

# Valneva Reports First Quarter 2025 Financial Results and Provides Corporate Updates

May 7, 2025



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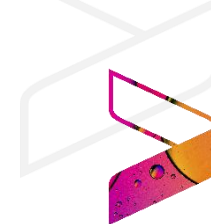
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This presentation presents information about investigational vaccine candidates that have not been approved for use and have not been determined by any regulatory authority to be safe or effective.

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 supplemental measure of performance used by investors and financial analysts. Management believes this measure provides additional analytical tools.

# Agenda



## Introduction

## Business Update

## Financial Report Q1 2025

## Financial Outlook

## Growth Drivers

## Q&A

## First Quarter 2025 Key Highlights



### Total Revenues

**€49.2m**

50% YoY growth

### Solid Cash Position

**€153m**

Excludes \$14.2m gross proceeds  
(April ATM transaction)

**Q1 2025**

### Strong Regulatory Execution

IXCHIQ® adolescent label extension;  
First endemic-market approval (Brazil)

### 71% Reduction in Operating Cash Burn\*

Targeting 50% reduction  
vs. 2024

\* €8.1 million compared to €28.4 million in the first quarter of 2024

# First Quarter 2025 Highlights



## Fulfilling Unmet Medical Needs

- New \$32.8 million IXIARO® U.S. Department of Defense contract
- Responding to French government's call for IXCHIQ® to combat chikungunya outbreaks in La Réunion and Mayotte
- Responding to cholera outbreak in Mayotte by supplying doses of DUKORAL®

## Regulatory Achievements

- Latest marketing authorization in the UK for IXCHIQ® in individuals 18 years of age and older; submitted adolescent label extension application
- First IXCHIQ® label extension in Europe in individuals 12 years of age and older
- World's first approval of a chikungunya vaccine in an endemic country; IXCHIQ® marketing authorization in Brazil

## Clinical Data & Pipeline Progress

- Reported high sustained immune response in adolescents one year after single IXCHIQ® vaccination (Phase 3)
- Reported positive Phase 2 pediatric results for IXCHIQ®; dose decision for planned Phase 3 study
- First vaccination in Phase 2 infant study of tetravalent Shigella vaccine candidate S4V2



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**Introduction**

**Business Update**

**Financial Report Q1 2025**

**Financial Outlook**

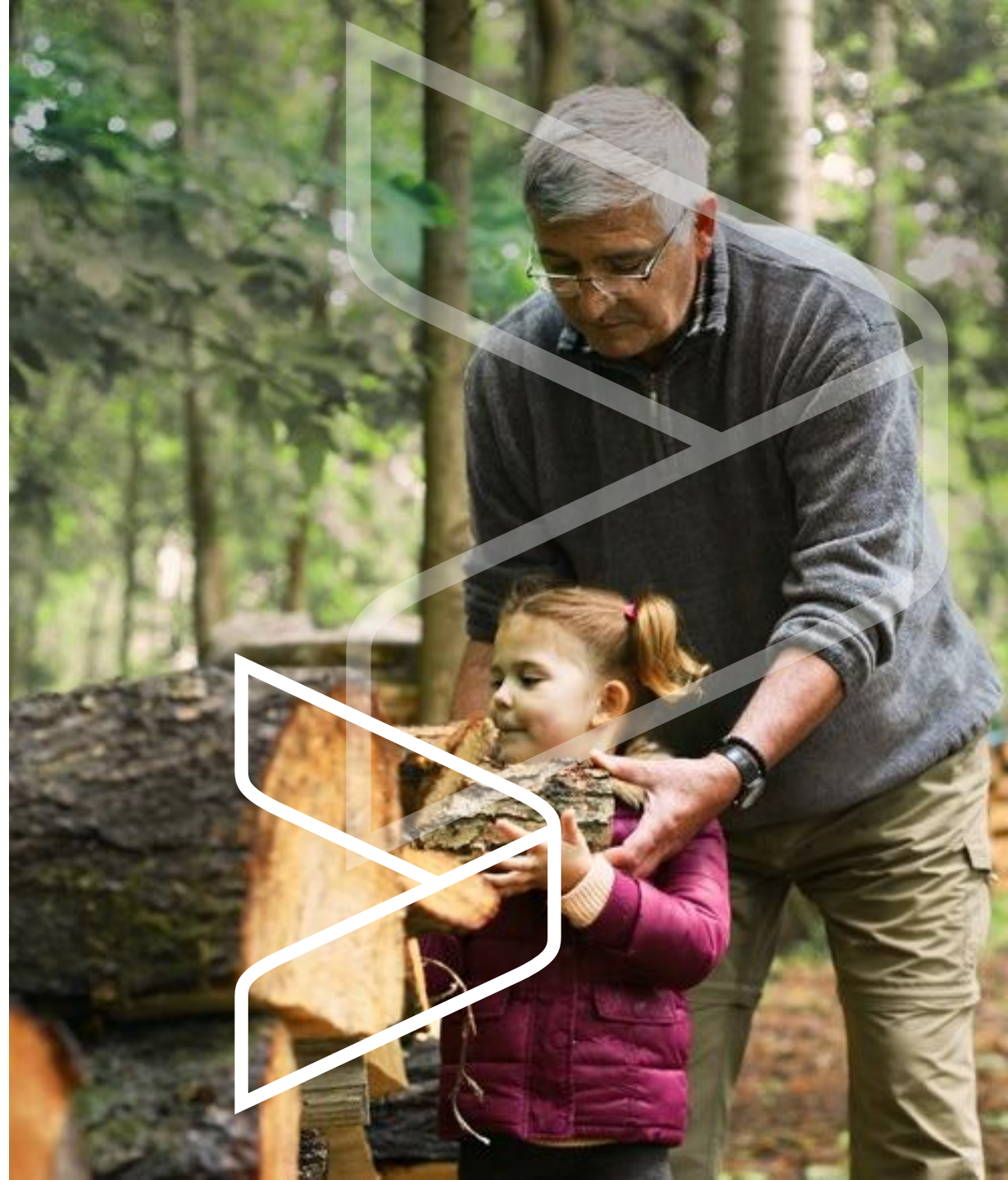
**Growth Drivers**

**Q&A**

# World's leading Lyme Disease Vaccine Candidate

VLA15

 valneva



# Lyme Disease Represents a Major Medical Need and Market Opportunity

No vaccine is currently available to prevent Lyme disease in humans



## Annual Burden of Disease

**U.S.<sup>1</sup>**  
**~476K** cases

**Europe<sup>2</sup>**  
**>129K** cases

### Severe Manifestations<sup>3</sup>

**10-30%**  
cases develop



Lyme carditis  
Lyme neuroborreliosis  
Lyme arthritis

### Persistent Symptoms<sup>4,5</sup>

**5-10%**

cases continue to have persistent symptoms following treatment

## Commercial opportunity for Valneva



**U.S.**  
**87 million**



**Europe**  
**202 million**

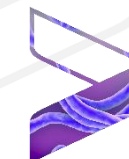
**Population Living in Endemic Regions<sup>1,2</sup>**

**>\$1 billion estimated global market<sup>6</sup>**

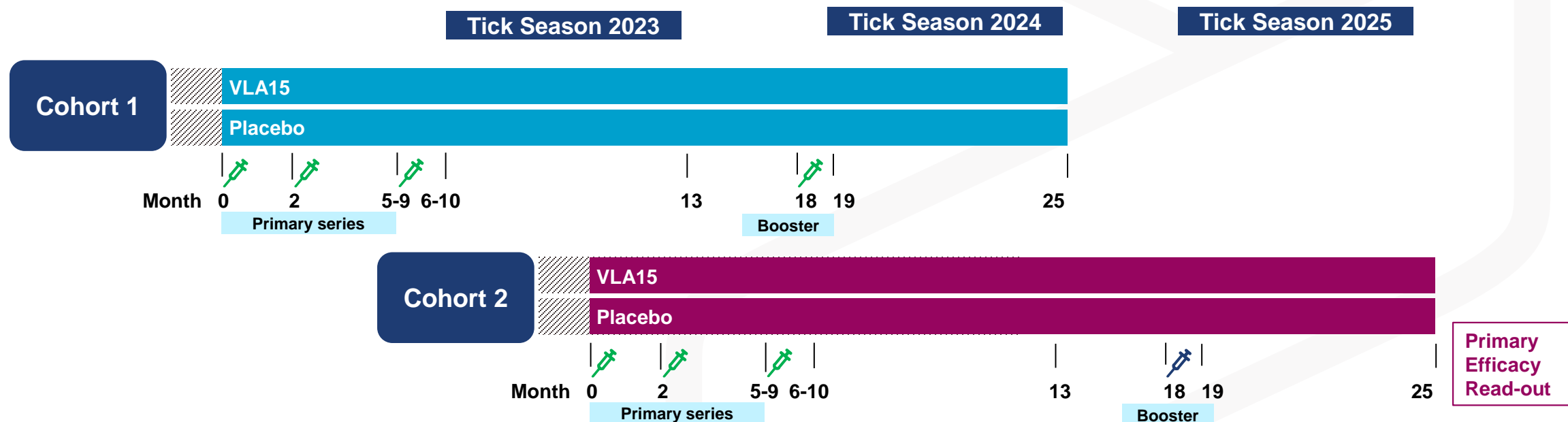
<sup>1</sup> Kugeler et al. Emerging Infectious Disease, 2021 (doi.org/10.3201/eid2702.202731); <sup>2</sup> Burn et al. Vector Borne and Zoonotic Disease, 2023 (DOI: 10.1089/vbz.2022.0071); <sup>3</sup> Schwartz et al. Morbidity and Mortality Weekly Report Nov. 10, 2017; <sup>4</sup> Ursinus: [https://www.thelancet.com/journals/lanpe/article/PIIS2666-7762\(21\)00119-8/fulltext](https://www.thelancet.com/journals/lanpe/article/PIIS2666-7762(21)00119-8/fulltext); <sup>5</sup> Aucott, J.N., et al., Risk of post-treatment Lyme disease in patients with ideally-treated early Lyme disease: A prospective cohort study. Int J Infect Dis, 2022. 116: p. 230-237.; <sup>6</sup> Lyme Disease research and analysis conducted by an independent market research firm

## Phase 3: First Data Expected at the End of 2025

Pfizer aims to submit regulatory applications in U.S. and Europe in 2026<sup>1</sup>



- **Population:** ~9,400 evaluable participants  $\geq 5$  years of age at high risk of Lyme disease (LD) (by residence and occupational/recreational activities) in U.S., Canada and Europe (randomization approx. 1:1 VLA15/Placebo and 2:1 N. America/EU)
- **Primary endpoint:** Rate of confirmed LD cases<sup>2</sup> after 2nd consecutive tick season (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed<sup>1</sup> LD cases after 1st tick season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol



<sup>1</sup> Subject to positive data; <sup>2</sup> Cases are evaluated and confirmed by an Endpoint Adjudication Committee

# A Highly Differentiated single-shot Chikungunya Vaccine

**IXCHIQ® / VLA1553**

IXCHIQ® is approved by the European Medicines Agency (EMA) in individuals 12 years of age and older. It is approved by the U.S. Food & Drug Administration (FDA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), Health Canada and the Brazilian health regulatory agency (ANVISA) in individuals 18 years of age and older

Continued approval of IXCHIQ® is contingent upon verification of clinical benefit in confirmatory studies.



## IXCHIQ® Builds on Key Differentiators to Drive Growth



Provides a strong and persistent immune response  
with a single dose

- 98.9% seroresponse rate at Day 29 - Sustained seroresponse rate at 96% after three years<sup>1</sup>
- Strong and persistent immune response in adults 18-64 yrs and 65+<sup>2</sup>, as well as adolescents
- Generally well tolerated among the >3,600 adults, 754 adolescents and 304 children evaluated for safety<sup>3</sup>

1. Two-year antibody persistence (97%) included in current EU label; submitted for inclusion in U.S., UK, and Canadian labels; 2. Included in current U.S., EU, UK, and Canadian labels; 3. No adverse drug reaction reported since approval of IXCHIQ® indicate any changes compared to knowledge from clinical trials.

# Recent Changes to IXCHIQ® Recommendations



## Responses to reports of serious adverse events (SAEs) in frail elderly individuals

- ACIP recommended a precaution for use in 65+ with comorbidities
- EMA cautioned against use in frail older adults, especially those with comorbidities potentially affecting immune responses to the vaccine
- Haute Autorité de Santé (HAS) in France suspended recommendation for use in 65+ in ongoing vaccination campaign to combat La Réunion outbreak; campaign remains active for people 18 to 64

## We are committed to the highest standards of safety and appreciate these precautionary decisions

- Investigations into SAEs remain ongoing and causality has not been definitively established
- We will continue to closely monitor reported adverse effects and cooperate fully with health authorities while working proactively on a potential update of the product's indication

## Positive risk-benefit in the vast majority of people with potential exposure to the disease

- SmPC\* states: IXCHIQ® must not be given to people who are immunodeficient or immunosuppressed due to a disease or treatment

\* Summary of product characteristics

# IXCHIQ®: Focused on Expanding Access, Label Extension, Product Profile

Robust clinical program supported by new \$43.1 million CEPI grant<sup>1</sup>



## Post-Marketing Effectiveness<sup>2</sup> (Phase 4)

*To confirm effectiveness following licensure based on an immunological surrogate of protection and to optimize description of the safety profile*

- Observational effectiveness study in Brazil
- Pragmatic randomized controlled effectiveness and safety study<sup>3</sup>: adults (and adolescents - tbc) in endemic countries
- Prospective safety cohort study and pregnancy surveillance in Brazil

## Label Extension

*To expand access to the vaccine for all age groups*

- Phase 3: Randomized, controlled study in adolescents aged 12 to 17 years
- Phase 3: Randomized, controlled study in children aged 1 to 11 years

Reported positive data up to Month 12

Planned, based on (+) Ph2<sup>4</sup>

## Product Profile

*To confirm the long-term durability of the immune response and further differentiate the vaccine*

- Phase 3: Ongoing antibody persistence and long-term safety study in adults; reported positive 36-month results to date

1. <https://valneva.com/press-release/cepi-expands-partnership-with-valneva-with-a-41-3-million-grant-to-support-broader-access-to-the-worlds-first-chikungunya-vaccine/>; 2. <https://www.fda.gov/media/173759/download>;

3. <https://www.fda.gov/media/172166/download>; 4. Valneva Reports Positive Phase 2 Results in Children for its Chikungunya Vaccine and Announces Phase 3 Dose Decision

# World's Most Clinically Advanced Tetravalent *Shigella* Vaccine Candidate

S4V2

 valneva




# S4V2: Opportunity to Develop First-in-Class Vaccine for a Life-Threatening Disease

Tetravalent bioconjugate vaccine with potential to cover up to ~85% of shigellosis infections<sup>1</sup>



## Vaccine Highlights



- World's most clinically advanced tetravalent *Shigella* vaccine candidate
- Exclusive global license from  (LMTB)<sup>2</sup>
- Includes four most common pathogenic *Shigella* bacteria serotypes: *S. flexneri* 2a, 3a, 6, and *S. sonnei*
- Positive Phase 1/2 clinical data reported<sup>3</sup>
- Awarded FDA Fast Track designation

## Market Opportunity



- Global market expected to exceed \$500 million annually<sup>4</sup>
- Travelers and military
- Endemic countries (LMICs<sup>5</sup>)
- Second-leading cause of fatal diarrheal disease; Up to estimated 165 million cases and 600,000 deaths annually<sup>6</sup>
- Identified as a priority vaccine by World Health Organization (WHO)<sup>7</sup>

## Upcoming Milestones



- Phase 2 infant study launched in 2025; data expected H2 2025
- Ongoing Phase 2b CHIM<sup>8</sup> study aiming to provide early look at potential efficacy; data expected H1 2026
- Upon success, Valneva to assume all further R&D, CMC<sup>9</sup> and regulatory activities; worldwide commercialization upon potential approved

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8878964/pdf/vaccines-10-00212.pdf>; 2. Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent *Shigella* Vaccine Candidate; 3. 20240221\_LimmaTech\_Shigella-Interim-Data-PR\_Final.pdf (lmtbio.com); 4. LEK 2024; Appox. 7 years after launch; 5. Low-and-Middle-Income Countries; 6. *Shigellosis* / CDC Yellow Book 2024; 7. Immunization, Vaccines and Biologicals (who.int); 8. Controlled Human Infection Model; 9. Chemistry, Manufacturing and Controls

# Novel Zika Virus Vaccine Candidate

VLA1601



# VLA1601: Optimized Vaccine Candidate Against Zika Virus

Phase 1 results expected this year



## Vaccine Highlights



- Novel adjuvanted inactivated whole-virus vaccine
- Leverages Valneva's proven / licensed platform (VLA2001)
- Phase 1 results from previous candidate showed excellent immunogenicity and safety results<sup>1</sup>

## Market Opportunity



- Flaviviral disease transmitted by *Aedes* mosquitoes<sup>2</sup>
- Devastating effects<sup>3</sup>:
  - Microcephaly & severe brain defects in newborns
  - Guillain-Barré syndrome in adults
- No vaccines or specific treatment available – PRV eligible; potential funding from public institutions

## Upcoming Milestones



- Execute Phase 1 clinical trial with enhanced process and optimized vaccine formulation
- Evaluate future development strategy based on:
  - Phase 1 results
  - Market potential
  - External, non-dilutive funding

<sup>1</sup> Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus; <sup>2</sup> <https://www.cdc.gov/zika/transmission/index.html>; <sup>3</sup> <http://www.who.int/mediacentre/factsheets/zika/en/>

# Agenda

**Introduction**

**Business Update**

**Financial Report Q1 2025**

**Financial Outlook**

**Growth Drivers**

**Q&A**



## Q1 2025 Financials: Product Sales of €48.6 million

Reflects IXCHIQ<sup>®</sup> launch, recovery from Q1 2024 supply shortages

€m (audited)	Q1 2025	Q1 2024	% Change
IXIARO <sup>®</sup> /JESPECT <sup>®</sup>	27.5	16.6	65.5%
DUKORAL <sup>®*</sup>	12.3	11.3	9.4%
IXCHIQ <sup>®**</sup>	3.0	0.2	1665%
Third party products	5.8	4.1	41.1%
<b>Total product sales</b>	<b>48.6</b>	<b>32.1</b>	<b>51.2%</b>

\* Includes €1.1 million related to supply of doses to the French island of Mayotte

\*\* Includes very small amount of the 40,000 doses Valneva supplied to La Réunion to respond to the chikungunya outbreak, as the large majority were only shipped in April 2025

## Q1 2025 Financials: Income Statement



€m (unaudited)	Q1 2025	Q1 2024
Product sales	48.6	32.1
Other Revenues	0.6	0.6
<b>Revenues</b>	<b>49.2</b>	<b>32.8</b>
Cost of goods and services	(23.0)	(22.2)
Research and development expenses	(15.0)	(13.1)
Marketing and distribution expenses	(10.4)	(11.3)
General and administrative expenses	(9.0)	(11.7)
Gain from sales of Priority Review Voucher, net	--	90.8
Other income / (expense), net	2.2	2.9
<b>Operating profit / (loss)</b>	<b>(6.0)</b>	<b>68.2</b>
Finance, investment in associates & income taxes	(3.3)	(9.3)
<b>Profit / (Loss) for the period</b>	<b>(9.2)</b>	<b>58.9</b>
<b>Adjusted EBITDA<sup>1</sup></b>	<b>(0.6)</b>	<b>73.0</b>

<sup>1</sup> Q1 2025 Adjusted EBITDA was calculated by excluding €8.6 million (Q1 2024: €14.0 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), depreciation, amortization and impairment from the €9.2 million loss (Q1 2024: €58.9 million profit) for the period as recorded in the consolidated income statement under IFRS. Click [here](#) for important information about Non-IFRS measures such as Adjusted EBITDA and a reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure.

# Agenda

**Introduction**

**Business Update**

**Financial Report Q1 2025**

**Financial Outlook**

**Growth Drivers**

**Q&A**

# Valneva Remains Solidly Funded with Strong Financial Outlook



## 2025 Guidance

- Product Sales: €170 - €180 million<sup>1</sup>; Commercial business expected to be cash-flow positive
- Total Revenues: €180 - €190 million
- R&D Expense: €90 - €100 million, partially offset by grant funding and anticipated R&D tax credits
- Targeting >50% lower operational cash burn:
  - <€30 (vs. >€60 in 2024)
- Stringent focus on cash management supporting sufficient cash runway to reach key inflection points



## Financial Outlook

- Continued revenue growth and cash flows from commercialized vaccines
- Focused and strategic investments in R&D
  - Next Phase 3 program entry post Lyme data
  - Further R&D support: potential non-dilutive funding
- Gross margin improvement
  - Focus on proprietary sales
  - Cost-efficient manufacturing leveraging new facilities
- Potential for sustained profitability from 2027 based on successful Lyme disease vaccine approval and commercialization

1. Assumes continued wind down of third-party sales business; 2. Low- and middle-income countries

# Agenda

**Introduction**

**Business Update**

**Financial Report Q1 2025**

**Financial Outlook**

**Growth Drivers**

**Q&A**

# Valneva Outlook: Growth Drivers for 2025 and Beyond



## VLA15 success case

- Potential for sustained profitability upon potential approval and commercialization\*, driven by substantial milestones and royalties starting in 2027

## Growing commercial revenues

- Near term: continued growth trajectory of IXIARO® and DUKORAL®
- Further growth as IXCHIQ® gains global traction

## Realizing future pipeline value

- Shigella and Zika in ongoing and planned studies
- Goal to enter next Phase 3 post-Lyme

\*Subject to positive Phase 3 data

# Agenda

**Introduction**

**Business Update**

**Financial Report Q1 2025**

**Financial Outlook**

**Growth Drivers**

**Q&A**

**Thank you**  
Merci  
Danke  
Tack

