



**valneva**

**A LEADING SPECIALTY  
VACCINE COMPANY**

**FIRST QUARTER 2023 RESULTS  
& CORPORATE UPDATE**

**ANALYST PRESENTATION**

**MAY 04, 2023**

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This presentation presents information about VLA1553, an investigational vaccine candidate that has not been approved for use and has not been determined by any regulatory authority to be safe or effective.

# Agenda



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# Valneva Reports Q1 2023 Results and Provides Corporate Updates



Good momentum driven by strong sales performance; clarity on catalysts

## Product sales nearly doubled year-over-year

**€32.1 million this period vs. €16.2 million in Q1 2022**

- Driven by IXIARO<sup>®</sup> and DUKORAL<sup>®</sup> sales, both of which more than quadrupled from Q1 2022

## Maintained position of financial strength

**Strong cash position of €254.5 million at March 31, 2023**

**Reiterated guidance: Expect product sales to reach or exceed pre-pandemic levels this year**

## Clear pathway toward transformative catalysts

**Chikungunya: Progressing toward delivery of the world's first chikungunya vaccine\***

- FDA PDUFA date confirmed in mid-cycle review for the end of August 2023
- Expect to commence additional ex-U.S. regulatory processes in 2023

**Lyme disease: Phase 3 design and endpoints unchanged, as previously agreed with regulators**

- Additional enrollment for primary immunization to begin in Q2; to include 2025 tick season
- Pfizer will bear the current projected incremental costs due to the agreed additional enrollment

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# Potential to Deliver the World's First Chikungunya Vaccine in Q3

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

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

- **First and only** chikungunya vaccine candidate to report positive Phase 3 data
- **First to submit a biologics license application (BLA)** to the FDA for potential approval
- Live-attenuated vaccine approach: believe is **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 sero-response** with a single dose
- 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<sup>1</sup>: Partnered with CEPI and Instituto Butantan, including local manufacturing

<sup>1</sup> Low- and middle-income countries

## 2023 Regulatory & Clinical Catalysts

- PDUFA date **confirmed: end of August 2023**
- Potential award/sale of PRV upon approval: **~\$100M**
- Adolescent trial: first results **expected mid-2023**
- Expect to commence **additional regulatory processes in 2023**, including CA and EU



# Only Lyme Disease Vaccine in Advanced Clinical Development Today

VLA15: multivalent recombinant protein vaccine candidate



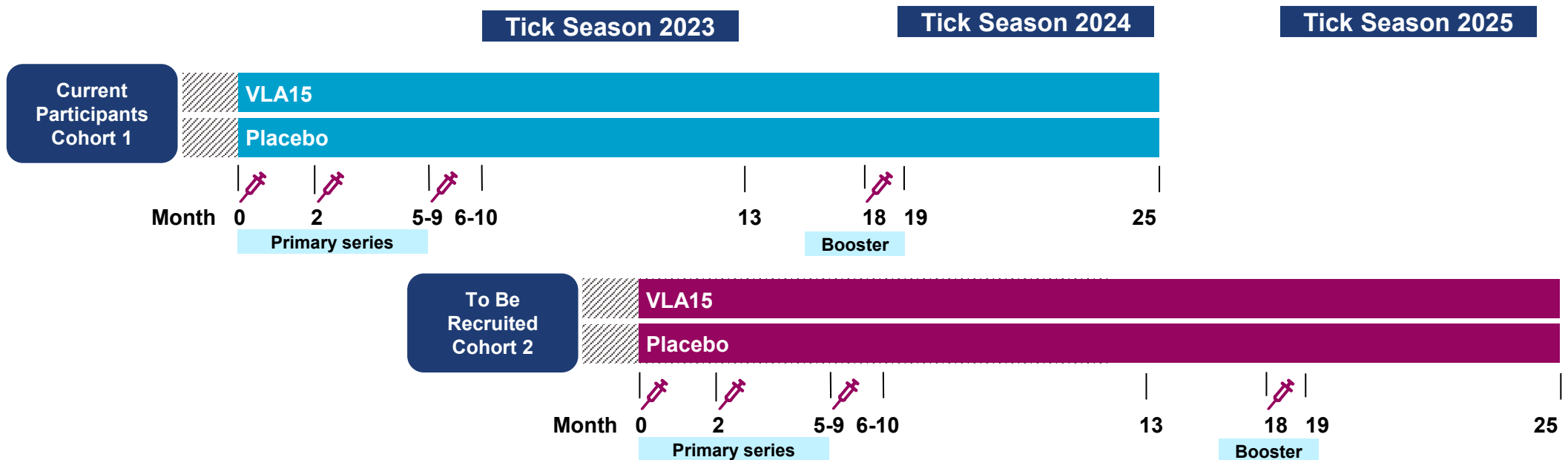
- 1** Phase 3 study initiated by Pfizer<sup>1</sup> supported by positive results for three Phase 2 clinical trials<sup>2,3,4</sup>, including first pediatric data<sup>5</sup>; Pivotal trial design and timeline confirmed after uncovering GCP violations by 3<sup>rd</sup>-party operator<sup>6</sup>
- 2** Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 (\$95) million equity investment in Valneva<sup>7</sup>
- 3** Investigational multivalent vaccine (six serotypes) designed to protect against 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 Reports First Quarter 2023 Financial Results and Provides Corporate Updates](#); [7 Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15](#);



# Phase 3 Efficacy Study Design

- **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 U.S./EU)
- **Primary endpoint:** Rate of confirmed<sup>1</sup> LD cases after two consecutive tick seasons (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed<sup>1</sup> LD cases after 1st Lyme season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol



**Pfizer now aims to submit regulatory applications in U.S. and Europe in 2026**

<sup>1</sup> Cases will be evaluated and confirmed by an Endpoint Adjudication Committee



# Advanced, Focused and Differentiated Clinical Pipeline and promising early stage targets

## R&D pipeline overview



	Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial	Next Inflection Point	Development Partners
Clinical Portfolio	VLA1553 <sup>2</sup> : Chikungunya						Potentially eligible for PRV	Potential BLA approval 3Q 2023	CEPI/ Butantan (LMIC)
	VLA15 <sup>3</sup> : Lyme disease							Additional enrollment starting in 2Q 2023	
	VLA84: Clostridium difficile							Developed to EoP2/ on-hold	Open to partnering
	VLA1601: Zika							Potential clinical re-entry end 2023/ early 2024	-
	VLA1554: hMPV							Initial pre-clinical PoC completed	Partnering under evaluation
	VLA2112: EBV							Antigen identification by end 2023	-
	Campylobacter							Pre-clinical entry subject to gating criteria	
	Parvovirus							Pre-clinical entry subject to gating criteria	

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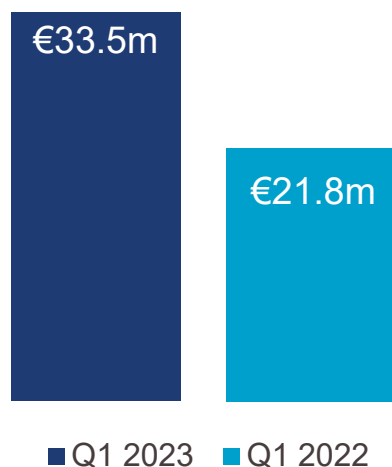
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# First Quarter 2023 Financials: Total Revenues of €33.5 million

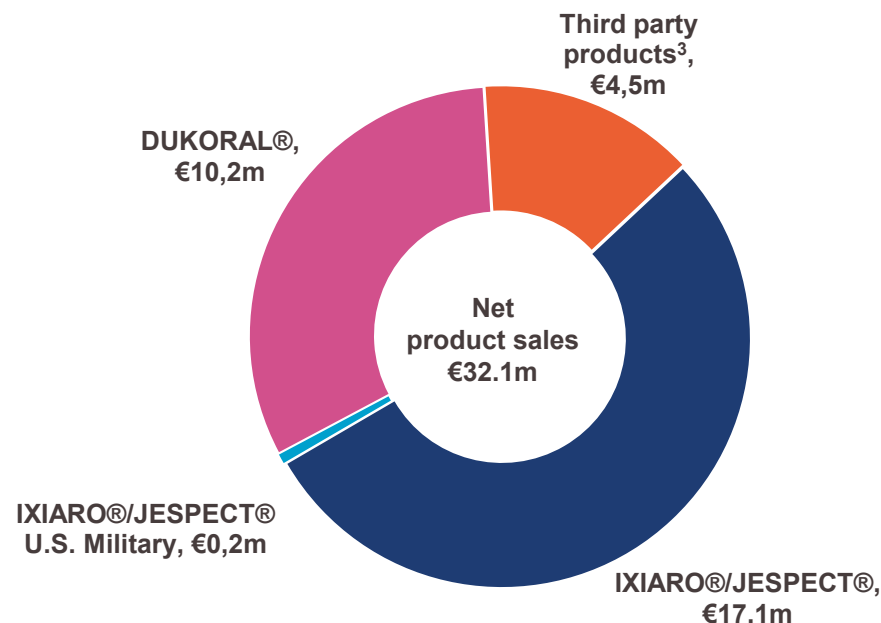
## Driven by Continued Recovery of Travel Vaccine Market



**Total Revenues<sup>1</sup>**  
+53.4%



**Product sales**  
+98.6%<sup>1</sup>  
+159.7% (excluding COVID-19 sales)<sup>2</sup>



**Direct sales<sup>4</sup>**  
71.6%

<sup>1</sup> YoY comparison for same period; <sup>2</sup> Excludes €3.8 million of COVID-19 vaccine sales in Q1 2022; no COVID-19 vaccine sales were recorded in Q1 2023; <sup>3</sup> Third party products sold by Valneva; <sup>4</sup> Sales generated in markets where Valneva operates its own commercial infrastructure

# First Quarter 2023: YoY Product Sales Doubled to €32.1 million

## Private Travel Markets Continue to Show Significant Recovery



€m (unaudited)	Q1 2023	Q1 2022	Q1 2022 at CER <sup>1</sup>	Q1 2023 vs. Q1 2022	Q1 2023 vs. Q1 2022 at CER
IXIARO <sup>®</sup> /JESPECT <sup>®</sup>	17.4	4.2	4.2	+315.2%	+314.5%
DUKORAL <sup>®</sup>	10.2	2.5	2.4	+302.6%	+317.3%
Third party products	4.5	5.6	5.5	-19.7%	-18.1%
COVID-19	0.0	3.8	3.8	-	-
<b>Total product sales</b>	<b>32.1</b>	<b>16.2</b>	<b>16.0</b>	<b>+98.6%</b>	<b>+101.0%</b>
<i>IXIARO<sup>®</sup>/JESPECT<sup>®</sup> (excluding U.S. Military)</i>	<i>17.1</i>	<i>3.9</i>	<i>3.9</i>	<i>+338.3%</i>	<i>+337.6%</i>
<i>Total Product Sales (excluding COVID-19)<sup>2</sup></i>	<i>32.1</i>	<i>12.4</i>	<i>12.2</i>	<i>+159.7%</i>	<i>+163.7%</i>

<sup>1</sup> Q1 2021 recalculated at actual average Q1 2022 exchange rates; <sup>2</sup> Excludes €3.8 million of COVID-19 vaccine sales in Q1 2022; no COVID-19 vaccine sales were recorded in Q1 2023



# First Quarter 2023 Financials: Adjusted EBITDA of - €12.3 million

Higher Sales Revenues Balanced by Increased Expenses Related to VLA1553 Launch Preparation<sup>1</sup>

€m (unaudited)	Q1 2023	Q1 2022
Product sales	32.1	16.2
Other Revenues	1.4	5.7
<b>Revenues</b>	<b>33.5</b>	<b>21.8</b>
Cost of goods and services	(20.5)	(13.9)
Research and development expenses	(14.1)	(20.7)
Marketing and distribution expenses	(9.0)	(2.0)
General and administrative expenses	(10.0)	(5.8)
Other income / (expense), net	3.5	2.1
<b>Operating loss</b>	<b>(16.6)</b>	<b>(18.4)</b>
Finance, investment in associates & income taxes	(1.5)	(7.6)
<b>Profit/loss for the period</b>	<b>(18.1)</b>	<b>(26.0)</b>
<b>Adjusted EBITDA<sup>2</sup></b>	<b>(12.3)</b>	<b>(13.3)</b>

<sup>1</sup> COGS, R&D, M&D and G&A expenses also benefited in Q1 2022 from an accrual adjustment income of €11.7 million related to the favorable effect of the Company's share price development on the employee share-based compensation programs; <sup>2</sup> Q1 2023 Adjusted EBITDA was calculated by excluding €5.8 million (Q1 2022: €12.8 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment from the €18.1 million (Q1 2022: €26.0 million) loss for the period as recorded in the consolidated income statement under IFRS.



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## Valneva 2023 Financial Guidance

Expect Product Sales to Reach or Exceed Pre-Pandemic Levels this year

**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 in 2023



## Chikungunya vaccine candidate VLA1553

- First adolescent study results mid-2023
- Potential BLA approval and first launch; Potential PRV sale in H2 2023
- Initiate additional ex-U.S. regulatory submissions in 2023

## Lyme disease vaccine candidate VLA15

- Additional enrollment for primary immunization to begin in 2Q 2023
- Additional antibody persistence results in H2

## Additional news flow

- Potential DoD contract for IXIARO® in the coming months
- Potential augmenting clinical pipeline through program acquisition or partnering
- Progression of selected pre-clinical programs towards clinical entry

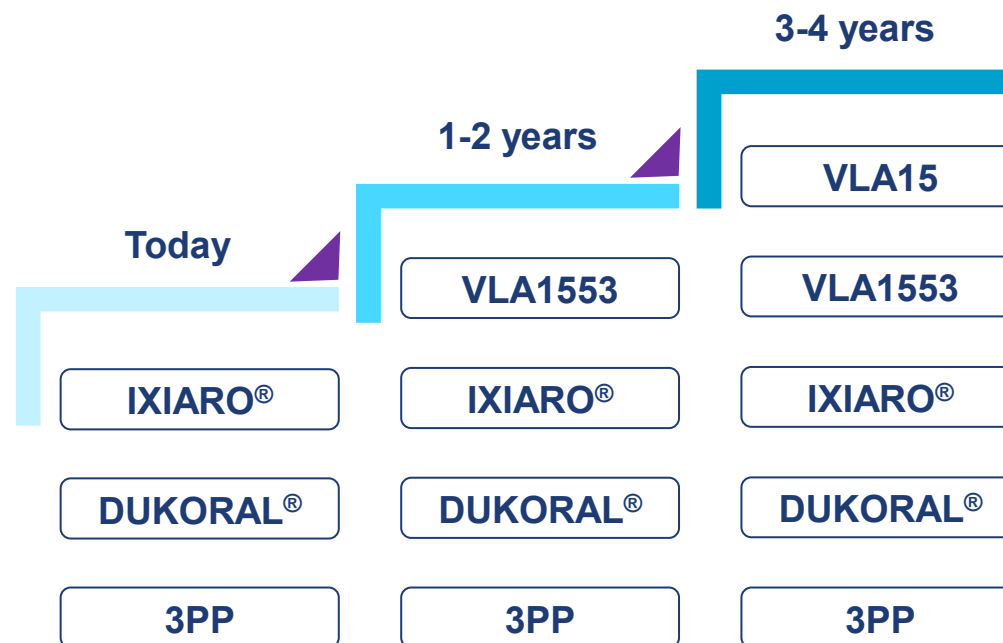


# Valneva is Poised for Substantial Growth

## Led by potential new product launches

### Additional potential growth drivers:

- Continued recovery of travel volumes toward pre-COVID levels and beyond
- New U.S. DoD contract for IXIARO<sup>®</sup> expected in the coming months
- Potential in-licensing or acquisition of additional clinical assets
- Potential U.S. reimbursement for CDC recommended travel vaccines





# Q&A

Thank you  
Merci  
Danke  
Tack

