



valneva

**A LEADING SPECIALTY
VACCINE COMPANY**

**9-MONTH FINANCIAL RESULTS
ANALYST PRESENTATION**

NOVEMBER 9, 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.



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Valneva Reports 9-Month 2023 Results and Provides Corporate Updates

R&D Highlights

- Progressing towards potential licensure 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 revenue of **€106.1m – 98.7% increase** in non-COVID sales
- On track to meet 2023 sales guidance of **€130m-150m**

Strong cash position

- Cash position of **€171.3m** (September 30, 2023)



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Potential to Deliver the World's First Chikungunya Vaccine This Month

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 biologics license application (BLA)** to FDA for potential approval; also **filed with EMA and 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 Days¹**; **favorable safety profile** regardless of prior infection²
- 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 LMICs³: 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**

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 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



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 Pfizer¹ 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 Valneva⁷

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

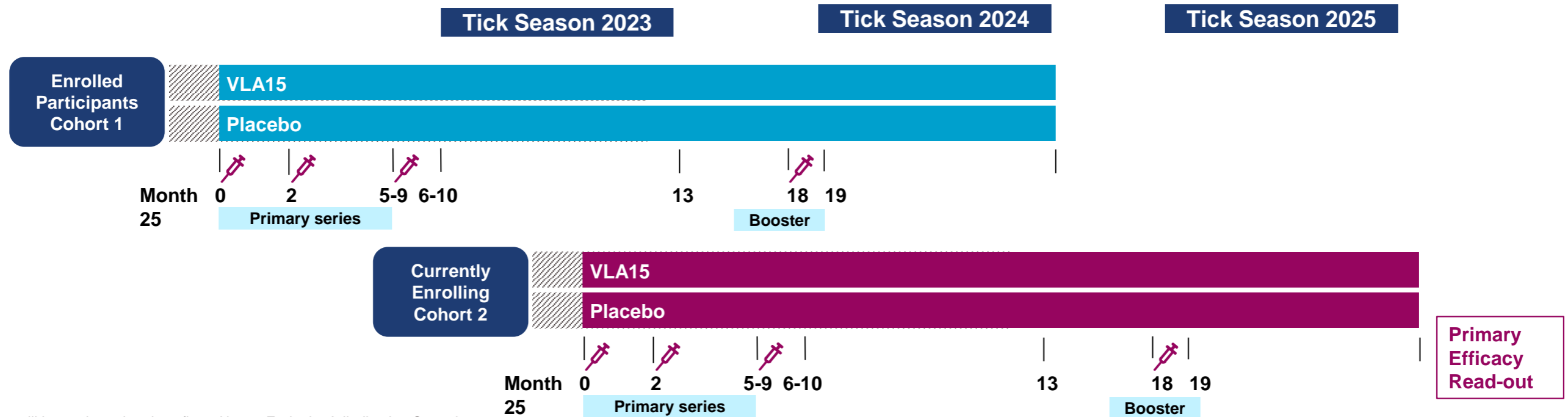
Fast Track Designation granted by U.S. FDA in July 2017

[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](#).



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 confirmed¹ LD cases after two consecutive tick seasons (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed¹ 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



Phase 3 Trial Updates

Conducted in partnership with Pfizer

VALOR Vaccine Efficacy Study

- First Subject In achieved in August 2022
- Enrollment ongoing (~5600/9000) enrolled in US, CA, NL, DE, FI, PL, SE and will complete enrollment December 2023
- Participants enrolled in 2022 completed primary series May 2023 and currently in season 1 follow-up (LD surveillance) and will be boosted in March/April 2024
- Last Subject Out targeted Q4 2025

Pediatric Safety Study¹

- First Subject In achieved December 2022
- Enrollment (US only) completed June 2023
- 3550 randomized and primary series targeted to complete December 2023
- Last Subject Out targeted Q2 2025

¹ Phase 3 randomized, placebo-controlled, observer-blinded trial to evaluate the safety of VLA15 in healthy children 5 through 17 years of age; <https://clinicaltrials.gov/study/NCT05634811>



VLA1601: Potential to be a Differentiated Zika Virus Vaccine Candidate

Adjuvanted, inactivated whole virus vaccine candidate

Zika viral disease

- Flaviviral disease transmitted by *Aedes* mosquitoes¹
- Common flu-like symptoms, lasting between 2 -7 days
- Devastating effects in newborns and adults:
 - Microcephaly and severe brain defects in newborns
 - Guillain-Barré syndrome² 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	[Progress bar from Discovery to Phase 3]					Potentially eligible for PRV	Potential BLA approval 4Q 2023	CEPI/ Butantan (LMIC)
	VLA15 ³ : Lyme disease	[Progress bar from Discovery to Phase 2]						Cohort 2 currently enrolling	
	VLA84: Clostridium difficile	[Progress bar from Discovery to Phase 1]						Developed to EoP2/ on-hold	Open to partnering
	VLA1601: Zika	[Progress bar from Discovery to Phase 1]						Expected clinical re-entry early 2024	-
	VLA1554: hMPV	[Progress bar from Discovery to Pre-Clinical]						Initial pre-clinical PoC completed	Partnering under evaluation
	VLA2112: EBV	[Progress bar from Discovery to Pre-Clinical]						Antigen identification by end 2023	-
	Other pre-clinical activities	[Progress bar from Discovery to Pre-Clinical]							

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9M 2023 Financials: Product Sales of €106.1m

Travel channel showing continued, significant recovery

€m (unaudited)	9M 2023	9M 2022	9M 2022 at CER*	% at CER
IXIARO [®] /JESPECT [®]	50.3	22.9	22.2	126.7%
DUKORAL [®]	21.1	9.2	8.7	142.7%
Third party products	29.1	18.4	18.0	61.1%
Total product sales (excl. COVID-19)	100.4	50.6	48.9	105.3%
COVID-19 vaccine	5.7	23.9	23.9	-76.2%
Total product sales	106.1	74.4	72.8	45.8%

*Constant Exchange Rate

9M 2023 Financials: Income Statement



€m (unaudited)	9M 2023	9M 2022
Product sales	106.1	74.4
Other Revenues	5.7	175.5
Revenues	111.8	249.9
Cost of goods and services	(74.8)	(202.7)
Research and development expenses	(42.2)	(75.4)
Marketing and distribution expenses	(33.9)	(13.1)
General and administrative expenses	(35.1)	(23.3)
Other income / (expense), net	17.0	7.5
Operating loss	(57.2)	(57.1)
Finance, investment in associates & income taxes	(12.1)	(42.0)
Profit/loss for the period	(69.3)	(99.1)
Adjusted EBITDA¹	(46.0)	(38.0)

¹ 9M 2023 Adjusted EBITDA was calculated by excluding €23.3 million (9M 2022: €61.1 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment from the €69.3 million (9M 2022: €99.1 million) loss for the period as recorded in the consolidated income statement under IFRS.

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Updated 2023 Financial Guidance

Reflects Lower R&D Expenditure

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 (assuming a sale of the Priority Review Voucher received upon a potential approval of VLA1553 before year-end)

R&D investments now expected between €60 million and €70 million

- Previously between €70 million and €90 million; mainly driven by lower than anticipated costs related to the closeout of the COVID-19 activities

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Chikungunya vaccine candidate VLA1553

- PDUFA action date, potential BLA approval by end of November
- Adolescent immunogenicity results in November 2023
- 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

- 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

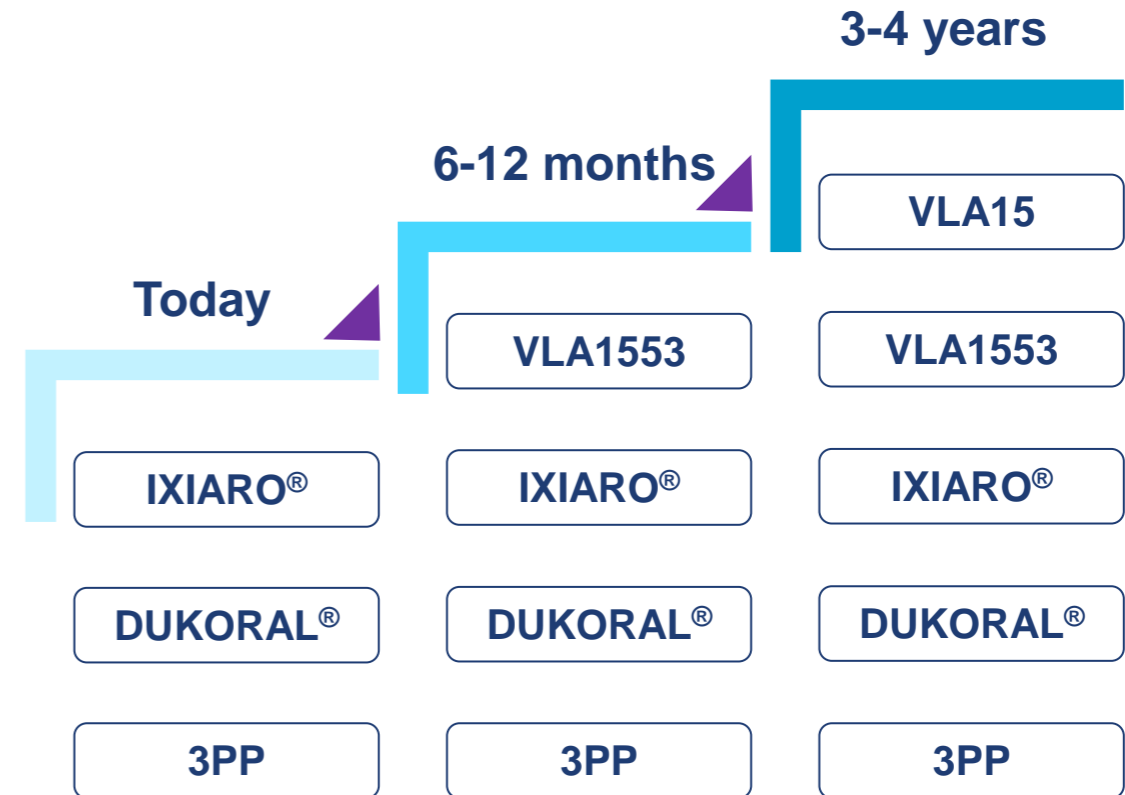


Valneva is Poised for Substantial Growth

Led by potential new product launches

Additional growth drivers:

- Continued recovery of travel market to pre-COVID levels and beyond
- 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

