



valneva

**A LEADING SPECIALTY VACCINE
COMPANY**

COMPANY PRESENTATION

SEPTEMBER 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.

Valneva Summary and Core Strengths



Fully integrated specialty vaccine company focused on development, manufacturing and commercialization of **prophylactic vaccines for infectious diseases** with significant unmet medical need



- **Highly specialized and targeted approach to development of unique prophylactic vaccines**
 - **Advanced pipeline of differentiated clinical-stage assets** designed to address large populations
 - **Highly experienced leadership team with vaccine development and regulatory expertise;** clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization
 - **Highly developed, nimble and sophisticated manufacturing infrastructure**
 - **Specialist sales infrastructure: three commercialized vaccines; distribution rights for third-party vaccines**
-
- **Product Sales of €114.8M in 2022 (+82.3% increase vs 2021); On track for 2023 guidance of €130 - €150M**
 - **Cash position of €254.5M at March 31, 2023**

Advanced, Focused and Differentiated Clinical Pipeline and Promising Early-Stage Targets



	Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial	Next Inflection Point	Development Partners
Clinical Portfolio	VLA1553: Chikungunya						<i>Potentially eligible for PRV</i>	Potential BLA approval 4Q 2023	CEPI/ Butantan (LMIC)
	VLA15: Lyme disease							Enrolling second cohort for 2024-2025 tick seasons	
	VLA84: Clostridium difficile							Developed to EoP2/ on-hold	Open to partnering
	VLA1601: Zika							Potential clinical re-entry in early 2024	-
	VLA1554: hMPV							Initial pre-clinical PoC completed	Open to partnering
	VLA2112: EBV							Antigen identification by end 2023	-
	Campylobacter							Pre-clinical entry subject to gating criteria	
	Parvovirus							Pre-clinical entry subject to gating criteria	



Chikungunya Vaccine Candidate – VLA1553*

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

Chikungunya: A Major Public Health Threat

Mosquito-transmitted disease with potentially debilitating consequences



Aedes aegypti



Aedes albopictus

- Chikungunya virus (CHIKV) is transmitted by **Aedes** mosquitoes¹
- Acute chikungunya, seen in up to 97% of those infected, typically presents with sudden onset of **high fever and joint pain**.¹
- Often causes **large, explosive outbreaks**, affecting one-third to three-quarters of the population¹; difficult to predict next outbreaks²
- High burden of disease: outbreaks can have substantial health-economic impact; infection can progress to **severe chronic symptoms** in many patients⁴
- **Outbreaks** have occurred in Asia, Africa and across Latin America¹ with the potential for it to happen in the U.S. and Europe^{2,4}; current outbreak in Paraguay⁵ with PAHO issuing an epidemiological alert for the Americas⁶
- **Returning infected travelers** can trigger local transmission in areas where relevant mosquitoes are established (e.g. Southern U.S./Europe)²

No curative treatment and no vaccines available to date

1. Staples et al. CDC Yellow Book 2020, Chapter 4 . 2. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069. 3. Lindsey et al. *Am J Trop Med Hyg*. 2018;98(1):192-197. doi:10.4269/ajtmh.17-0668 4. Silva LA et al. *J Clin Invest*. 2017 Mar 1;127(3):737-749; 5 [PAHO provides guidance to countries in response to increased chikungunya cases](#); 6 [Epidemiological Alert: Chikungunya increase in the Region of the Americas](#)



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 sero-response** with a single dose; 100% sero-response rate after **14 Days** shown in preceding trial¹; **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

- PDUFA date: **end of November 2023**
- Potential award/sale of PRV upon approval: **~\$100M**
- Adolescent trial: reported positive initial safety and immunogenicity data 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: Clinical Data Highlights^{1,2}

Live-attenuated CHIKV vaccine candidate targeting rapid and long-lasting immunity with a single shot

Immunogenicity Data

- Seroresponse³ Rate (SRR) in 99% of participants after a single vaccination
- Immunogenicity profile maintained over time: 99% SRR after 12 months⁴
- Older adults (≥ 65 years) achieved similar SRR and neutralizing antibody titers as younger adults (<65 years)^{1,4}
- 100% sero-response after 14 days and sustained to Month 12 in preceding trial²

Safety Data¹

- VLA1553 was generally well tolerated among the >3,600 adults and 754 adolescents evaluated for safety
- Pivotal Safety Data:
 - ~50% of study participants had solicited systemic adverse events, most commonly headache, fatigue and myalgia
 - Majority of solicited adverse events mild or moderate. 2.0% of study participants reported severe solicited adverse events, most commonly fever.
- Adolescent trial in Brazil suggests favorable safety profile regardless of previous CHIKV infection⁵

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 μ PRNT₅₀ (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 Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate



Chikungunya Global Market Segments

Global market for chikungunya vaccines estimated to exceed \$500 million per year by 2032¹

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



VLA1553 Fits Perfectly Within our Existing Commercial Infrastructure

High-caliber team with significant experience in the vaccine space

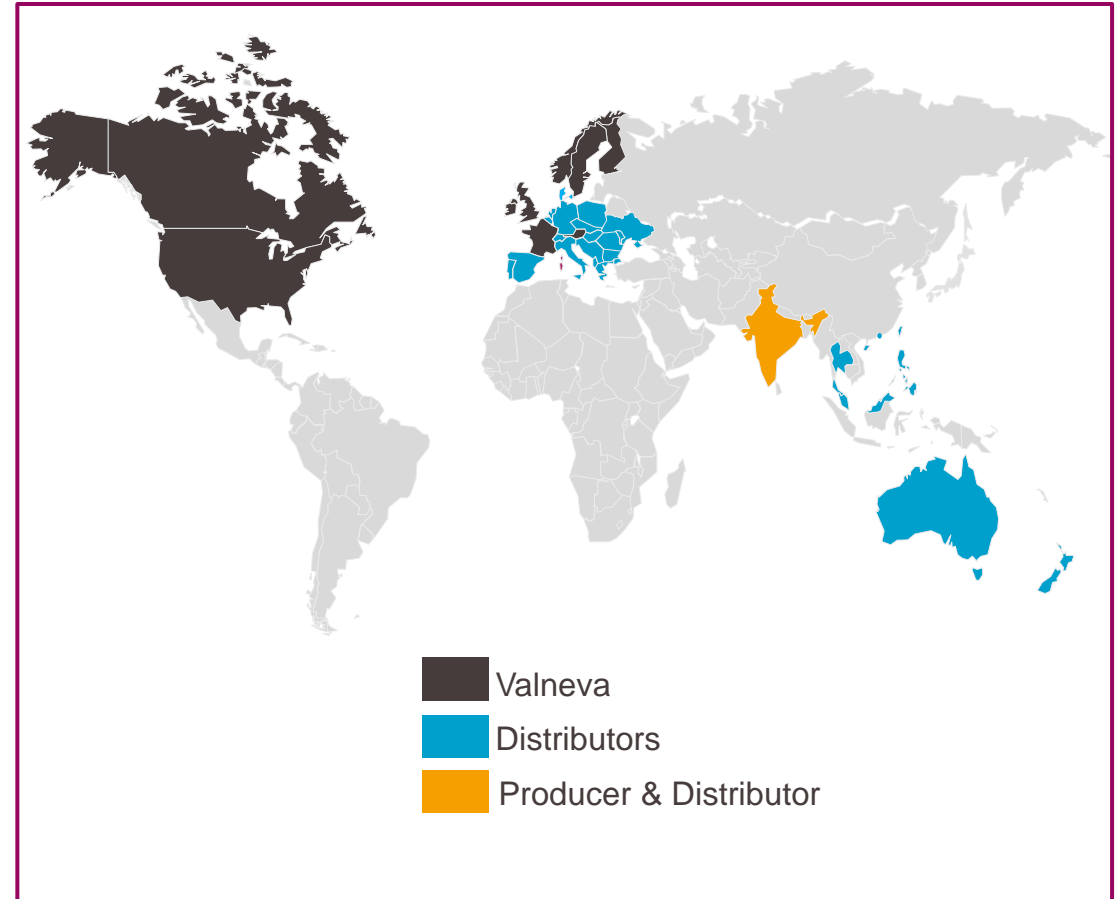
Highly experienced teams with deep expertise in vaccine commercialization

Commercial infrastructure present in most key travel markets; footprint extended through distribution partners

Integrated sales, marketing, medical and government affairs capabilities focused on unlocking brand potential

Leverage data driven insights and digital tools to enhance commercial capabilities

Commercial Footprint





Lyme disease Vaccine Candidate – VLA15



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}, including first pediatric and adolescent data (priming and 12-month 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 (six serotypes) to help 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 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;

Valneva's and Pfizer's Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine VLA15



Established	April 2020
Updated	June 2022; Equity Investment of \$95 Million by Pfizer; Phase 3 cost split 40/60% (Valneva/Pfizer)*
Rationale	Maximize Lyme disease opportunity by leveraging Pfizer's outstanding development and commercial expertise
Scope	Pfizer leading late-stage development and will have sole control over global commercialization
Key Financial Terms	<p>Valneva eligible to receive up to \$408 million (\$165 million received)</p> <ul style="list-style-type: none"> • \$130 million upfront payment (received) • \$35 million in development milestone payments (received) • \$143 million in early commercialization milestones • \$100 million in cumulative sales milestones <p>Tiered sales royalties ranging 14-22%</p>
Co-development costs	Valneva responsible for 40%; Pfizer 60%
Status	Pivotal Phase 3 study currently enrolling adult and pediatric participants

* As of 1st May 2022



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

VLA15-221: First positive pediatric data (April 2022¹)

- Strong immunogenicity profile in adult² (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 vaccination³; 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

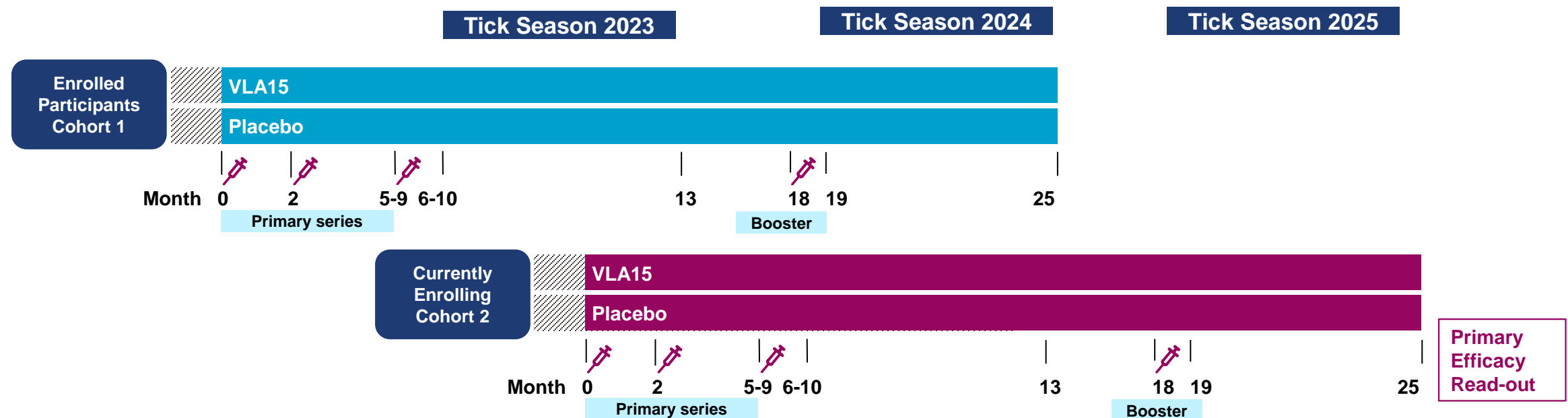
VLA15-201: First positive immunogenicity data (July 2020)⁷

- 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 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









Valneva Commercial Products



Current Commercial Portfolio



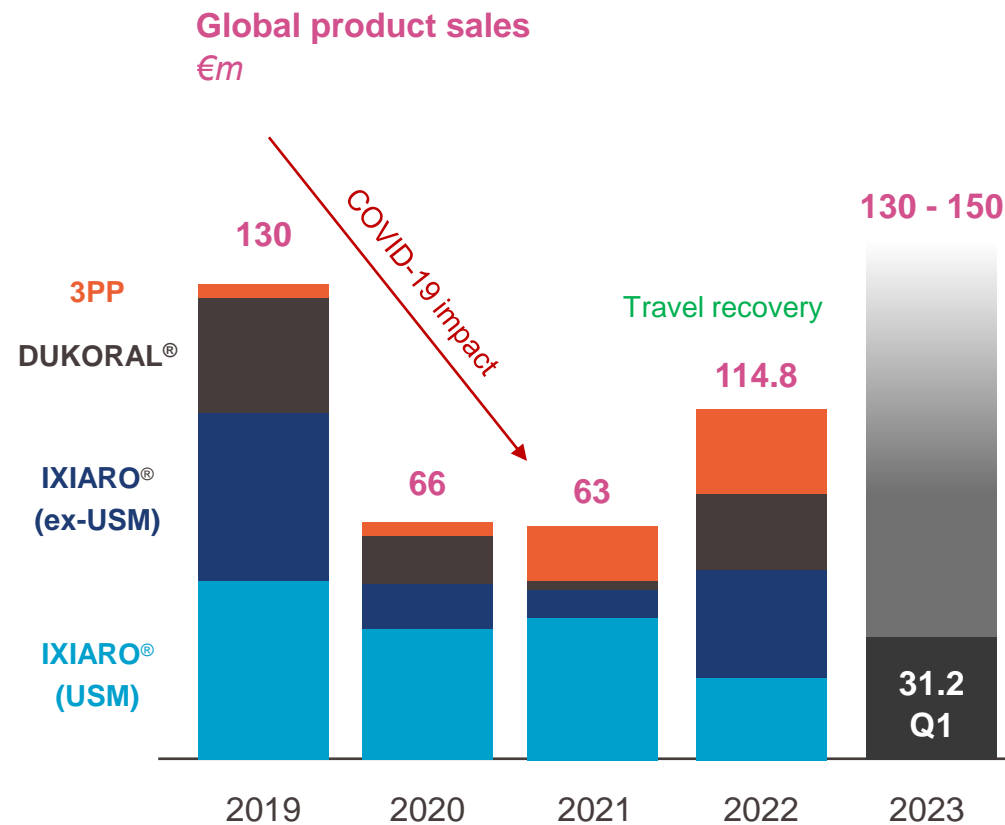
	Brand	Indication*	Partner / Year		Valneva commercial rights & key markets
Proprietary	IXIARO [®]	Active immunization against Japanese encephalitis from 2 months of age		Global Rights	Valneva direct markets : US, CA, UK, FR, Nordics, BE, NL, AT Key markets addressed by Partners : DE, AU, IL
	DUKORAL [®]	Active immunisation against Cholera and ETEC** from 2 years of age		Global Rights	Valneva direct markets : CA, UK, FR, Nordics, AT Key markets addressed by Partners : DE, AU, IL, PL
3rd-Party Distribution	FLUAD[®] FLUCELVAX[®]	Active immunization against Flu		2016	Rights licensed from Seqirus in Austria
	KamRAB	Passive, transient post-exposure prevention of rabies infection		2018	Rights licensed from Kamada in Canada
	Rabipur [®]	Active immunization against rabies in individuals of all ages		2020	Rights licensed from Bavarian Nordic in select markets: CA, UK, FR, BE, NL, AT
	Encepur [®]	Active immunization against tick-borne encephalitis in adults and children			Rights licensed from Bavarian Nordic in select markets: Austria & France
	PreHevbri	Active immunization against hepatitis B virus in adults		2022	Rights licensed from VBI in select markets: UK, Nordics, Netherlands, & Belgium

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

Product Sales: Strong Growth Anticipated, Driven by Recovery of Travel Segment



Revenues Expected to Recover to Pre-Pandemic Levels in 2023¹; and on volume basis by 2024²



2023 guidance

Product sales of €130 million to €150 million, including:

- Marginal COVID-19 vaccine sales under an existing supply agreement

Other income of €90 million to €110 million

R&D expense of €70 million to €90 million

¹ Valneva Reports Full Year 2022 Revenue and Cash, Provides First 2023 Guidance ² IATA/ Tourism Economics (July 2022)

Commercial Portfolio: Strong Sales Performance of €114.8 Million in 2022



2022 product sales grew by 82.3% vs. prior period

Significant recovery in travel markets

- Product sales of the **Japanese encephalitis vaccine** in the travel market increased to €28.8 million compared to €7.1 million (FY 2021)
- Product sales of the **cholera vaccine** increased 610.3% to reach €17.3 million compared to €2.4 million (FY 2021)
- **Third-party product** sales increased to €26.5 million from €15.4 million (FY 2021)
- Strong growth offset by IXIARO® sales to U.S. Department of Defense of €12.5 million vs €38 million (FY 2021); **expect new supply contract in 2023**
- The **COVID-19 vaccine** generated sales of €29.6 million

2023 guidance

Product sales of €130 million to €150 million, including:

- Marginal COVID-19 vaccine sales under an existing supply agreement

Other income of €90 million to €110 million

R&D expense between €70 million and €90 million



Executing Our Commercial Strategy

Three key levers to accelerate commercial performance

Travel health recovery

Customer engagement through Valneva Travel Health

- Building brand identity
- Elevate Valneva's reputation as a committed travel health partner for HCP and travelers
- Provide tools and services to customers supporting acceleration of travel health recovery



Expand vaccine portfolio

Evaluation of new in-licensing and product acquisitions

Distribution partnerships in selected regions

- Bavarian Nordic for Rabies and TBE vaccines
- Seqirus for flu vaccines
- Kamada for Rabies IgG
- VBI for Hep B vaccine
- Adding complementary distribution partnerships



VLA1553 launch preparedness

Evolution of commercial infrastructure

- Optimize commercial infrastructure to support launch excellence
- Market access/recommendations
- Market and brand development





Financial Overview

Company is Well Capitalized to at Least 2024

Balance sheet strengthened by successful capital raises

May 2021: U.S. Initial Public Offering with gross proceeds of \$107.6 million

2021-2022: Follow on offerings and debt financing

- Most recent upsized Global Offering brought in €102.9 million in gross proceeds; led by new U.S. investor¹, with strong support from existing holders in the U.S. and Europe
- Increased the principal amount of existing debt financing agreement²

June 2022: €90.5 (\$95) million investment by Pfizer³ to support Valneva's contribution to Phase 3 trial of VLA15

Cash position of €254.5 million (March 31, 2023)⁴



Nasdaq: VALN – Euronext Paris: VLA

¹ Valneva Announces Pricing of €102.9 Million Global Offering of American Depositary Shares and Ordinary Shares; ² Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed; ³ Valneva and Pfizer Announce Closing of Equity Investment; ⁴ Valneva Reports First Quarter 2023 Financial Results and Provides Corporate Updates

Key Upcoming Catalysts and News Flow



Chikungunya vaccine candidate VLA1553

- Adolescent study immunogenicity results November 2023
- Potential BLA approval and first launch Q4 2023; Potential award of PRV
- Initiate EMA regulatory submission in 2023

Lyme disease vaccine candidate VLA15

- Continued enrollment of second cohort
- Timely priming (Cohort 2) and boosting (Cohort 1) in advance of 2024 tick season

Additional potential news flow

- Potential for VLA1601 (Zika virus vaccine) to re-enter clinical development for further program evaluation
- 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® expected in Q4
- Potential clinical re-entry of VLA1601 (Zika vaccine)
- Potential in-licensing or acquisition of additional clinical assets
- Potential U.S. reimbursement for CDC-recommended travel vaccines

