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Valneva Reports Half Year 2024 Financial Results and Provides Corporate Updates

First-Half Sales Performance in Line with Full-Year 2024 Guidance

- Total revenues of €70.8 million, including product sales of €68.3 million, in line with anticipated supply and sales phasing
- Net Profit of €34.0 million, including proceeds from PRV sale
 - Operating profit of €46.7 million compared to an operating loss of €35.0 million in the first half of 2023
- Cash position of €131.4 million
 - Substantially lower cash burn expected in the second half of 2024 as Valneva completed its cost contributions to the agreed R&D budget for its partnered Lyme disease program in the second quarter
 - Significantly extended cash runway with update of debt financing agreement¹

Full-year 2024 Financial Guidance Confirmed

- Expected total revenues between €170 million and €190 million, including €160 million to €180 million of product sales
- Expected R&D investments between €60 million and €75 million
- Expected Other income between €100 million and €110 million, including €95 million from the PRV sale

Strategic Pipeline Expansion, Strong Clinical and Regulatory Execution

- Exclusive worldwide license for S4V *Shigella* vaccine candidate, adding an attractive Phase 2 clinical asset to Valneva's R&D pipeline without impacting full-year or mid-term financial quidance²
- Additional marketing authorizations for single-shot IXCHIQ[®] granted in Europe and Canada ahead of initial guidance; Ongoing regulatory reviews in the UK and Brazil; Recommended by ACIP and adopted by U.S. CDC³
- New CEPI grant⁴ of \$41.3 million contributes significantly to Phase 4 costs and other studies supporting broader access to the world's first chikungunya vaccine

August 13, 2024 VALNEVA SE

¹ Valneva Announces Extension of the Interest-Only Period of Its Debt Facility with Deerfield and OrbiMed - Valneva

² Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate - Valneva

³ ACIP Vaccine Recommendations and Schedules | CDC

⁴ CEPI Expands Partnership with Valneva with a \$41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva



- Reported positive six-month data for Phase 3 adolescent study of IXCHIQ^{®5}; expects to submit label extensions for 12 to 17 years old in the U.S., Europe and Canada in the second half of 2024
- IXCHIQ® two-year antibody persistence data published in the Lancet Infectious Diseases
- IXCHIQ® pediatric Phase 2 study fully enrolled
- Completed primary vaccinations (three doses) of VALOR Lyme disease Phase 3 trial participants⁶
- Initiated Phase 1 clinical trial for second-generation Zika vaccine candidate⁷

Financial Information

(Unaudited results, consolidated per IFRS)

€ in million	6 months ended June 30,	
	2024	2023
Total revenues	70.8	73.7
Product sales	68.3	69.7
Net profit / loss	34.0	(35.0)
Adjusted EBITDA ⁸	56.2	(28.3)
Cash	131.4	204.4

Saint-Herblain (France), August 13, 2024 – <u>Valneva SE</u> (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its consolidated financial results for the first half of the year, ended June 30, 2024. 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 (<u>Financial Reports – Valneva</u>).

Valneva will provide a live webcast 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/mmuf8305

Peter Bühler, Valneva's Chief Financial Officer, commented, "Our first half sales performance is in line with our expectations. We aim to further capitalize on the travel industry recovery as we focus on ramping up sales for IXCHIQ® to support our commercial growth, while continuing to execute on our key R&D and regulatory milestones. The successful sale of our PRV and deferral of our loan reimbursement allow us to maintain a solid cash position and, with completion of our payments for the Lyme disease program in the second quarter, we anticipate a significantly lower cash burn in 2024."

⁵ Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva

⁶ Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion - Valneva

⁷ Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva

⁸ 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 half of 2024 were €68.3 million compared to €69.7 million (€64.0 million excluding final COVID-19 vaccine sales) in the first half of 2023. While product sales grew meaningfully in the second quarter and included first sales for IXCHIQ®, first half 2024 sales were affected by previously reported supply constraints for IXIARO® and third-party products.

JAPANESE ENCEPHALITIS VACCINE IXIARO®/JESPECT®

In the first half of 2024, IXIARO®/JESPECT® sales increased by 38% to €41.9 million compared to €30.3 million in the first half of 2023. The increase primarily reflects sales to the U.S. military, which were minimal in the first half of 2023, as well as increased sales to travelers.

CHOLERA / ETEC9-DIARRHEA VACCINE DUKORAL®

In the first half of 2024, DUKORAL[®] sales were €14.9 million compared to €17.1 million in the first half of 2023. The decrease was due to reduced marketing investments while Valneva's new manufacturing site in Sweden underwent regulatory evaluation and approval.

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. ¹⁰, Europe¹¹, and Canada¹² 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 guarter 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)¹³ at the beginning of March 2024, Valneva recognized initial sales of €1.0 million in the first half of 2024. Key launch metrics, 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.

In addition to ramping up sales, Valneva is focusing on expanding the vaccine's label and access. The Company expects marketing authorizations in the UK and Brazil in the second half of 2024 and

⁹ 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.

¹⁰ Valneva Announces Ú.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva

¹¹ Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva

¹² Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva

¹³ ACIP Vaccine Recommendations and Schedules | CDC



recently expanded its partnership with CEPI¹⁴ to support broader access to the vaccine in Low Middle-Income Countries (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 European Union's (EU) Horizon Europe program.

Based on positive pivotal six-month Phase 3 data reported in May 2024¹⁵, Valneva expects to file for potential label extensions for use in adolescents aged 12 to 17 years in the second half of 2024. These data show that a single-dose vaccination with IXCHIQ[®] induces a high and sustained immune response in 99.1% of adolescents, and that the vaccine was generally well tolerated. Conducted in Brazil in collaboration with Instituto Butantan, 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, Valneva recently completed enrollment of a Phase 2 pediatric trial, VLA1553-221, in children aged 1 to 11 years¹⁶, designed to support a Phase 3 pivotal pediatric study and potential future label extension to this age group.

The peer-reviewed medical journal, The Lancet Infectious Diseases, also just published the vaccine's Phase 3 antibody persistence results two years after vaccination with a single dose. The data show that IXCHIQ®'s robust immune response was sustained for two years by 97% of participants and was equally durable in younger and older adults¹7. These data, which further support the anticipated long-term durability of the immune response, will also be used to potentially expand the vaccine's current label. Valneva will continue to measure antibody persistence for a period of at least five years and expects to report three-year durability results later this year.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. During the first half of 2024, third-party sales decreased by 37% to €10.5 million compared to €16.5 million in the first half of 2023 as a result of anticipated supply constraints.

Valneva expects third-party sales to gradually wind down to less than 5% of overall product sales by 2026/2027, allowing the Company to improve gross margins.

Clinical Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15 Phase 3 primary vaccination completed

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

¹⁴ CEPI Expands Partnership with Valneva with a \$41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva

¹⁵ Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva

¹⁶ Valneva Vaccinates First Participant in Pediatric Trial of Single-Shot Chikungunya Vaccine - Valneva

¹⁷ https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00357-8/fulltext



Valneva and Pfizer reported results for the Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which high levels of antibodies against all six serotypes were observed. Results of Phase 2 trials VLA15-201 and VLA15-202 were published in the peer-reviewed medical journal, the Lancet Infectious Diseases, in June 2024¹⁸. Additional 18-month booster results from Study VLA15-202 were also published in the same journal in July 2024¹⁹.

In July 2024, Valneva and Pfizer announced completion of primary vaccinations (three doses) of over 9,000 participants in the Phase 3 trial "Vaccine Against Lyme for Outdoor Recreationists" (VALOR)²⁰.

Completion of the VALOR trial is still 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.

Based on the agreement with Pfizer, Valneva's agreed-upon 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 - S4V

Valneva recently entered into a strategic partnership and exclusive licensing agreement with LimmaTech Biologics AG for the development, manufacturing and commercialization of Shigella4V (S4V), a tetravalent bioconjugate vaccine candidate against shigellosis²¹.

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 year²², particularly among children in Low- and Middle-Income Countries (LMICs). No approved Shigella vaccine is currently available and the development of Shigella vaccines has been identified as a priority by the World Health Organization (WHO)23. 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 annually²⁴.

Under the terms of the agreement with Valneva, LimmaTech will receive an upfront payment of €10 million and be 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. LimmaTech will conduct a Phase 2 Controlled Human Infection Model study (CHIM) in the U.S. and a Phase 2 pediatric study in LMICs. Both clinical trials are 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.

¹⁸ Valneva Announces Publication of Lyme Disease Phase 2 Trials in the Lancet Infectious Diseases - Valneva

¹⁹ Immunogenicity and safety of an 18-month booster dose of the VLA15 Lyme borreliosis vaccine candidate after primary immunisation in healthy adults in the USA: results of the booster phase of a randomised, controlled, phase 2 trial - The Lancet Infectious Diseases

Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion - Valneva

²¹ LimmaTech Biologics AG

²² Shigellosis | CDC Yellow Book 2024

²³ Immunization, Vaccines and Biologicals (who.int)

²⁴ Valneva's Initial internal assessment



The anticipated development path follows a staggered and risk-mitigated strategy, allowing an efficient capital allocation in line with Valneva's communicated plan of having a new R&D program in Phase 3 by 2027.

ZIKA VACCINE CANDIDATE - VLA1601 Phase 1 ongoing with second-generation vaccine candidate

VLA1601 is a second-generation adjuvanted inactivated vaccine candidate against the mosquitoborne 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. The randomized, placebocontrolled, 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 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.

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

First Half 2024 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €70.8 million in the six months ended June 30, 2024 compared to €73.7 million in the six months ended June 30, 2023.

Valneva's total product sales reached €68.3 million in the six months ended June 30, 2024 compared to €69.7 million in the same period of 2023. The impact of currency fluctuations of €0.1 million was minimal.

Excluding final COVID-19 vaccine sales in the six months ended June 30, 2023, travel vaccine sales show a growth of €4.3 million or 7% year-over-year.

IXIARO®/JESPECT® sales were €41.9 million in the six months ended June 30, 2024 compared to €30.3 million in the six months ended June 30, 2023. The 38% increase primarily reflects sales to the U.S. military, which were minimal in the first half of 2023, as well as increased sales to travelers. The impact of foreign currency movements in IXIARO®/JESPECT® sales was negligible.

 ²⁵ Valneva Initiates Phase 1 Trial of Second-Generation Zika Vaccine Candidate - Valneva
 ²⁶ Zika virus disease (who.int)

²⁷ Tropical Disease Priority Review Voucher Program | FDA



DUKORAL® sales were €14.9 million in the six months ended June 30, 2024 compared to €17.1 million in the comparative period of 2023. This 13% decrease was due to reduced marketing investments while Valneva's new manufacturing site in Sweden underwent regulatory evaluation and approval. Foreign currency fluctuations had an immaterial impact on DUKORAL® sales.

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) at the beginning of March 2024, Valneva recognized initial sales for IXCHIQ® of €1.0 million in the first half of 2024. Third Party product sales were €10.5 million in the six months ended June 30, 2024 compared to €16.5 million in the six months ended June 30, 2023. This 37% decrease was mainly driven by lower sales of Rabipur®/RabAvert® and Encepur®, under the distribution agreement with Bavarian Nordic, due to supply shortages.

Other revenues, including revenues from collaborations, licensing and services amounted to €2.5 million in the six months ended June 30, 2024 compared to €4.1 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 and the divestment of the CTM unit in Sweden in July 2023.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €45.6 million in the six months ended June 30, 2024. The gross margin on commercial product sales, excluding IXCHIQ®, amounted to 47.7% compared to 40.0% in the six months ended June 30, 2023. COGS of €17.8 million related to IXIARO® product sales, yielding a product gross margin of 57.5%. COGS of €9.7 million related to DUKORAL® product sales, yielding a product gross margin of 34.8%. Product gross margins are expected to improve in the second half of the year as the supply shortages during the first half have been resolved. Of the remaining COGS in 2024, €7.7 million related to the third-party products distribution business, €4.0 million to IXCHIQ®, €2.1 million to idle capacity costs and €4.6 million to cost of services. In 2023, overall COGS were €53.8 million, of which €48.4 million related to cost of goods and €5.5 million related to cost of services.

Research and development expenses amounted to €29.7 million in the six months ended June 30, 2024, compared to €26.0 million in the six months ended June 30, 2023. This increase was mainly driven by higher costs related to the ongoing transfer of operations into the new Almeida manufacturing facility and higher R&D costs for IXCHIQ®. Marketing and distribution expenses in the first six months of 2024 amounted to €23.2 million compared to €20.0 million in the first six months of 2023. The increase is mainly related to €9.8 million of expenses associated with launch activities for IXCHIQ® (first half of 2023: €7.8 million). In the six months ended June 30, 2024, general and administrative expenses remained stable at €22.8 million after €22.9 million in the same period of 2023. The largest expense categories were employee-related expenses of €10.5 million and consulting and other services of €9.6 million.

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.

Other income, net of other expenses decreased to €6.4 million in the six months ended June 30, 2024 from €14.0 million in the six months ended June 30, 2023. In the first half of 2023, Valneva



recorded income from grants and tax credits for research and development totaling €14.9 million, of which €8.7 million were awarded by Scottish Enterprise (SE) for non-COVID-19 vaccine development (IXCHIQ® and IXIARO®).

Valneva recorded an operating income of €46.7 million in the six months ended June 30, 2024 compared to an operating loss of €35.0 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 six months ended June 30, 2024 was €56.2 million, whereas in the six months ended June 30, 2023 an adjusted EBITDA loss of €28.3 million was recorded.

Net Result

In the six months ended June 30, 2024, Valneva generated a net profit of €34.0 million, mainly resulting from the sale of the PRV in February 2024. This compared to a net loss of €35.0 million in the first half of 2023.

Finance expense and currency effects in the first half of 2024 resulted in a net finance expense of €12.8 million, compared to a net finance expense of €3.9 million in the first half of 2023. This increase was mainly due to €5.7 million higher interest expenses on loans resulting from the amendment of the Deerfield Management Company and OrbiMed (D&O) loan facility. Additionally foreign exchange losses of €1.7 million were recorded in the first half of 2024 compared to gains of €4.5 million observed in the first half 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 €66.3 million in the six months ended June 30, 2024 compared to €65.4 million of cash used in operating activities in the same period of 2023. Cash outflows in the first half of 2024 were largely derived from the operating loss for the period (net of gains from PRV sale) amounting to €56.9 million and from working capital in the amount of €31.2 million, which includes all payments to the Lyme disease clinical program as per the R&D budget agreed between Pfizer and Valneva. In 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 €87.6 million in the six months ended June 30, 2024 compared to cash outflows of €6.6 million in the six months ended June 30, 2023. While both years include outflows from construction activities across production sites in Scotland and Sweden, the sale of the PRV positively impacted 2024 by €90.8 million.

Net cash used in financing activities increased to €16.6 million in the six months ended June 30, 2024 from €9.5 million in the six months ended June 30, 2023. This increase was primarily due to €5.4 million higher interest payments resulting from the increase in the D&O loan facility.

Cash and cash equivalents were €131.4 million as at June 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 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)	2024	2023
Net profit / (loss)	34.0	(35.0)
Add:		
Income tax benefit	(0.2)	(3.8)
Total Finance income	(0.8)	(0.5)
Total Finance expense	12.0	8.9
Foreign exchange (gain)/ loss – net	1.7	(4.5)
Amortization	2.5	3.2
Depreciation	7.0	5.4
Impairment, excluding impairment loss of disposal	-	(1.9)
Adjusted EBITDA	56.2	(28.3)

About Valneva

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.

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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 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 forwardlooking 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 financial 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.