valneva

A LEADING SPECIALTY
VACCINE COMPANY

# HALF YEAR 2023 RESULTS & CORPORATE UPDATE

## ANALYST PRESENTATION

## SEPTEMBER 21, 2023

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This presentation presents information about VLA1553, VLA15 and VLA1601, 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 FY 2023
- Financial Outlook
- Newsflow
- Q&A

# Valneva Reports Half Year 2023 Results and Provides Corporate Updates

## R&D Highlights

- Progress towards potential FDA approval of the **world's first chikungunya vaccine**
- **Lyme disease**: Phase 3 VALOR study continues; Cohort 1 completing first tick season; Cohort 2 currently enrolling
- Re-initiation of **Zika vaccine development:** clinical trial start expected Q1 2024

## Commercial business

- Total product sales of **€69.7m – more than 100% increase** in non-COVID sales
- On track to meet 2023 sales guidance of **€130m-150m**

## Strong cash position

- Cash position of **€204.4m** (June 30, 2023)
- Further strengthened by up to **$100m new debt facility**

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# Potential to Deliver the World's First Chikungunya Vaccine in Q4

## VLA1553* - Live-attenuated vaccine candidate under FDA priority review

### Pioneering Vaccine Development in an Area of High Unmet Need – Preparing for Success

- **First** chikungunya vaccine candidate to report **positive Phase 3 data** – met all trial endpoints
- **First to submit a biologics license application (BLA)** to the FDA for potential approval; filing accepted by Health Canada
- Live-attenuated vaccine approach: believed to be **particularly well suited to target long-lasting protection** compared to other chikungunya assets being evaluated in clinical trials
- Pivotal immunogenicity/safety data, antibody persistence **results demonstrate long-lasting, high seroresponse** with a single dose; **100% seroresponse after 14 Days**[1]; **favorable safety profile** regardless of prior infection[2]
- Preparing for launch: VLA1553 **fits perfectly within Valneva's existing commercial infrastructure**

### Target Populations & Geographic Reach

- **Non-endemic** countries: travelers / military / outbreak preparedness in U.S., EU, CAN
- **Endemic** use in LMICs[3]: Partnered with CEPI and Instituto Butantan, including local manufacturing

### 2023 Regulatory & Clinical Catalysts

- FDA PDUFA date: **end of November 2023**
- Potential award/sale of PRV upon BLA approval: **~$100M**
- Adolescent trial: reported positive initial safety data; immunogenicity data expected in November **2023**
- Expect to commence **additional regulatory processes in 2023**, including EMA

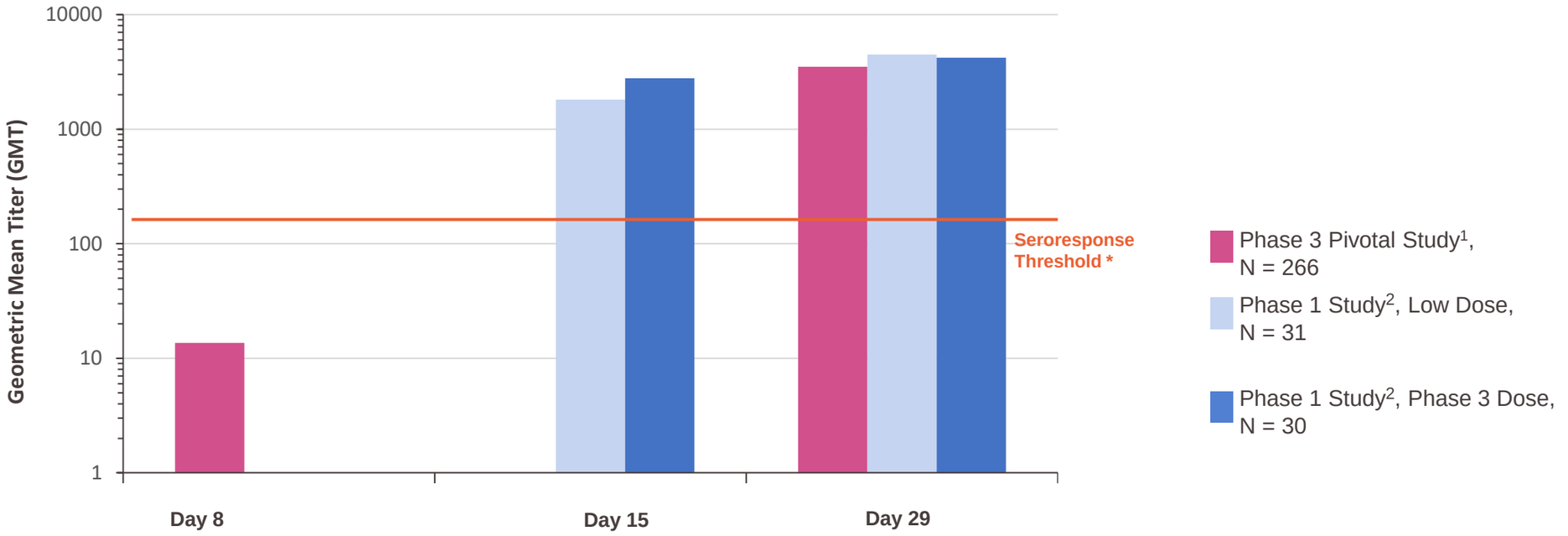
**1** Re-testing of Phase 1 sera (vaccinated with liquid formulation of VLA1553) using the final assay/threshold used for the pivotal endpoint; data presented at CISTM18, May 2023**; 2** Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate; **3** Low- and middle-income countries



*VLA1553 is an investigational chikungunya vaccine candidate and is not approved for use in the United States or any other jurisdiction

# Fast and Robust Induction of Neutralizing CHIKV Antibodies

## High neutralizing antibody titers at Day 15 in Phase 1; by Day 29 for pivotal trial endpoint




* Seroresponse: µPRNT50 ≥ 150, titer reasonably likely to predict protection

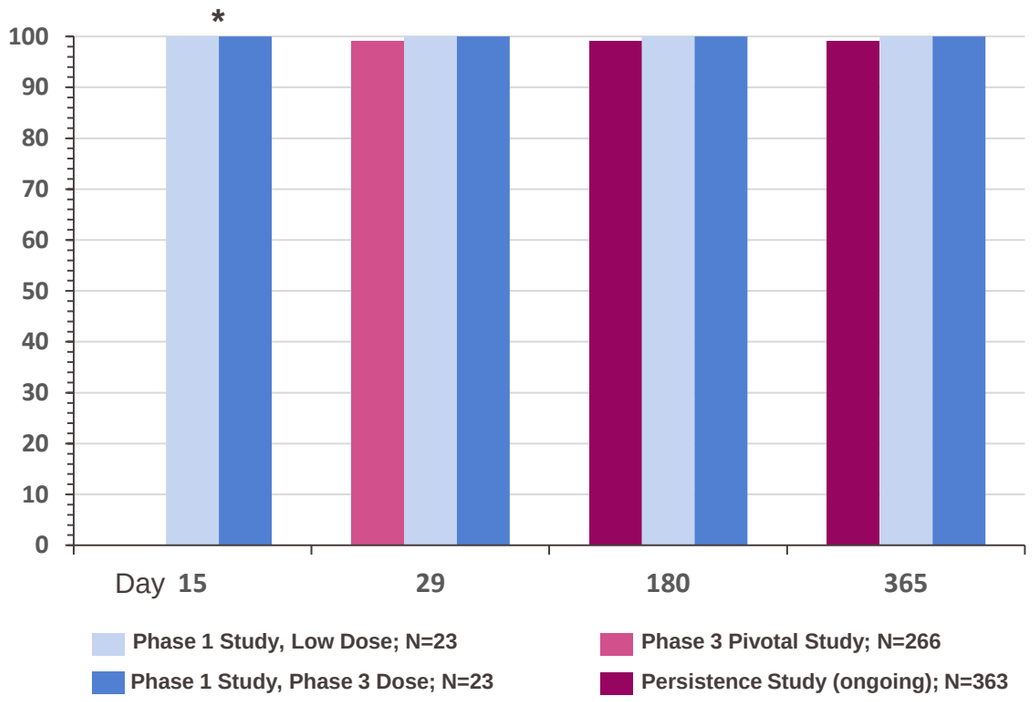
Note: All GMT used same, validated µPRNT assay

**1** Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; **2** Wressnigg et al, Lancet ID: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext; 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

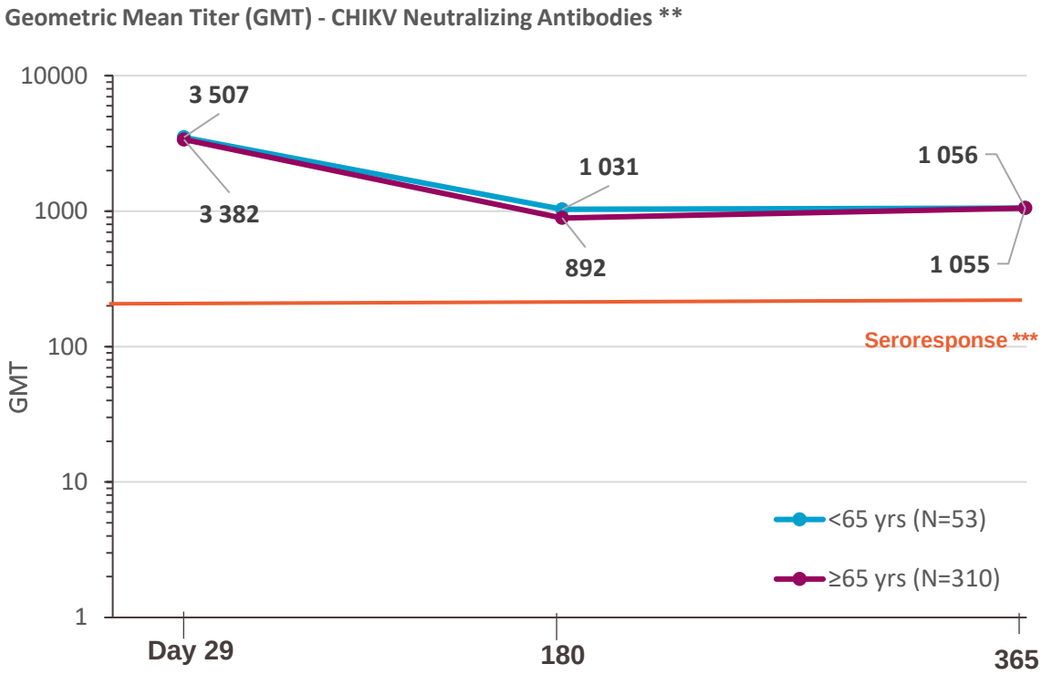
# VLA1553 Induces Early and Sustained Response Regardless Of Age

## High seroresponse rates across different studies

### Seroresponse sustained at highest levels up to Month 12




### Comparable titers in younger and older adults




** Persistence Study, Whole Sample Population
*** Seroresponse : µPRNT50 ≥ 150, titer reasonably likely to predict protection

***** Wressnigg et al, Lancet ID: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext; 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

# Positive Initial Safety Results in Adolescent and Pre-Exposed Participants[1]

Conducted in partnership with Instituto Butantan, funded by CEPI

## Adolescent Trial Design

- 754 Adolescents aged 12 to 17 years
- Randomized 2:1 to VLA1553 or placebo
- Includes 20% participants with prior exposure to chikungunya virus
- Primary endpoint: Seroresponse Rate on Day 29; data expected in November
- Immunogenicity and Safety follow-up to Month 6
- 12-month follow-up for immunogenicity subset

## Initial Safety Data[1]

- Generally well tolerated, including in individuals previously infected with chikungunya virus
- AE profile consistent with adults; majority of solicited AEs were mild or moderate and resolved within three days
- Initial data suggest a favorable safety profile in seropositive participants (in line with Phase 1 “re-vaccination challenge”[2])
- Independent DSMB has not identified any safety concerns

**1** Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate; **2** Wressnigg et al, Lancet ID: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext

# VLA1553 Development Outlook

First chikungunya program worldwide to report pivotal trial results and antibody persistence

## Working collaboratively with FDA to align on post-approval Phase 4 program

- Phase 4 likely to set future standard for outbreak disease indications under FDA accelerated approval pathway

## Additional studies ongoing

- **Antibody persistence trial:** 363 volunteers followed-up annually for at least five years – reported 12-month results in Dec 2022; 24-month data expected in 2023
- **Adolescent Phase 3 trial:** support potential label expansion and licensure in Brazil, funded by CEPI – Positive initial safety data reported, immunogenicity data expected November 2023

## Anticipated future trials

- Co-vaccination, pediatric and special populations, Phase 4 effectiveness in endemic setting

# Chikungunya Global Market Segments

## Global market for chikungunya vaccines estimated to exceed $500 million per year by 2032[1]

### Segments Targeted Directly by Valneva

**Travelers from Non-Endemic Regions**

Travel vaccine for individuals travelling to areas with risk of chikungunya

**Military from Non-Endemic Regions**

Vaccine for troops stationed in areas with risk of chikungunya

**Outbreak Preparedness Non-Endemic Regions**

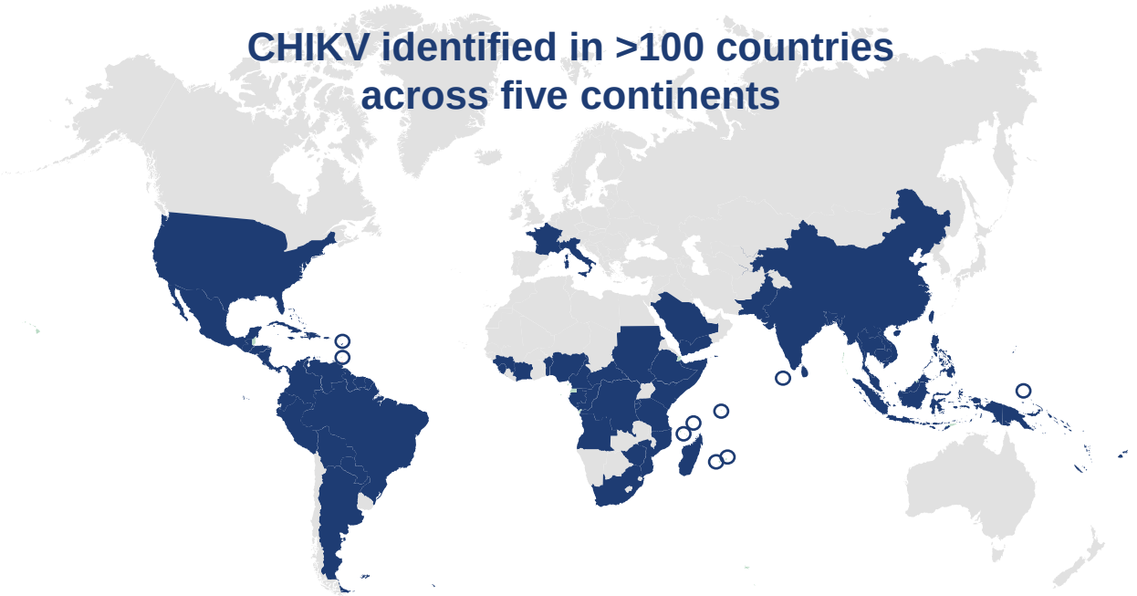
Vaccine in areas in response to / at risk for a domestic outbreak

### Segments Targeted via Partnership

**Endemic Region Use**

Vaccine in endemic / LMIC markets, Targeted via **CEPI / Instituto Butantan Partnership**

### CHIKV identified in >100 countries across five continents



**1** VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020

# Multivalent Recombinant Protein Vaccine Candidate for Lyme Disease

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

1. **Phase 3 study ongoing, sponsored by Pfizer[1] and supported by positive results for three Phase 2 clinical trials[2,3,4], incl. first pediatric/adolescent data (priming and 12-mo booster)[5,6]**
2. **Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 ($95) million equity investment in Valneva[7]**
3. **Investigational multivalent vaccine targeting the six most prevalent serotypes causing Lyme disease in the United States and Europe**
4. **Follows established mechanism of action for a Lyme disease vaccine candidate**
5. **Fast Track Designation granted by U.S. FDA in July 2017**

**1** Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; **2** Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate**; 3** Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. **4** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate **; 5** Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate/; **6** Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate; **7** Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15.

# VLA15 Demonstrated Strong Immunogenicity Across 1,030 Adult and Pediatric Participants

## VLA15-221: First positive pediatric data (April 2022[1])

- Strong immunogenicity profile in adult [2] (ages 18-65) and pediatric participants (ages 5-17)
- More immunogenic in pediatric participants than in adults, with both two-dose and three-dose vaccination schedules; three-dose schedule selected for all ages in Phase 3
- Antibody levels remained above baseline six months after primary vaccination[3]; strong anamnestic antibody response across all serotypes and age groups (age 5 - 65), one month after booster dose (Month 19)[4]

## VLA15-202: First positive booster data (September 2021)[4]

- High antibody responses confirmed across all serotypes and dose groups after primary vaccination series (primary endpoint)[6]
- 12-month booster dose elicited strong anamnestic response

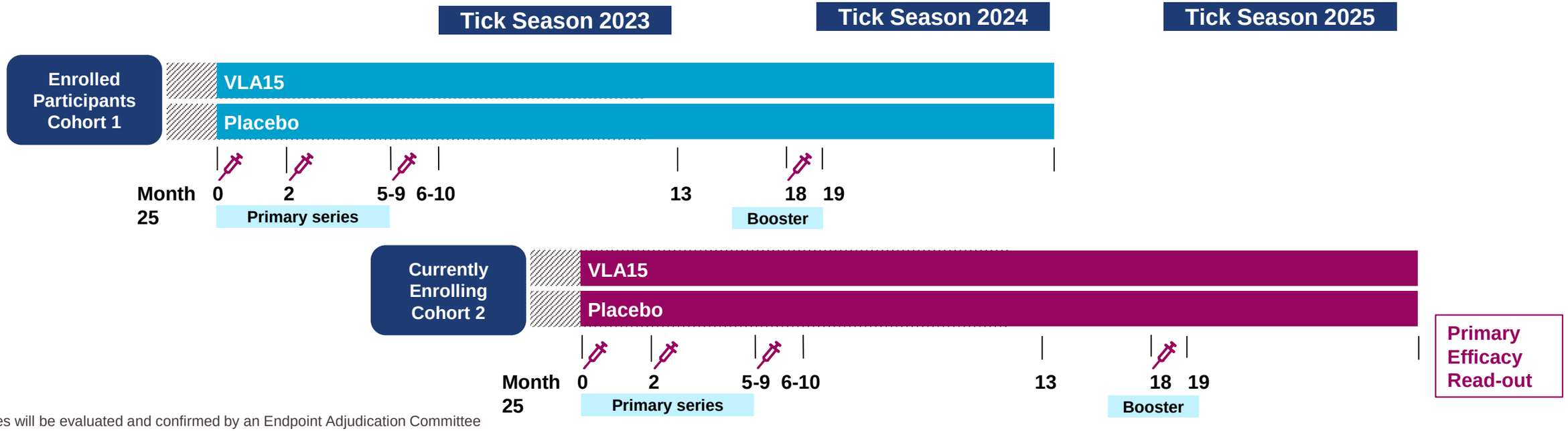
## VLA15-201: First positive immunogenicity data (July 2020)[7]

- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Encouraging immunogenicity profile confirmed, including in older adults (ages 50-65)

**1** Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate; **2** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; **3** Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate; **4** Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate; **5** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate, **6** Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15 **7** Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate

# Phase 3 Efficacy Study

- **Population**: ~9000 total 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[1] LD cases 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 Cases will be evaluated and confirmed by an Endpoint Adjudication Committee

**Pfizer aims to submit regulatory applications in U.S. and Europe in 2026, subject to positive data**

# VLA1601: Potential to be a Differentiated Zika Virus Vaccine Candidate

Adjuvanted, inactivated whole virus vaccine candidate

## Zika viral disease

- **Flaviviral disease transmitted by *Aedes* mosquitoes[1]**
- **Common flu-like symptoms, lasting between 2 -7 days**
- **Devastating effects in newborns and adults:**
  - Microcephaly and severe brain defects in newborns
  - Guillain-Barré syndrome[2] in adults
- **No vaccines or specific treatment available**

## Valneva's vaccine candidate

- **Highly purified**
- **Adjuvanted inactivated whole-virus vaccine**
- **Leverages Valneva's proven/ licensed platform(s):**
  - IXIARO®, VLA2001

## Final Phase 1 data confirmed excellent safety profile[3,4]

- **Met primary endpoint showing excellent safety profile in all tested doses and schedules**
  - Comparable to IXIARO® and other clinical stage Zika vaccines
- **Immunogenic at all doses and schedules tested**
  - Dose- and schedule-dependent

**Expect to re-initiate Phase 1 clinical trial in Q1 2024 with updated formulations**

1 https://www.cdc.gov/zika/transmission/index.html; 2 http://www.who.int/mediacentre/factsheets/zika/en/; 3 Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus; 4 Valneva Reports H1 2019 Results Marked by Strong Operational Performance and Major Corporate Progress

# Valneva's R&D Pipeline
## Overview

| | Program | Discovery | Pre-Clinical | Phase 1 | Phase 2 | Phase 3 | Commercial | Next Inflection Point | Development Partners |
|---|---|---|---|---|---|---|---|---|---|
| Clinical Portfolio | **VLA1553[2]:** Chikungunya | | | | | | ***Potentially eligible for PRV*** | Potential BLA approval 4Q 2023 | *CEPI/ Butantan (LMIC)* |
| | **VLA15[3]:** Lyme disease | | | | | | | Cohort 2 currently enrolling | Pfizer |
| | **VLA84:** Clostridium difficile | | | | | | | Developed to EoP2/ on-hold | *Open to partnering* |
| | **VLA1601:** Zika | | | | | | | Expected clinical re-entry early 2024 | - |
| | **VLA1554:** hMPV | | | | | | | Initial pre-clinical PoC completed | *Partnering under evaluation* |
| | **VLA2112:** EBV | | | | | | | Antigen identification by end 2023 | - |
| | Other pre-clinical activities | | | | | | | | |

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# H1 2023 Financials: Product Sales of €69.7m

## Travel channel showing continued, significant recovery

| €m (unaudited) | H1 2023 | H1 2022 | H1 2022 at CER* | % at CER |
|---|---|---|---|---|
| IXIARO®/JESPECT® | 30.3 | 12.3 | 12.1 | **150.8%** |
| DUKORAL® | 17.1 | 5.8 | 5.5 | **213.0%** |
| Third party products | 16.5 | 11.5 | 11.3 | **46.8%** |
| **Total product sales** *(excl. COVID-19)* | **64.0** | **29.5** | **28.8** | **122.0%** |
| COVID-19 vaccine | 5.7 | 3.8 | 3.8 | 49.8% |
| **Total product sales** | **69.7** | **33.3** | **32.6** | **113.6%** |

*Constant Exchange Rate

# H1 2023 Financials: Income Statement

| €m (unaudited) | H1 2023 | H1 2022 |
|---|---|---|
| Product sales | 69.7 | 33.3 |
| Other Revenues | 4.1 | 59.9 |
| **Revenues** | **73.7** | **93.2** |
| Cost of goods and services | (53.8) | (171.5) |
| Research and development expenses | (26.0) | (51.9) |
| Marketing and distribution expenses | (20.0) | (7.8) |
| General and administrative expenses | (22.9) | (16.0) |
| Other income / (expense), net | 14.0 | 3.6 |
| **Operating loss** | **(35.0)** | **(150.4)** |
| Finance, investment in associates & income taxes | (0.1) | (21.1) |
| **Profit/loss for the period** | **(35.0)** | **(171.5)** |
| **Adjusted EBITDA**[1] | **(28.3)** | **(136.0)** |

[1] H1 2023 Adjusted EBITDA was calculated by excluding €6.7 million (H1 2022: €35.5 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment from the €35.0 million (H1 2022: €171.5 million) loss for the period as recorded in the consolidated income statement under IFRS.

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# Reiterating 2023 Financial Guidance

**Total revenues and other income expected between €220 to €260 million, including:**

- €130 to €150 million of product sales, including marginal COVID-19 vaccine sales under the Bahrain supply agreement
- €90 to €110 million of other income

**R&D investments expected between €70 million and €90 million**

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# Key Upcoming Catalysts and News flow 2H23 – 1H24

## Chikungunya vaccine candidate VLA1553

- PDUFA action date, potential BLA approval by end of November
- Adolescent immunogenicity results in November 2023
- EMA regulatory submissions in Q4
- Additional 24-month antibody persistence data in Q4
- ACIP recommendation expected Q1 2024

## Lyme disease vaccine candidate VLA15

- Continued trial execution; recruitment of Cohort 2 in advance of 2024 tick season

## Additional news flow

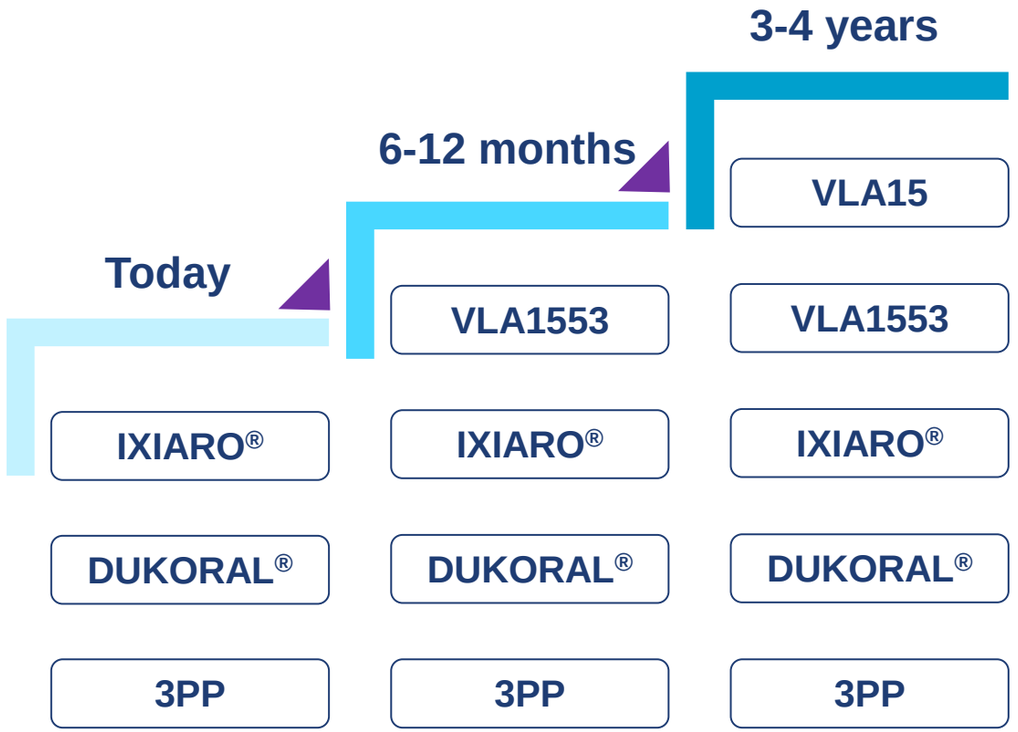
- New U.S. DoD contract for IXIARO® expected imminently
- Potential granting and sale of FDA priority review voucher upon VLA1553 approval
- Initiation of VLA1601 Zika vaccine Phase 1 clinical trial in Q1 2024
- Advancement of select pre-clinical programs

# Valneva is Poised for Substantial Growth

## Led by potential new product launches

**Additional growth drivers:**

- Continued recovery of travel market to pre-COVID levels and beyond
- New U.S. DoD contract for IXIARO® expected imminently
- Potential label expansion for VLA1553 after initial approval in adults
- Potential in-licensing or acquisition of additional clinical candidate(s)



Thank you
Merci
Danke
Tack