Valneva Reports First Nine Months 2024 Financial Results and Provides Corporate Updates

November 7, 2024

valneva

Disclaimer

This presentation does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva SE shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful.

Valneva is a European company. Information distributed is subject to European disclosure requirements that are different from those of the United States. Financial statements and information may be prepared according to accounting standards which may not be comparable to those used generally by companies in the United States.

This presentation includes only summary information provided as of the date of this presentation only and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time without notice. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of its affiliates, directors, officers, advisors and employees is under any obligation to update such information or shall bear any liability for any loss arising from any use of this presentation. The information has not been subject to independent verification and is qualified in its entirety by the business, financial and other information that Valneva is required to publish in accordance with the rules, regulations and practices applicable to companies listed on Euronext Paris and the NASDAQ Global Select Market, including in particular the risk factors described in Valneva's universal registration document filed with the French Financial Markets Authority (*Autorité des Marchés Financiers*, or AMF) on March 22, 2024 (*document d'enregistrement universel* 2023) under number D. 24-0157 (the "2023 URD"), and in the Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 22, 2024, as well as the information in any other periodic report and in any other press release, which are available free of charge on the websites of Valneva (www.valneva.com) and/or the AMF (www.amf-france.org) and SEC (www.sec.gov).

Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including with respect to business partnerships, the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and review of existing products. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva

This presentation presents information about 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 9M 2024**
- **Financial Outlook**
- **Newsflow**
- **Q&A**

First Nine Months 2024 Key Results

Performance in Line with 2024 Guidance

Product Sales
€112.5m

Guidance €160-170m*

Cash Position
€156.3m**

Well financed

9M 2024

Strong R&D execution

Lyme, Chik adolescents/peds and persistence

Long-term R&D strategy

Scientific Positioning & Partnering

IXCHIQ®: Lancet, CEPI

Shigella / LimmaTech

*Guidance narrowed, **Including €61.2m from recent private placement

Valneva Strategy for Growth

Mid-Term Vision: A Major Turning Point in Valneva's Evolution

- Targeting sustained profitability from 2027;
  driven by success of the Lyme disease vaccine program*
  - On track in pivotal Phase 3 trial
  - Regulatory filings (2026), first approvals and sales (2027)*
  - $143m in potential milestone payments in 2027
  - Substantial royalties and up to $100m in sales milestones
- Near-term focus on growing commercial sales
  - Remain confident in long-term IXCHIQ® prospects – uptake will be carefully reviewed in coming months: U.S., Canada, first EU launches and demand from existing and potential future LMIC partners
  - Commercial business with improved margins expected to generate cash from 2025
- Building for the future by advancing an attractive and differentiated R&D pipeline
  - "Mandatory" R&D: Chik development (Phase 3 ped, Phase 4) – financial support through CEPI grant
  - Risk-mitigating, with stringent focus on efficient capital allocation for clinical assets (Shigella, ZIKA)
  - Next clinical entries post Lyme licensure*

*Subject to positive Phase 3 data

Agenda

- Introduction
- **Business Update**
- Financial Report 9M 2024
- Financial Outlook
- Newsflow
- Q&A

Valneva's Augmented Commercial and R&D Portfolio

Further extending a unique, differentiated portfolio

	Program	Vaccine Design	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial
Commercial Products	**IXIARO®**	Only U.S./ EU approved vaccine against Japanese encephalitis					
	DUKORAL®	Established Cholera (ETEC[1]) vaccine approved in >30 countries					
	IXCHIQ®	World's first and only approved chikungunya vaccine (U.S., Europe, Canada); Reviews ongoing in UK and Brazil					
Clinical Programs	**VLA15:** Lyme disease	Advanced the furthest in clinical development – two Phase 3 trials in progress					
	VLA1553: Chikungunya	Phase 3 adolescent study (Brazil) and Phase 2 pediatric study support potential label expansion					
	S4V2: Shigellosis	Phase 2 CHIM[2] and pediatric studies to begin H2 2024					
	VLA1601: Zika	Potential for first/best-in-class					
Key Pre-Clinical Activities	**VLA2112:** EBV						
	Various Enteric diseases						

1 ETEC indication in some markets only; 2 Controlled human infection model

World’s leading Lyme Disease Vaccine Candidate

VLA15

valneva

Lyme Disease Represents A Major Medical Need And Market Opportunity

No vaccine is currently available to prevent Lyme disease in humans

Annual Burden of Disease

U.S.[1]

~476K cases

Europe[2]

>129K cases

Severe Manifestations[3]

10-30% cases develop → Lyme carditis, Lyme neuroborreliosis, Lyme arthritis

Persistent Symptoms[4,5]

5-10% cases continue to have persistent symptoms following treatment

Commercial opportunity for Valneva

U.S.
87 million

Europe
202 million

Population Living in Endemic Regions[1,2]

>$1 billion estimated global market[6]

1 Kugeler et al. Emerging Infectious Disease, 2021 (doi.org/10.3201/eid2702.202731); **2** Burn at al. Vector Borne and Zoonotic Disease, 2023 (DOI: 10.1089/vbz.2022.0071); **3** Schwartz et al. Morbidity and Mortality Weekly Report Nov. 10, 2017; **4** Ursinus: https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(21)00119-8/fulltext; **5** Aucott, J.N., et al., Risk of post-treatment Lyme disease in patients with ideally-treated early Lyme disease: A prospective cohort study. Int J Infect Dis, 2022. 116: p. 230-237.; **6** Lyme Disease research and analysis conducted by an independent market research firm

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 (>97% coverage)
- Established mechanism of action
- U.S. FDA Fast Track Designation
- Phase 3 fully recruited; primary vaccination completed[1]

Market Opportunity

- Exclusive, worldwide partnership[2]

Pfizer

- >$1billion estimated global market[3]
- Valneva eligible for upfront and milestone payments up to $408 million ($165 million received)
- Tiered sales royalties 14-22%

Upcoming Milestones

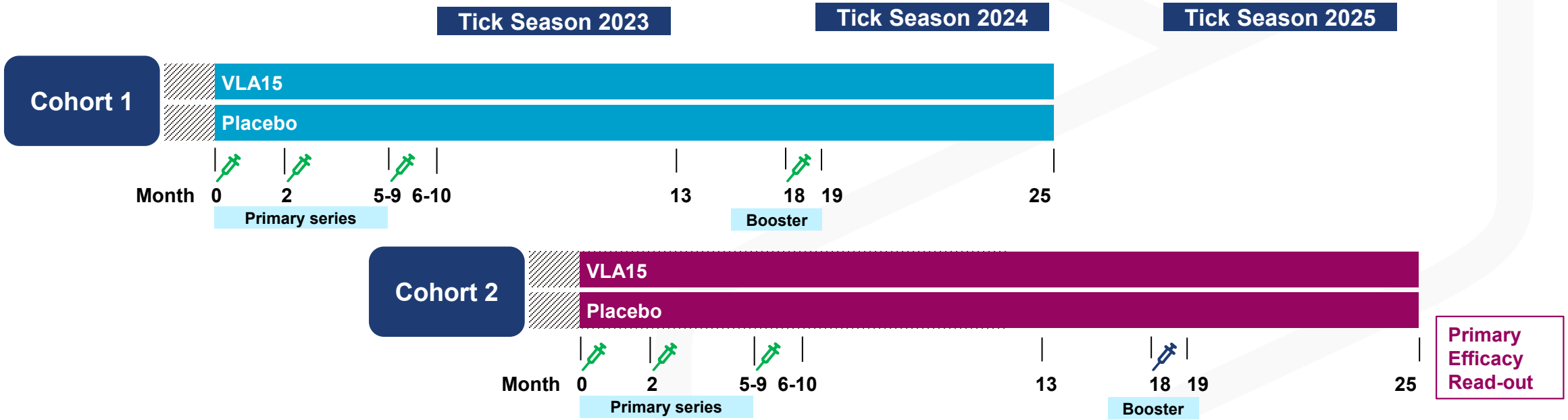
- On track for Phase 3 trial conclusion (end 2025); Regulatory filings (U.S.+ EU) in 2026[4]
- Completed Valneva contribution to Phase 3 trial costs in H1 2024
- Recently reported two-year antibody persistence and booster results

1 Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion; **2** Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; **3** Lyme Disease research and analysis conducted by an independent market research firm; **4** Subject to positive data

Phase 3 Efficacy Study Fully Enrolled; Completed Primary Vaccination

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

- **Population**: ~9,400 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

The World’s First and Only Chikungunya Vaccine

IXCHIQ® / VLA1553

IXCHIQ® is currently approved by the U.S. Food & Drug Administration (FDA), European Medicines Agency (EMA) and Health Canada for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older.

Continued approval of IXCHIQ® in the U.S. is contingent upon verification of clinical benefit in confirmatory studies.

valneva

IXCHIQ® Builds on Key Differentiators to Drive Growth

IXCHIQ®
(CHIKUNGUNYA VACCINE, LIVE)

The 1st and only vaccine against chikungunya providing a strong and persistent immune response with only one dose

- 98.9% seroresponse rate at Day 29 - Sustained seroresponse rate at 97% after two years (EU label)
- Only chikungunya vaccine to show strong immunogenicity in adults 18-64 yrs and 65+ (U.S., EU, CA labels)
- Generally well tolerated among the >3,600 adults and 754 adolescents evaluated for safety
- Convenient single dose

Key Achievements Focused on Expanding Access to IXCHIQ®

Milestones Achieved

- Phase 3 adolescent trial showed strong safety and immunogenicity profile (up to six months)
- Enrollment in Phase 2 pediatric trial to support Phase 3 and enable further label extension
- Published long-term antibody persistence results (up to 24 months) following single vaccination
- Filed for label extension for adolescents: EMA and Health Canada; included two-year persistence data in Canadian filing
- Achieved first sales in Canada in Q3 2024: initial stocking orders; preparing to launch in France
- Secured substantial non-dilutive funding from CEPI to enhance access in LMICs and support Phase 4 and other key IXCHIQ® trials

Near-Term Catalysts

- Potential approvals in Brazil (Q4 2024) and the UK (Q1 2025)
- File for U.S. label extension to adolescents as well as two-year antibody persistence data (Q4 2024)
- Report three-year antibody persistence results (Q4 2024)
- Report Phase 2 pediatric trial topline results (Q4 2024)
- Potential new LMIC partner (Asia)

Upcoming and Future Opportunities to Capture Greater Penetration

Upcoming and Future Opportunities

- MMWR[1] publication expected to drive further retail growth in U.S.
- Launches in Europe; Channel expansion in Canada
- Additional ACIP[2] and European recommendations
- Travel software protocol updates
- Significant label updates in the next 12 months expected to further differentiate IXCHIQ®
- LMIC[3] approval(s); additional partnership(s)
- Continued discussions with U.S. Department of Defense

1. Morbidity and Mortality Weekly Report; 2. CDC Advisory Committee on Immunization Practices; 3 Low and middle income countries

World's Most Clinically Advanced Tetravalent *Shigella* Vaccine Candidate

S4V2

valneva

S4V2: Opportunity to develop first-in-class vaccine for a life-threatening disease

Tetravalent bioconjugate vaccine with potential to cover up to ~85% of shigellosis infections[1]

Vaccine Highlights

- World's most clinically advanced tetravalent *Shigella* vaccine candidate
- Exclusive global license from LimmaTech Biologics (LMTB)[2]
- Includes four most common pathogenic *Shigella* bacteria serotypes: *S. flexneri* 2a, 3a, 6, and *S. sonnei*
- Positive Phase 1/2 clinical data reported[3], including robust immunogenicity; favorable safety and tolerability

Market Opportunity

- Global market expected to exceed $500 million annually[4]
  - Travelers and military
  - Endemic countries (LMICs[5])
- Second-leading cause of fatal diarrheal disease; Up to estimated 165 million cases and 600,000 deaths annually[6]
- Identified as a priority vaccine by World Health Organization (WHO)[7]

Upcoming Milestones

- Phase 2 CHIM[8] and pediatric studies to begin in Q4 2024 (conducted by LMTB)
- Valneva to assume all further R&D, CMC[9] and regulatory activities; worldwide commercialization upon potential approved
- Supported by FDA Fast Track

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8878964/pdf/vaccines-10-00212.pdf; **2.** Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate; **3** 20240221_LimmaTech_Shigella-Interim-Data-PR_Final.pdf (lmtbio.com); **4** : LEK 2024; Appox. 7 years after launch; **5**. Low-and-Middle-Income Countries; **6**. *Shigellosis* | CDC Yellow Book 2024; **7**. Immunization, Vaccines and Biologicals (who.int); **8**. Controlled Human Infection Model; **9**. Chemistry, Manufacturing and Controls

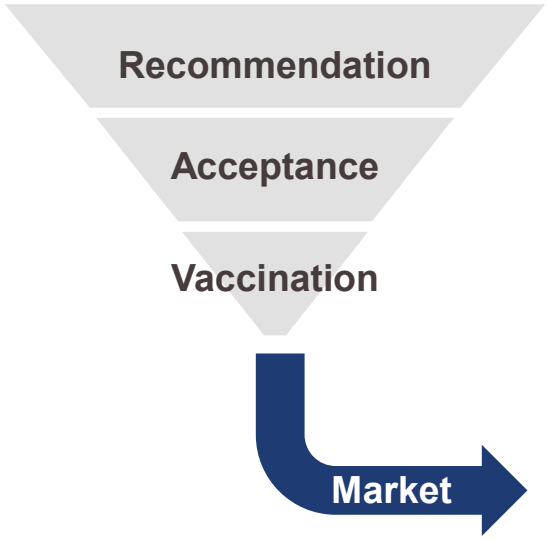
Historical and Planned Clinical Studies

Multiple catalysts and decision points for envisaged development strategy

* *If needed*

Commercial Assessment of Shigella vaccine

Shigella vaccine market estimated to peak at ~€500 million[1]



	Traveler (~23%)	Children in endemic countries (~76%)	Military (<1%)
Recommendation	20-50% (Med-high risk destinations)	30-100% (OOP-reimb.)	70-90% (Med-high risk destinations)
Acceptance	30% (OOP)	15-60% (OOP) 50-90% (reimb.)	90%
Vaccination	2-5%	9-11%[2] (OOP) 15-50%[2] (reimb.)	100%
Market	▪ Europe, North America, Japan, South Korea and Singapore with €80-85 million from the U.S. alone	▪ Non-Gavi endemic countries: public funding anticipated, driven by high disease burden notably in India, Brazil, Indonesia and Gavi supported countries. ▪ Gavi-supported countries, vaccines could cover over 10m children per year	▪ U.S. representing c.50% of the revenue

Source: Market Study: LEK 2024, 1 Appox. 7 years after launch; 2 Converted to vaccination rate by applying the yearly vaccination penetration every year over a cohort of 5 years

Second-Generation Zika Virus Vaccine Candidate

VLA1601

valneva

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/

Agenda

- Introduction
- Business Update
- **Financial Report 9M 2024**
- Financial Outlook
- Newsflow
- Q&A

9M 2024 Financials: Product Sales of €112.5 million

Commercial business on track for continued growth

€m (audited)	9M 2024	9M 2023	% Change
IXIARO®/JESPECT®	66.0	50.3	+31%
DUKORAL®	22.3	21.1	+6%
IXCHIQ®	1.8	--	--
Third party products	22.5	29.1	-23%
Total product sales	**112.5**	**100.4**	**+12%**
COVID-19	--	5.7	-100%
Total product sales including COVID-19	112.5	106.1	+6%

9M 2024 Financials: Income Statement

€m (unaudited)	9M 2024	9M 2023
Product sales	112.5	106.1
Other Revenues	4.2	5.7
Revenues	**116.6**	**111.8**
Cost of goods and services	(71.3)	(74.8)
Research and development expenses	(48.6)	(42.2)
Marketing and distribution expenses	(35.7)	(33.9)
General and administrative expenses	(32.6)	(35.1)
Gain from sales of Priority Review Voucher, net	90.8	--
Other income / (expense), net	14.9	17.0
Operating Profit / (loss)	**34.2**	**(57.2)**
Finance income / (expense) & income taxes, net	(9.5)	(12.1)
Profit / (Loss) for the period	**24.7**	**(69.3)**
Adjusted EBITDA[1]	**48.6**	**(46.0)**

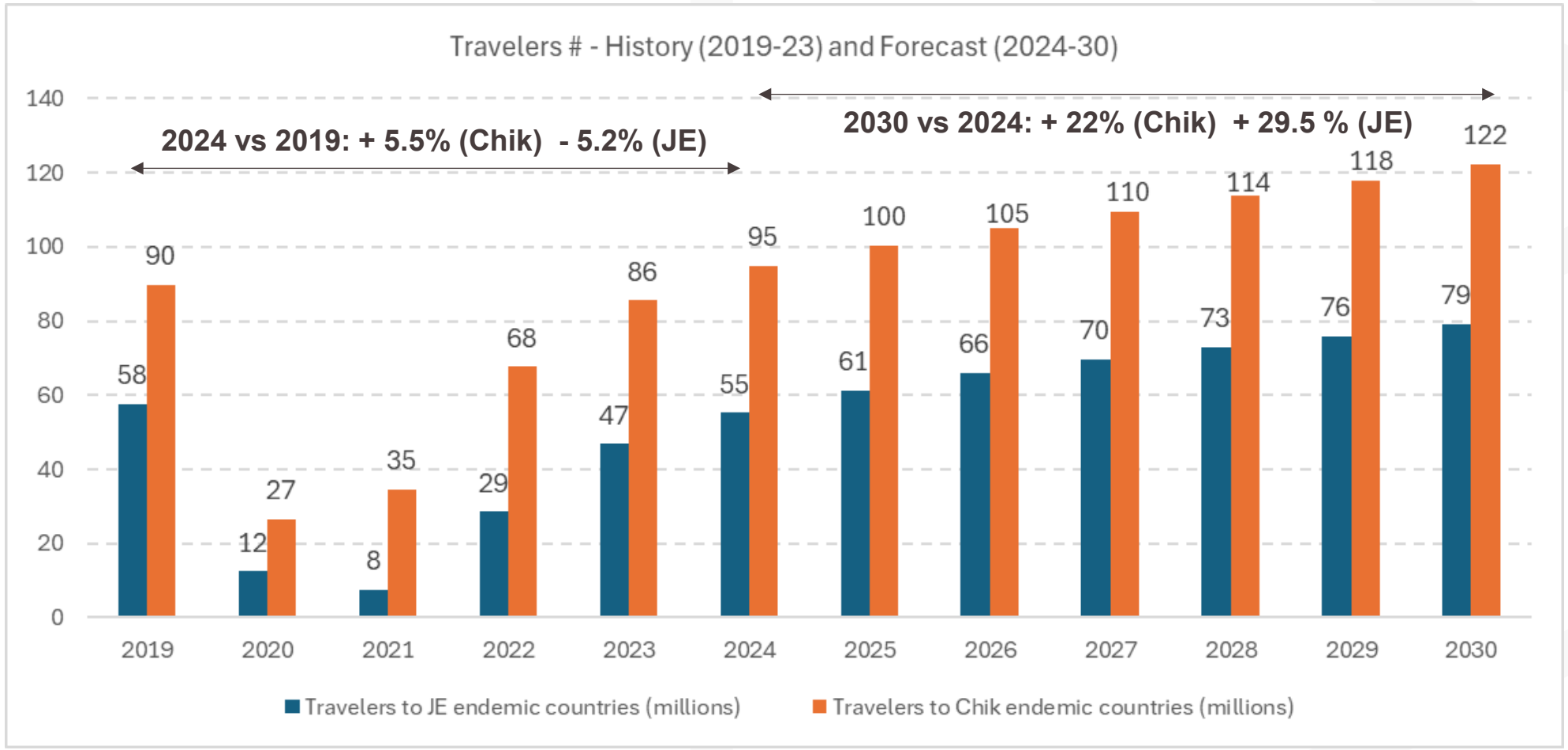
1 9M 2024 Adjusted EBITDA was calculated by excluding €23.9 million (9M 2023: €23.3 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), depreciation, amortization and impairment (excluding impairment loss of disposal) from the €24.7 million profit (9M 2023: €69.3 million 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.

Agenda

- Introduction
- Business Update
- Financial Report 9M 2024
- **Financial Outlook**
- Newsflow
- Q&A

Traveler from U.S. and EU: History and Forecast

Recovering from pre-COVID-19; strong growth anticipated



Data source: IATA data – last update August 2024

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

Narrowed 2024 Guidance

- Product Sales: €160 - €170 million*
- Total Revenues: €170 - €180 million
- Other Income: €100 - €110 million
- R&D Expense: €65 - €75 million
- Significantly lower cash burn vs. 2023
  - Completed agreed-upon cost contribution to Phase 3 Lyme disease trial in Q2 2024
  - Commercial business expected to be cash-flow positive in 2024 (excluding IXCHIQ®)

Mid-Term Outlook

- Commercial business expected to be cash-flow positive from 2025
  - Continued travel sales growth for IXIARO® and DUKORAL®
  - Double-digit CAGR for IXIARO® for at least the next 3 years
  - IXCHIQ® mid-term guidance of ~ €100m to be reviewed in the coming months
- 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 R&D support: sizable non-dilutive funding

* Assumes ~20-30% reduction in third party sales based on external supply constraints

Agenda

- Introduction
- Business Update
- Financial Report 9M 2024
- Financial Outlook
- **Newsflow**
- Q&A

Key Upcoming Catalysts and News Flow

Chikungunya vaccine

- Upcoming potential approvals: Anvisa (Brazil), MHRA (UK)
- 36-month antibody persistence data expected in Q4 2024
- Initiate Phase 4 clinical program

Lyme disease vaccine candidate VLA15

- Complete final booster dosing for by mid-2025
- Monitoring for occurrence of Lyme disease until the end of the Lyme disease season in 2025
- Potential FDA and EMA submissions in 2026, subject to positive Phase 3 data

Additional newsflow

- Initiate Phase 2 S4V2 *Shigella* vaccine studies in H2 2024 (CHIM and pediatric)
- Report Phase 1 data for second-generation Zika vaccine in H1 2025
- New U.S. Department of Defense supply contract for IXIARO®

Valneva's Near- and Mid-Term Value Drivers

VLA15 success

- Potential for major value inflection with key study conclusions next year
- Sustained profitability upon potential approval, driven by substantial commercial milestones and royalties

Growing commercial revenues

- Near term: continued growth of IXIARO® and DUKORAL®
- Further growth as IXCHIQ® gains global traction (driven by awareness, additional launches, label expansion)

Realizing future pipeline value

- *Shigella* clinical catalysts and de-risking steps in Phase 2
- Goal to enter Phase 3 post-Lyme
- Advances in Zika and select pre-clinical candidates

Agenda

- Introduction
- Business Update
- Financial Report 9M 2024
- Financial Outlook
- Newsflow
- **Q&A**

Thank you
Merci
Danke
Tack

valneva