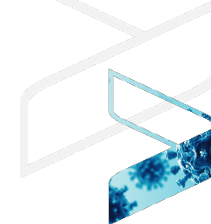


# Valneva's Full Year 2024 Results and Business Update

March 20, 2025



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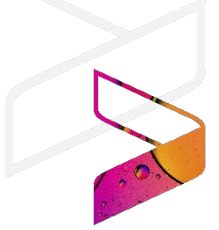
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IXCHIQ® has been approved for use in the United States, Canada, Europe, and the United Kingdom in individuals 18 years of age and older. Continued approval of IXCHIQ® is contingent upon verification of clinical benefit in confirmatory studies. Regulatory review of the VLA1553 chikungunya vaccine candidate remains ongoing in other jurisdictions, and prior approvals do not guarantee approval in other jurisdictions, on similar terms or at all.

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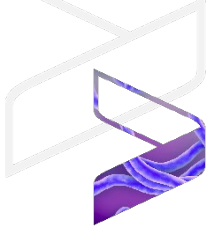
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## Full Year 2024 Key Highlights



**13% YoY Sales Growth**  
**€163.3m**

Aligned with 2024 guidance

**Solid Cash Position**  
**€168.3m**

67% lower operating cash burn  
Successful €57m financing

**FY 2024**

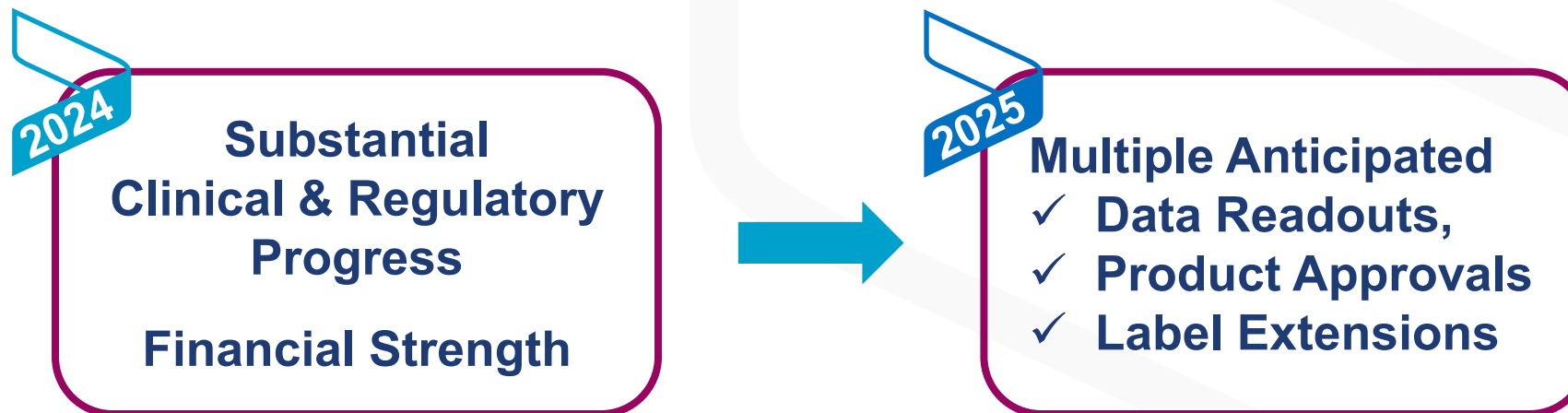
**Strong Regulatory Execution**

3 additional IXCHIQ<sup>®</sup> approvals;  
upcoming label extension(s)

**Pipeline Optimization**

Leading Phase 2 Shigella Program

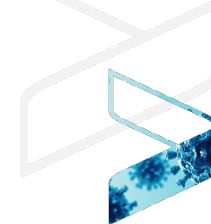
## Execution in 2024 Sets the Stage for Multiple 2025 Milestones



- **Significantly expanded access to IXCHIQ®**
  - Launches underway in Canada, EU, UK
  - New Asian partnership for key endemic markets
- **Reported key clinical findings to support:**
  - Potential label extension(s) for IXCHIQ®
  - IXCHIQ® product differentiation: antibody persistence
  - VLA15 product profile in seasonal Lyme disease
- **Financial position enables continued R&D investment**
  - Solid cash + continued double-digit revenue growth
  - Additional grant funding supports key IXCHIQ® R&D
- **Transformative potential: VLA15 Phase 3 Study**
  - On track for first data readout (2025)
  - Regulatory filings\* (2026), first approvals/sales\* (2027)
- **Further expanded access to IXCHIQ® anticipated**
  - Potential approval in Brazil; first endemic market
  - Adolescent label extension(s) in key markets
  - Further recommendations
- **Meaningful clinical milestones to drive further value**
  - Phase 2b results for Shigella vaccine candidate
  - Phase 1 results for novel Zika vaccine candidate

\*Filings and approvals subject to positive data, and sales subject to successful licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer

# 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<sup>®</sup> and DUKORAL<sup>®</sup>
- Further growth as IXCHIQ<sup>®</sup> 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

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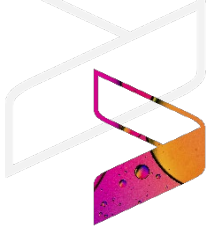
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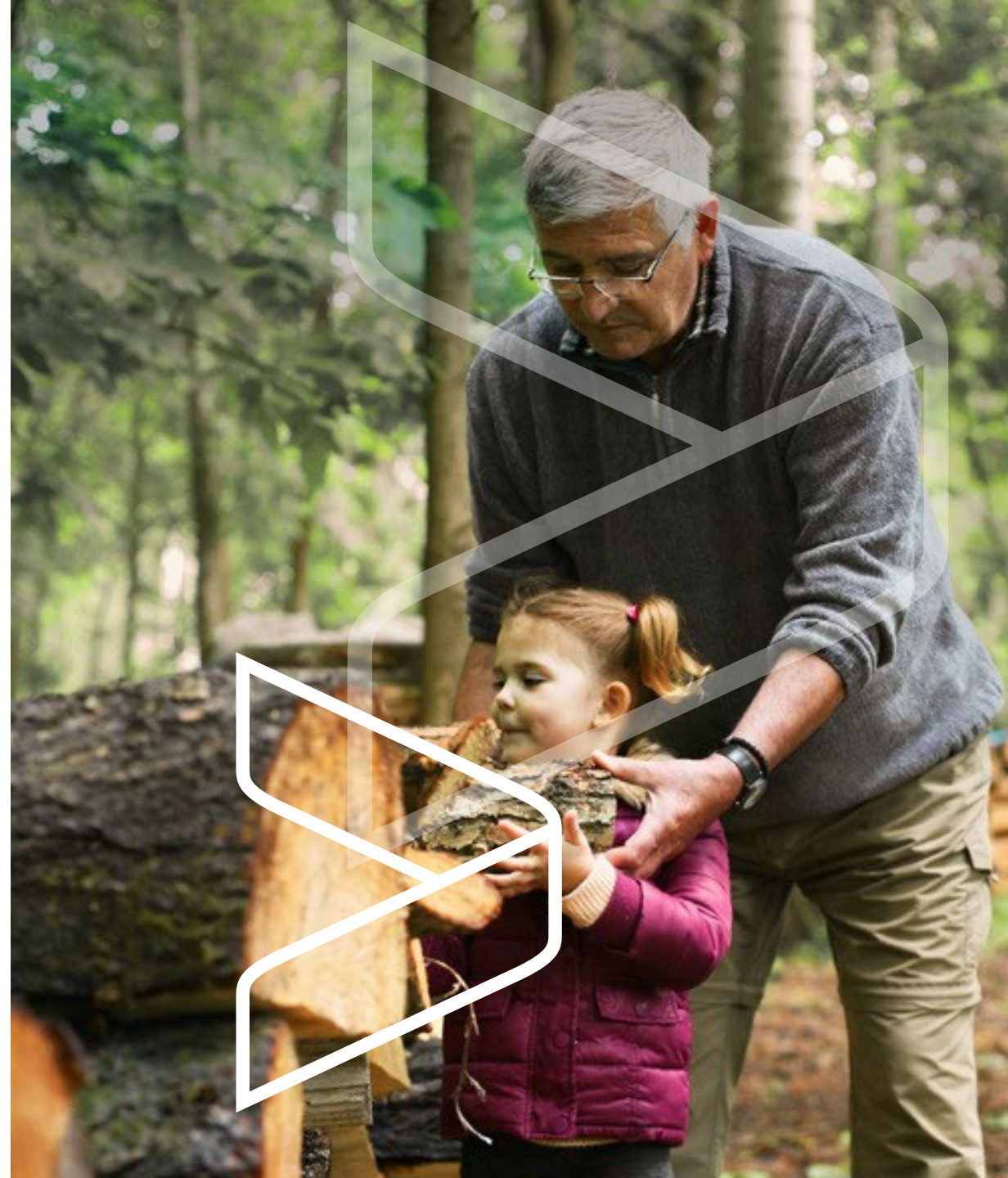




# World's leading Lyme Disease Vaccine Candidate

VLA15

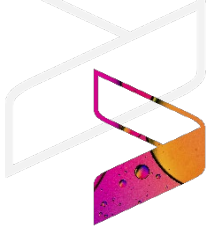
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# Lyme Disease Represents a Major Medical Need and Market Opportunity

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**

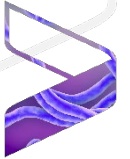
**Population Living in Endemic Regions<sup>1,2</sup>**

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

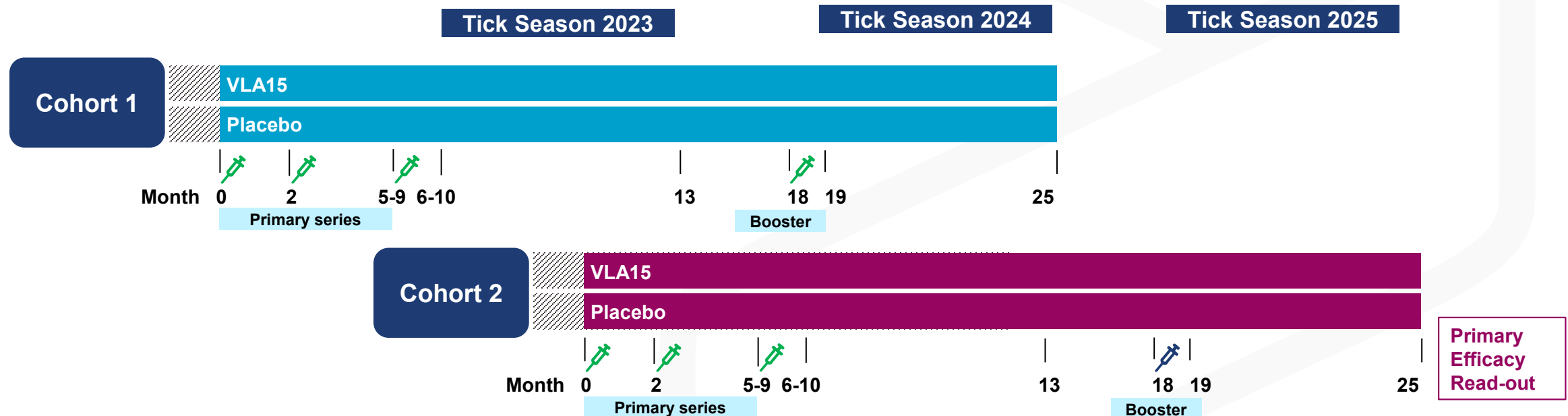
<sup>1</sup> Kugeler et al. Emerging Infectious Disease, 2021 (doi.org/10.3201/eid2702.202731); <sup>2</sup> Burn et al. Vector Borne and Zoonotic Disease, 2023 (DOI: 10.1089/vbz.2022.0071); <sup>3</sup> Schwartz et al. Morbidity and Mortality Weekly Report Nov. 10, 2017; <sup>4</sup> Ursinus: [https://www.thelancet.com/journals/lanpe/article/PIIS2666-7762\(21\)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 Readout 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 ≥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

# The World's First Chikungunya Vaccine

**IXCHIQ<sup>®</sup> / VLA1553**

IXCHIQ<sup>®</sup> is currently approved by the U.S. Food & Drug Administration (FDA), European Medicines Agency (EMA), The UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older.

Continued approval of IXCHIQ<sup>®</sup> is contingent upon verification of clinical benefit in confirmatory studies.

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## IXCHIQ® Builds on Key Differentiators to Drive Growth



The 1<sup>st</sup> vaccine against chikungunya  
providing a strong and persistent immune response  
with only one 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>
- Convenient single dose

1. Two-year antibody persistence (97%) included in current EU label; submitted for inclusion in U.S. 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.



# 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

Starting Q4 2025, 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

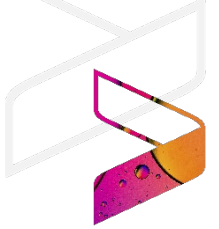
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# S4V2: Opportunity to Develop First-in-Class Vaccine for a Life-Threatening Disease

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



- Ongoing Phase 2 CHIM<sup>8</sup> study aiming to provide early look at potential efficacy
- Phase 2 pediatric study to launch in 2025; to be conducted by LMTB
- 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

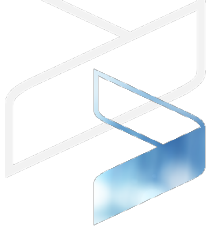
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# VLA1601: Optimized Vaccine Candidate Against Zika Virus

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/>

# Valneva Commercial Business

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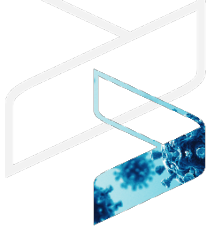
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## FY 2024 Financials: Product Sales of €163.3 million

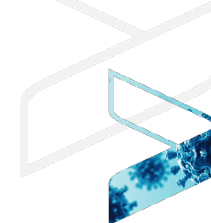
Commercial business showing continued, significant growth

€m (audited)	FY 2024	FY 2023	% Change	% at CER*
IXIARO <sup>®</sup> /JESPECT <sup>®</sup>	94.1	73.5	+28%	+27%
DUKORAL <sup>®</sup>	32.3	29.8	+8%	+9%
IXCHIQ <sup>®</sup>	3.7	--	--	--
Third party products	33.2	35.7	-7%	-8%
<b>Total product sales (excl. COVID-19)</b>	<b>163.3</b>	<b>138.9</b>	<b>+18%</b>	<b>+17%</b>
COVID-19 vaccine	--	5.7	--	--
<b>Total product sales</b>	<b>163.3</b>	<b>144.6</b>	<b>+13%</b>	<b>+13%</b>

\* Constant Exchange Rate



## FY 2024 Financials: Income Statement



€m (audited)	FY 2024	FY 2023
Product sales	163.3	144.6
Other Revenues	6.3	9.1
<b>Revenues</b>	<b>169.6</b>	<b>153.7</b>
Cost of goods and services	(98.5)	(100.9)
Research and development expenses	(74.1)	(59.9)
Marketing and distribution expenses	(52.4)	(48.8)
General and administrative expenses	(42.8)	(47.8)
Gain from sales of Priority Review Voucher, net	90.8	--
Other income / (expense), net	20.7	21.5
<b>Operating Profit / (loss)</b>	<b>13.3</b>	<b>(82.1)</b>
Finance, investment in associates & income taxes	(25.6)	(19.3)
<b>Loss for the period</b>	<b>(12.2)</b>	<b>(101.4)</b>
<b>Adjusted EBITDA<sup>1</sup></b>	<b>32.9</b>	<b>(65.2)</b>

<sup>1</sup> FY 2024 Adjusted EBITDA was calculated by excluding €45.2 million (FY 2023: € 36.2 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), depreciation, amortization and impairment (excluding impairment loss of disposal) from the €12.2 million (FY 2023: €101.4 million) loss 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.

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# 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 grand 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

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## Realizing future pipeline value

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\*Subject to positive Phase 3 data

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Thank you  
Merci  
Danke  
Tack

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