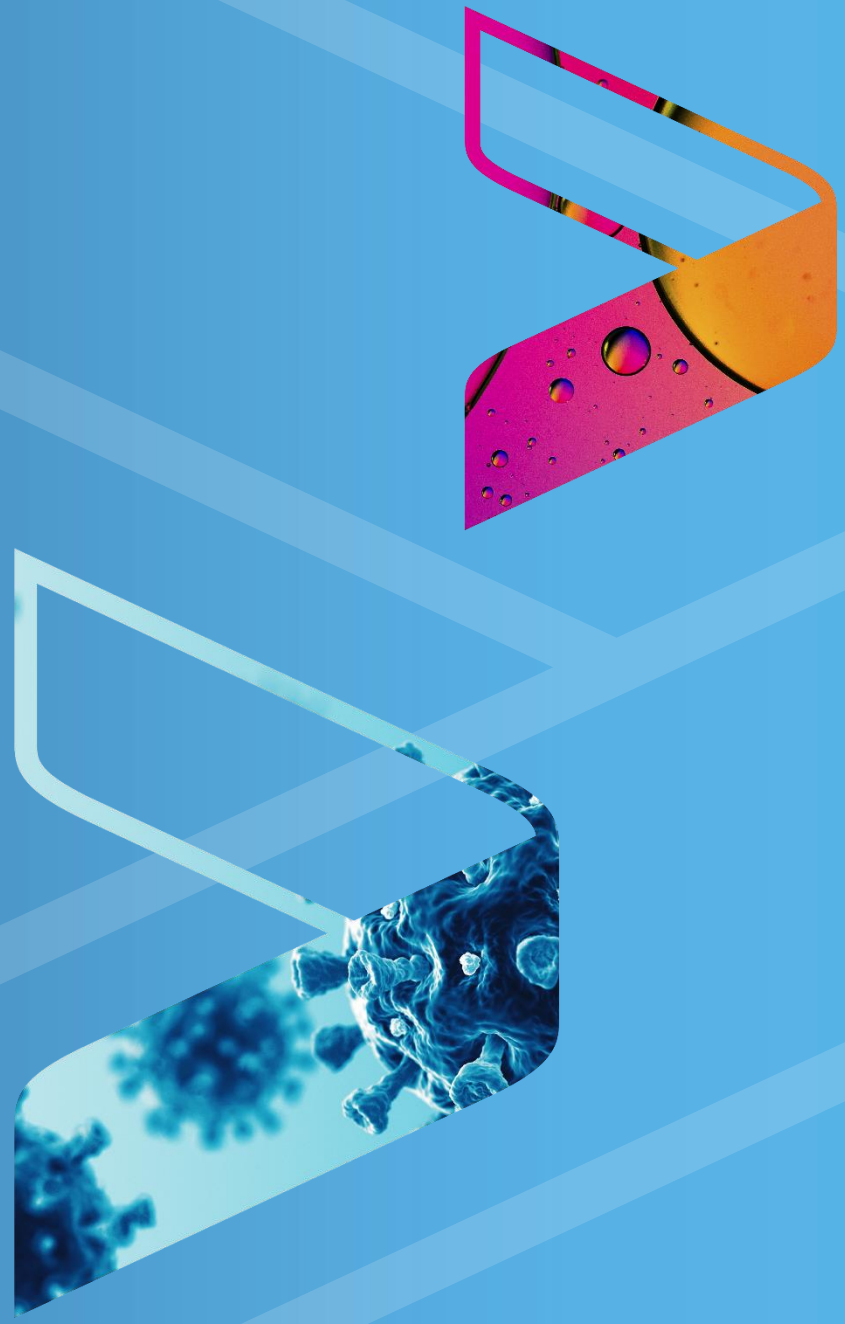
# Valneva's Full Year 2023 Results and Business Update

March 20, 2024



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IXCHIQ® is approved by the U.S. Food & Drug Administration (FDA) and is 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. Continued approval of IXCHIQ® in the United States is contingent upon verification of clinical benefit in confirmatory studies. Regulatory review of the VLA1553 chikungunya vaccine candidate remains ongoing in other jurisdictions, and approval by the FDA does not guarantee approval in other jurisdictions, on similar terms or at all.

# Agenda

- **Introduction**
- Business Update
- Financial Report FY 2023
- Financial Outlook
- Newsflow
- Q&A

# Full Year 2023 Key Results and Corporate Updates

## Excellent progress across R&D Pipeline

- Chikungunya: FDA approval and ACIP recommendation
- Lyme disease: Phase 3 study with Pfizer fully enrolled
- Zika virus: Re-entering Phase 1 with second-generation candidate


## Significant growth of commercial business

- Product sales surpassed pre-pandemic (2019) sales by 12% and 2022 sales by 26%
- IXIARO® and DUKORAL® grew 78% and 72%, respectively, vs 2022
- Product sales grew 63% vs 2022 (excl. COVID-19 sales)

## Solidly funded with strong mid-term financial outlook

- €126.1m in cash at year-end; augmented by €95m in proceeds from PRV sale (Feb 2024)
- 18-month extension of interest-only period of existing loan facility combined with significantly lower cash burn
- Operational business considered sufficiently funded (excluding debt repayment) until Lyme commercial revenues enable sustained profitability*

*Subject to successful development, licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer.

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# Our Strategy to become a Globally Recognized Vaccine Company

Contribute to a world where no one dies or suffers from a vaccine preventable disease

## Drive Commercial Growth

- Unlock IXCHIQ® value by building awareness and market
- Capitalize on the bundle effect within travel business
- Expand global reach; reach more LMICs via partnerships
- Expect cash-flow positivity from 2025

## Capture R&D Upside

- Invest in new vaccines that address high unmet needs
- Leverage proven R&D engine and strategic partnerships
- Focus on vaccines that can make a difference (first, only, best-in-class)
- Generate meaningful catalysts – Next Phase 3 entry post Lyme

## Maximize integrated biotech model

- Build continual value from R&D and commercial execution
- Support timely Lyme approval(s)
- Achieve sustained profitability with potential VLA15 commercial revenues from partner Pfizer*

*Subject to successful development, licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer

# The World’s First and Only Chikungunya Vaccine

## IXCHIQ® / VLA1553

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# IXCHIQ®: The World's First and Only Licensed Chikungunya Vaccine

## FDA-approved in adults, with potential additional regulatory approvals in 2024

### Vaccine Highlights

- Live-attenuated: offers strong and long-lasting protection from a single shot
- FDA approved (Nov 2023) – PRV sold for $103 million (Feb 2024)
- ACIP recommended vaccine for certain travelers and laboratory workers
- U.S. launch underway: sales through Valneva's commercial infrastructure

### Market Opportunity

- Travelers
- Military
- Outbreak preparedness

- Partnership for Latin America and certain LMICs[1] (Insituto Butantan)
- Estimated global market to exceed $500 million per year[2]; $300-$400 represented by travel segment

### Upcoming Milestones

- Potential upcoming approvals: EMA, Health Canada, Anvisa (Brazil)
- Initiate regulatory process in the UK
- Initiate further clinical trials, including Phase 4 clinical program
- Filings for potential label extension

1 Low- and middle-income countries; **2** VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020

# Only CHIKV vaccine to achieve target immunogenicity with a single shot

## Differentiated vaccine shows rapid, long-lasting immunity across all age groups tested[1,2,5]

### Immunogenicity Data

- 99% Seroresponse[3] Rate (SRR) after single vaccination → maintained at 97% after 24 months[4,5]
- Similar SRR and antibody titers in age 65+ adults as younger adults[1,4]
- 100% SRR after 14 days and sustained to Month 12[2]
- Adolescent trial met primary endpoint[6]: highly immunogenic in baseline-negative individuals; 99% SRR

### Safety Data

- Generally well tolerated by >3,600 adults and 754 adolescents
- Pivotal Safety (solicited systemic AEs):
  - ~50% of participants, most commonly headache, fatigue, myalgia
  - Majority mild or moderate; 2.0% reported as severe, most commonly fever
- Adolescent trial suggests favorable safety profile regardless of previous CHIKV infection[7]

1. Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; 2. Re-testing of Phase 1 sera (vaccinated with liquid formulation of VLA1553) using the final assay/threshold used for the pivotal endpoint; data presented at CISTM18, May 2023; 3. CHIKV neutralizing antibody titer of ≥150 by $\mu PRNT_{50}$ (Micro Plaque Reduction Neutralization Test), agreed with regulators to be used as a surrogate endpoint in Phase 3; 4. Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate; 5. Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®; 6. Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate; 7. Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate

# World’s leading Lyme Disease Vaccine Candidate

## VLA15

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# World's leading Vaccine Candidate Against Lyme Disease

## VLA15: the only Lyme disease program in advanced clinical development today

### Vaccine Highlights

- Multivalent, recombinant proteins
- Targets six most prevalent *Borrelia* serotypes causing Lyme disease in U.S. and Europe
- Established mechanism of action
- U.S. FDA Fast Track Designation
- Phase 3 fully recruited

### Market Opportunity

- Exclusive, worldwide partnership[1]
- >$1billion estimated global market[2]
- Valneva eligible for milestones up to $408 million ($165 million received)
- Tiered sales royalties 14-22%

### Upcoming Milestones

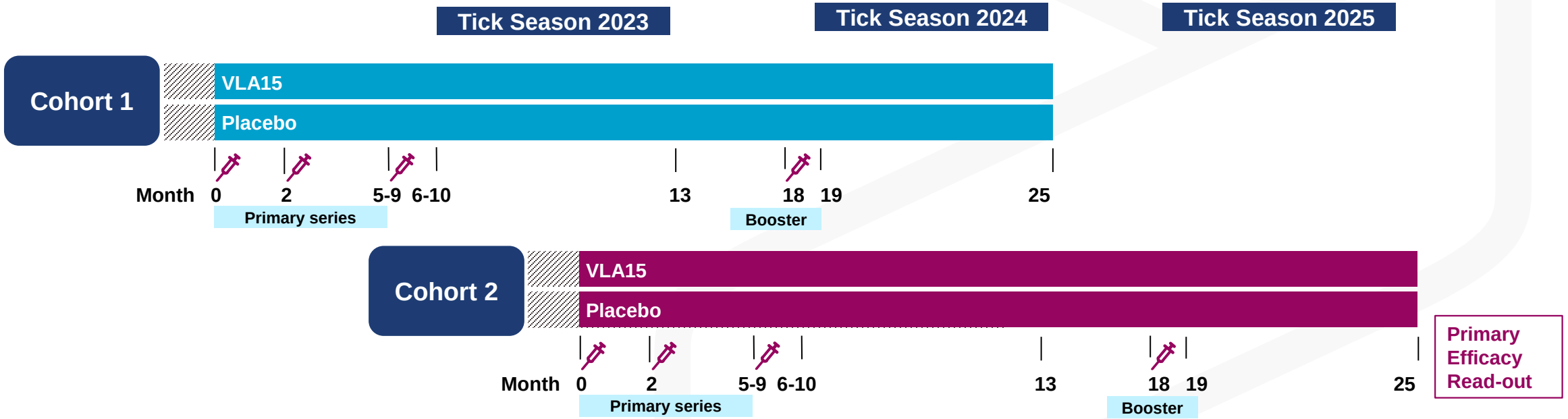
- Complete Valneva contribution to Phase 3 trial costs in H1 2024
- Phase 3 trial execution (Q2 2024):
  - Complete full vaccination for Cohort 1
  - Complete primary vaccination for Cohort 2
- Two-year antibody persistence and booster results in Q3 2024
- Efficacy results from Phase 3 trial (end 2025); Regulatory filings (U.S. + EU) in 2026[2]

**1** Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; **2** Lyme Disease research and analysis conducted by an independent market research firm; **3** Subject to positive data;

# Phase 3 Efficacy Study Fully Enrolled

## Pfizer aims to submit regulatory applications in U.S. and Europe in 2026[1]

- **Population**: 9,437 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[2] after two consecutive tick seasons (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed[1] LD cases after 1st Lyme season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol




1 Subject to positive data; 2 Cases will be evaluated and confirmed by an Endpoint Adjudication Committee

# Second-Generation Zika Virus Vaccine Candidate

## VLA1601

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# VLA1601: Optimized Second-Generation Vaccine Candidate Against Zika Virus

## Entering Phase 1, further program evaluation planned

### Vaccine Highlights

- Second-generation adjuvanted inactivated whole-virus vaccine
- Leverages Valneva's proven / licensed platform (VLA2001)
- Previous Phase 1 results from first-generation candidate showed excellent immunogenicity and safety results[1]

### Market Opportunity

- Flaviviral disease transmitted by *Aedes* mosquitoes[2]
- Devastating effects[3]:
  - 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 in H1 2025 based on:
  - Phase 1 results
  - Market potential
  - External, non-dilutive funding

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

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# FY 2023 Financials: Product Sales of €144.6 million

## Commercial business showing continued, significant growth

| €m (audited) | FY 2023 | FY 2022 | % Change | % at CER* |
|---|---|---|---|---|
| IXIARO®/JESPECT® | 73.5 | 41.3 | +78% | +84% |
| DUKORAL® | 29.8 | 17.3 | +72% | +82% |
| Third party products | 35.7 | 26.5 | +34% | +37% |
| **Total product sales** *(excl. COVID-19)* | **138.9** | **85.2** | **+63%** | **+69%** |
| COVID-19 vaccine | 5.7 | 29.6 | -81% | -81% |
| **Total product sales** | **144.6** | **114.8** | **+26%** | **+29%** |

* Constant Exchange Rate

# FY 2023 Financials: Income Statement

| €m (unaudited) | FY 2023 | FY 2022 |
|---|---|---|
| Product sales | 144.6 | 114.8 |
| Other Revenues | 9.1 | 246.5 |
| **Revenues** | **153.7** | **361.3** |
| Cost of goods and services | (100.9) | (324.4) |
| Research and development expenses | (59.9) | (104.9) |
| Marketing and distribution expenses | (48.8) | (23.5) |
| General and administrative expenses | (47.8) | (34.1) |
| Other income / (expense), net | 21.5 | 12.2 |
| **Operating loss** | **(82.1)** | **(113.4)** |
| Finance, investment in associates & income taxes | (19.3) | (29.8) |
| **Loss for the period** | **(101.4)** | **(143.3)** |
| **Adjusted EBITDA**[1] | **(65.2)** | **(69.2)** |

**1** FY 2023 Adjusted EBITDA was calculated by excluding €36.2 million (FY 2022: €74.1 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment (excluding impairment loss of disposal) from the €101.4 million (FY 2022: € 143.3 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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# Commercial Business* Expected to Deliver Substantial Growth

IXIARO®

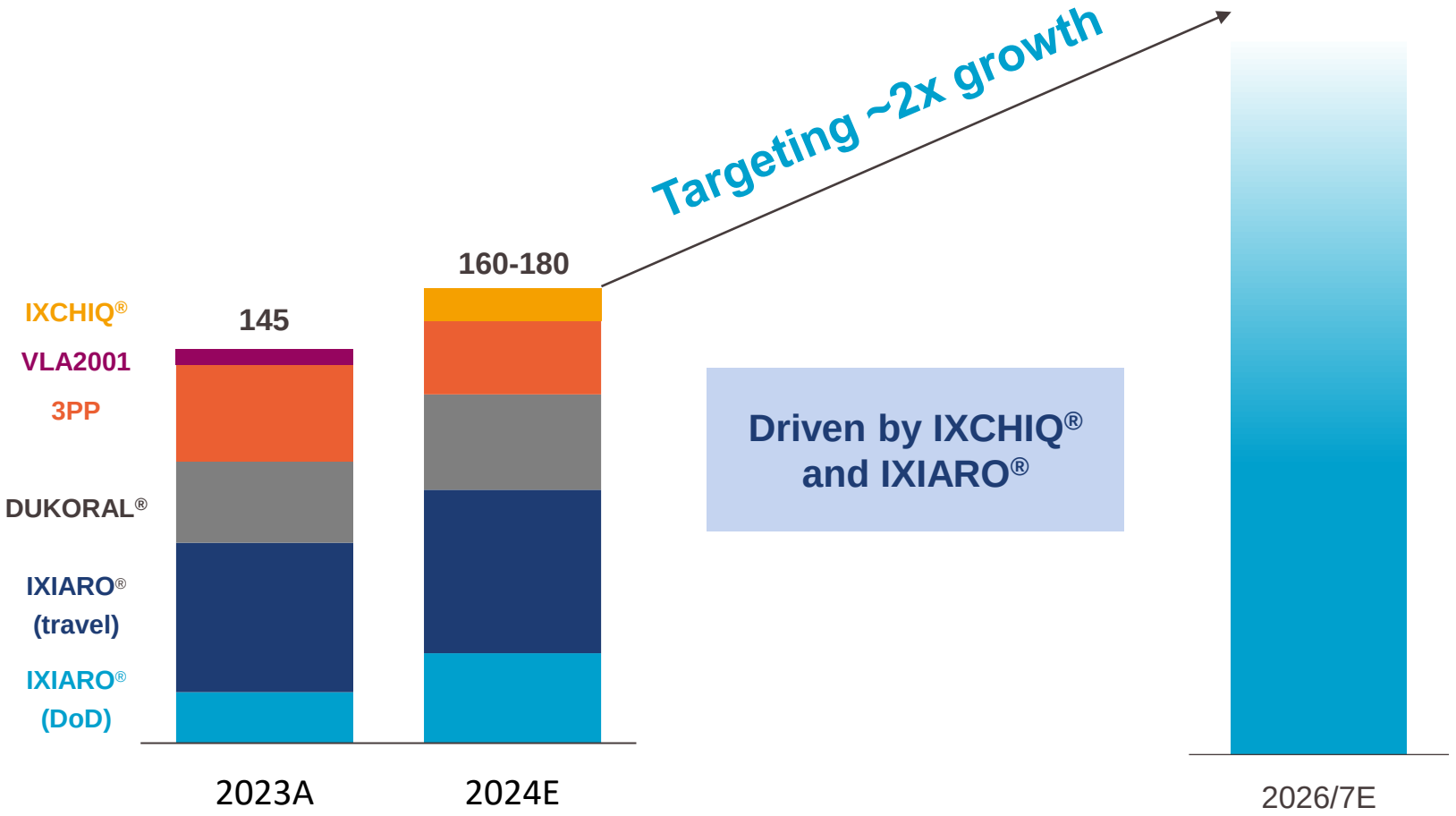
**Only** Japanese encephalitis vaccine approved in U.S. and Europe; **vaccine requirement** for U.S. military deployed to parts of Asia

IXCHIQ®

**First and only** approved single-shot chikungunya vaccine

DUKORAL®

**Only** Cholera and ETEC** vaccine approved




**Driven by IXCHIQ® and IXIARO®**

*Please refer to Product / Prescribing Information (PI) / approved in your respective country for complete information about this vaccine. **ETEC indication in some markets only

# Valneva is Solidly Funded with Strong Near- and Mid-term Financial Outlook

## Improved 2024 Guidance

- Product Sales: €160 - €180 million*
- Total Revenues: €170 - €190 million
- Other Income: €100 - €110 million
- R&D Expense: €60 - €75 million
- Significantly lower cash burn vs. 2023
  - Expect to complete contribution to Phase 3 Lyme disease trial in H1 2024
  - Commercial business expected to be cash-flow positive (excluding IXCHIQ®)

## Mid-Term Outlook

- Commercial business expected to cash-flow positive (including IXCHIQ®) from 2025
  - Continued travel sales growth for IXIARO® and DUKORAL®
  - Double-digit CAGR for IXIARO® for at least the next 3 years
  - IXCHIQ® sales to exceed €100 million in year 3 of launch, even assuming competitive product entry
- Focused and strategic investments in R&D
  - Next Phase 3 program entry post Lyme data
- Gross margin improvement
  - Focus on proprietary sales
  - Cost-efficient manufacturing leveraging new facilities
- Expect further support for R&D: sizable non-dilutive funding

* Due to improved outlook regarding IXIARO® supply constraints; assumes ~20-30% reduction in third party sales (external supply constraints)

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# Key Upcoming Catalysts and News Flow

## Chikungunya vaccine

- Initiate Phase 3 immunocompromised individuals study in H1 2024
- Upcoming potential approvals: EMA, Health Canada, Anvisa (Brazil)
- File for potential label extension
- Initiate Phase 4 clinical program

## Lyme disease vaccine candidate VLA15

- VALOR trial: complete booster vaccination for Cohort 1 in Q2 2024
- VALOR trial: complete initial three-dose vaccination for Cohort 2 in Q2 2024
- Complete Valneva contribution to Phase 3 trial costs in H1 2024
- Phase 2 two-year antibody persistence and booster results expected in Q3 2024

## Additional newsflow

- New U.S. Department of Defense supply contract for IXIARO® in H2 2024
- Further advance select R&D programs

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**Thank you**
Merci
Danke
Tack

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