]
    - Substantially lower cash burn expected in 2024 as Valneva expects to complete its cost contributions for the Lyme disease Phase 3 study in the second quarter

- Net Profit of €58.9 million, reflecting PRV sale

2024 financial guidance confirmed

- Expected total revenues between €170 million and €190 million, including:
    - €160 million to €180 million of sales driven by growth of Valneva's proprietary products

- Expected R&D investments between €60 million and €75 million, mostly dedicated to ongoing chikungunya development activities, the Zika trial and advancement of pre-clinical programs

- Expected Other income between €100 million and €110 million, reflecting €95 million in proceeds from the PRV sale

Strong R&D execution

- Single-shot chikungunya vaccine IXCHIQ® recommended by ACIP and adopted by U.S. CDC[3]; Regulatory processes with the European, Canadian and Brazilian authorities on track;

- Six-month data for Phase 3 adolescent study of IXCHIQ® to be reported shortly and label extensions to be submitted based on results; Enrolment of children for pediatric Phase 2 study on track;

- Primary vaccinations for all participants in the VALOR Lyme disease Phase 3 trial expected to be completed in Q2;

- Phase 1 clinical trial for second-generation Zika vaccine candidate initiated[4].

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[1] *Valneva Announces Sale of Priority Review Voucher for $103 Million - Valneva*
[2] *Valneva Announces Extension of the Interest-Only Period of Its Debt Facility with Deerfield and OrbiMed - Valneva*
[3] *ACIP Vaccine Recommendations and Schedules | CDC*
[4] *Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva*

Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	3 months ending March 31	
	2024	2023
Product sales	32.1	32.1
Total revenues	32.8	33.5
Net profit/(loss)	58.9	(18.1)
Adjusted EBITDA (profit/loss)	73.0	(12.3)
Cash	176.6	254.5

Saint-Herblain (France), May 7, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its financial results for the first quarter ending March 31, 2024, and provided corporate updates. The condensed consolidated interim financial results are available on the Company's website (Financial Reports – Valneva).

Valneva will host a live webcast of its first quarter 2024 results conference call 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/wrc2a7s3.

Peter Bühler, Valneva's Chief Financial Officer, commented, "The first quarter performance has been in line with our expectations. We are aiming to further capitalize on the travel industry recovery during the rest of the year including ramping-up sales for IXCHIQ® to support our commercial sales growth while executing on our key R&D milestones. The successful sale of our PRV and deferral of our loan reimbursement in Q1 allowed us to maintain a solid cash position and, with the expected completion of our payments for the Lyme Phase 3 trial in the second quarter, we anticipate a significantly lower cash burn in 2024."

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.

JAPANESE ENCEPHALITIS VACCINE IXIARO®/JESPECT®

In the first quarter of 2024, IXIARO®/JESPECT® sales were €16.6 million compared to €17.4 million in the first quarter of 2023. Sales to the U.S. military counterbalanced most of the supply constraints experienced during the period. These constraints have now been resolved, and as communicated last month in its full-year publication[5], Valneva expects double-digit annual growth for IXIARO® sales for at least the next three years.

[5] *Valneva Reports Full Year 2023 Results and Provides Business Updates and Outlook - Valneva*

CHOLERA / ETEC[6]-DIARRHEA VACCINE DUKORAL®

In the first quarter of 2024, DUKORAL® sales increased by 10.3% to €11.3 million compared to €10.2 million in the first quarter of 2023, as the vaccine continued to benefit from the significant recovery in the private travel markets.

CHIKUNGUNYA VACCINE IXCHIQ®

IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. Following adoption of the U.S. Advisory Committee on Immunization Practices (ACIP)'s recommendations[7] by the U.S. Centers for Disease Control and Prevention (CDC)[8] at the beginning of March 2024, Valneva has focused on launching its single-dose chikungunya vaccine in the U.S. and recorded initial sales of €0.2 million in the first quarter.

IXCHIQ® is also under regulatory review in Canada, Brazil and Europe, where it was granted accelerated assessment by the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP). Decisions on these submissions are expected in 2024.

A clinical study in adolescents, VLA1553-321, is ongoing. Valneva reported initial safety data in August 2023[9] and expects to report six-month data in the coming weeks. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and conducted in Brazil in collaboration with Instituto Butantan, the VLA1553-321 adolescent trial is intended to support the label extension to this age group following initial approvals in adults. The trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations. Additionally, the Company initiated a Phase 2 pediatric trial, VLA1553-221, in children aged 1 to 11 years, in January 2024[10]. This is designed to support a Phase 3 pivotal pediatric study and potentially extend the label to this age group following initial regulatory approvals in adults and possibly in adolescents.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. During the first quarter of 2024, third-party sales decreased by 8.9% to €4.1 million compared to €4.5 million in the first quarter of 2023 as a result of anticipated supply constraints. Valneva expects that third-party sales will gradually wind down to less than 5% of overall product sales by 2026/2027, allowing the Company to improve gross margins.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 3 study ongoing

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 strains found in the United States

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[6] *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.*
[7] *ACIP Vaccine Recommendations and Schedules | CDC*
[8] *ACIP Vaccine Recommendations and Schedules | CDC*
[9] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*
[10] *Valneva Vaccinates First Participant in Pediatric Trial of Single-Shot Chikungunya Vaccine - Valneva*

and Europe. VLA15 is the only Lyme disease program in late-stage clinical development today and has received Fast Track designation from the FDA.

Vaccinations across the two cohorts of the Phase 3 trial "Vaccine Against Lyme for Outdoor Recreationists" (VALOR) are on track and Valneva and Pfizer expect all participants (9,437) to complete primary vaccinations (three doses) in the coming weeks.

Topline data from the VALOR trial are expected by the end of 2025, with the aim for Pfizer to submit a Biologic License Application (BLA) to the FDA and a Marketing Authorization Application (MAA) to the EMA in 2026, subject to positive data.

Valneva's cost contributions for the Lyme disease Phase 3 study are expected to be completed in the second quarter of 2024. All remaining payments to Pfizer are included in current refund liability at December 31, 2023, and will not impact the Profit & Loss statement in 2024.

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 viral disease caused by the Zika virus (ZIKV). In March 2024, Valneva initiated a Phase 1 clinical trial to investigate the safety and immunogenicity of VLA1601[11]. 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. Topline 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 infection[12]; 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 theFDA's Tropical Disease Priority Review Voucher Program[13].

A vaccine against ZIKV would be a valuable addition to Valneva's portfolio of travel vaccines against mosquito-borne diseases, which already includes IXCHIQ® and IXIARO®.

First Quarter 2024 Financial Review
(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €32.8 million in the first quarter of 2024 compared to €33.5 million in the first quarter of 2023.

Valneva's sales reached €32.1 million in the first quarter of 2024 and remained comparable to the first quarter of 2023. Currency fluctuations had an immaterial impact on sales compared to the comparator period.

[11] *Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva*
[12] *Zika virus disease (who.int)*
[13] *Tropical Disease Priority Review Voucher Program | FDA*

IXIARO®/JESPECT® sales were €16.6 million in the first quarter of 2024 compared to €17.4 million in the first quarter of 2023. The 4% decrease in sales is primarily the result of constrained supplies, which temporarily impacted sales during the first quarter and are now resolved.

DUKORAL® sales were €11.3 million in the first quarter of 2024 compared to €10.2 million in the first quarter of 2023. This 10% increase results from the continued recovery in the private travel markets primarily driven by Canada, and price increases.

IXCHIQ® sales were €0.2 million in the first quarter of 2024. The U.S. CDC adopted recommendations by the ACIP[14] at the beginning of March 2024.

Third Party product sales were €4.1 million in the first quarter of 2024 compared to €4.5 million in the first quarter of 2023, a 9% decrease which was mainly driven by supply constraints of Rabipur®/RabAvert® and Encepur® sold under the distribution agreement with Bavarian Nordic.

Other revenues, including revenues from collaborations, licensing and services amounted to €0.6 million in the first quarter of 2024 compared to €1.4 million in the first quarter of 2023 with the reduction mainly resulting 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 €22.2 million in the first quarter of 2024. The gross margin on commercial product sales amounted to 43.9% (excluding IXCHIQ®) compared to 48.4% in the first quarter of 2023. COGS of €8.0 million related to IXIARO® sales, yielding a product gross margin of 52.0%, which was impacted by €1.7 million recorded as write-offs for failed batches. COGS of €7.0 million related to DUKORAL® sales, yielding a product gross margin of 37.9%. Of the remaining COGS in the first quarter of 2024, €3.0 million related to the third-party products distribution business, €0.8 million to IXCHIQ®, €1.0 million to idle capacity costs and €2.4 million to cost of services. In the first quarter of 2023, overall COGS were €20.5 million, of which €17.9 million related to cost of goods and €2.6 million related to cost of services.

Research and development expenses amounted to €13.1 million in the first quarter of 2024, compared to €14.1 million in the first quarter of 2023. This decrease was mainly driven by lower spend on Valneva's COVID-19 vaccine, VLA2001 as well as lower spend on IXCHIQ® following licensure in the fourth quarter of 2023. At the same time, costs related to the ongoing transfer of operations into the new Almeida manufacturing facility resulted in higher R&D spend on commercial products. Marketing and distribution expenses in the first quarter of 2024 amounted to €11.3 million compared to €9.0 million in the first quarter of 2023. The increase is mainly related to €4.9 million of expenses associated with launch activities for IXCHIQ® (first quarter of 2023: €3.4 million). In the first quarter of 2024, general and administrative expenses increased to €11.7 million from €10.0 million in the first quarter of 2023, mainly resulting from higher costs related to the Company's stock-based employee compensation program, higher recruiting charges and higher costs for digitalization & automation initiatives.

During the first quarter of 2024, a net gain of €90.8 million from the sale of the PRV was recorded in the income statement. The net 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 €2.9 million in the first quarter of 2024 from €3.5 million in the first quarter of 2023. The decrease was mainly driven by lower R&D tax credits recorded in the first quarter of 2024 following the reduction in eligible R&D spend.

[14] ACIP Vaccine Recommendations and Schedules | CDC

Valneva recorded an operating profit of €68.2 million in the first quarter of 2024 compared to an operating loss of €16.6 million in the first quarter of 2023. The significant improvement is largely related to the proceeds from the sales of the PRV recorded in the income statement in the first quarter of 2024. Adjusted EBITDA (as defined below) profit in the first quarter of 2024 was €73.0 million, compared to an EBITDA loss of €12.3 million in the first quarter of 2023.

Net Result

In the first quarter of 2024, Valneva generated a net profit of €58.9 million compared to a net loss of €18.1 million in the first quarter of 2023.

Finance expenses and currency effects in the first quarter of 2024 resulted in a net finance expense of €9.3 million, compared to a net finance expense of €1.7 million in the first quarter of 2023. The increase in finance expenses, net was mainly due to foreign exchange losses of €2.5 million in the first quarter of 2024 compared to a profit of €3.2 million in the first quarter of 2023, primarily related to the development of the USD / EUR exchange rate. In addition, interest charges increased to €7.0 million in the first quarter of 2024 compared to €5.1 million in the first quarter of 2023 following the increase of the Deerfield Management Company and OrbiMed (D&O) loan facility during the second half of 2023.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €28.4 million in the first quarter of 2024 compared to €24.3 million in the first quarter of 2023. Cash outflows in the first quarter of 2024 were mainly a result of the net loss for the period excluding proceeds from the sale of the PRV and by increases in working capital.

Cash inflows from investing activities amounted to €86.7 million in the first quarter of 2024 compared to cash outflows of €3.6 million in the first quarter of 2023. Cash inflows in the first quarter of 2024 were driven by €90.8 million net proceeds from the sale of the PRV, partly offset by construction activities in the Almeida manufacturing site in Scotland as well as equipment purchases.

Net cash used in financing activities increased to €7.5 million in the first quarter of 2024 from €3.8 million in the first quarter of 2023. The increase in cash outflows in the first quarter of 2024 were primarily due to increased interest payments and transaction costs resulting from the upsized loan facility provided by D&O.

Cash and cash equivalents were €176.6 million as at March 31, 2024, compared to €126.1 million as 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 earnings (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 to net loss for the period, which is the most directly comparable IFRS measure, is set forth below:

€ in million	Three months ending March 31	
(consolidated per IFRS)	**2024**	**2023**
Profit/(Loss) for the period	58.9	(18.1)
Add:		
Income tax expense	-	(0.1)
Total Finance income	(0.3)	(0.3)
Total Finance expense	7.0	5.1
Foreign exchange gain/(loss) – net	2.5	(3.2)
Amortization	1.3	1.6
Depreciation	3.5	2.6
Impairment	-	-
Adjusted EBITDA	**73.0**	**(12.3)**

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®.

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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 guidance for certain financial results in fiscal year 2024 and mid-term outlook on financial results, cash position, and other business developments, including results of ongoing clinical trials, the timing and possible occurrence of further or initial regulatory approvals of its product candidates, the anticipated size of markets for its approved products and sales of those products, receipt of funding from external sources, supply of products sold by Valneva, and relationships with current business partners. 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. These risks and uncertainties include those developed or identified in any public documents filed with the French financial markets authority (*Autorité des marchés financiers*) and the U.S. Securities and Exchange Commission made or to be made by Valneva. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines (including in relation to organic or strategic expansion of Valneva's clinical pipeline), 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 economic or political events, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, the impact of a pandemic, and changes in the regulatory environment in which Valneva operates. The occurrence of any of these risks and uncertainties 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.