

# Valneva presents its nine-month 2017 financial results

Analyst Presentation  
November 9, 2017



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# Agenda



- 1. Introduction – Highlights – Thomas Lingelbach**
2. Financial report nine months 2017 – David Lawrence
3. Commercialized products – Franck Grimaud
4. R&D programs – Thomas Lingelbach
5. 2017 outlook – Thomas Lingelbach
6. Q&A

# Valneva Nine-Month Results Highlights



## **Strong operational performance in first nine months 2017**

- + Ongoing excellent revenue growth
  - › Driven by c20% Product sales growth
  - › Supplementary \$39.6 million IXIARO<sup>®</sup> supply contract with US government announced this week
- + Strong EBITDA results >€12m
- + Positive operating cash flow of >€18 million

## **Major R&D progress and upcoming newsflow**

- + Lyme Phase I study fully recruited
  - › Phase I data expected in Q1 2018
- + Two new Phase I trials to commence in Q1 2018
  - › Chikungunya (potential for unique profile)
  - › Zika (Partnership with Emergent BioSolutions)

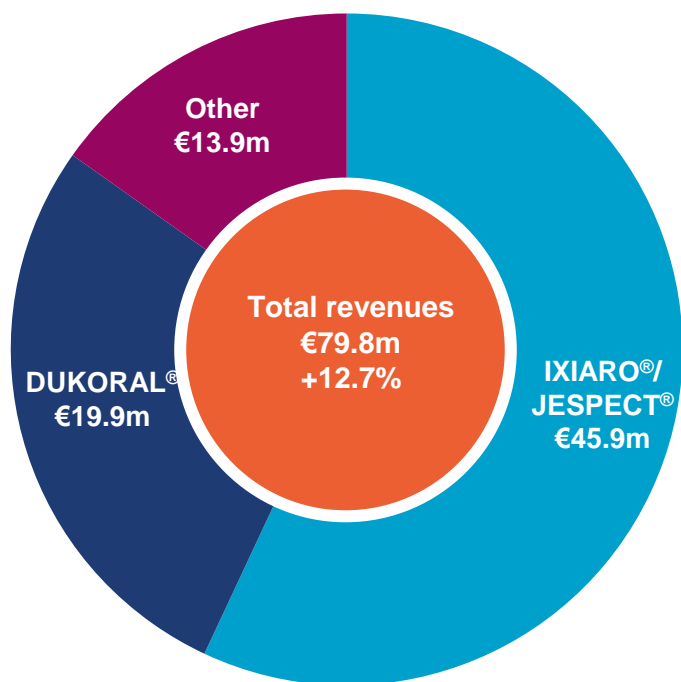
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# Valneva Nine-Month 2017 Results

Product sales growth meeting guidance, margin improvement

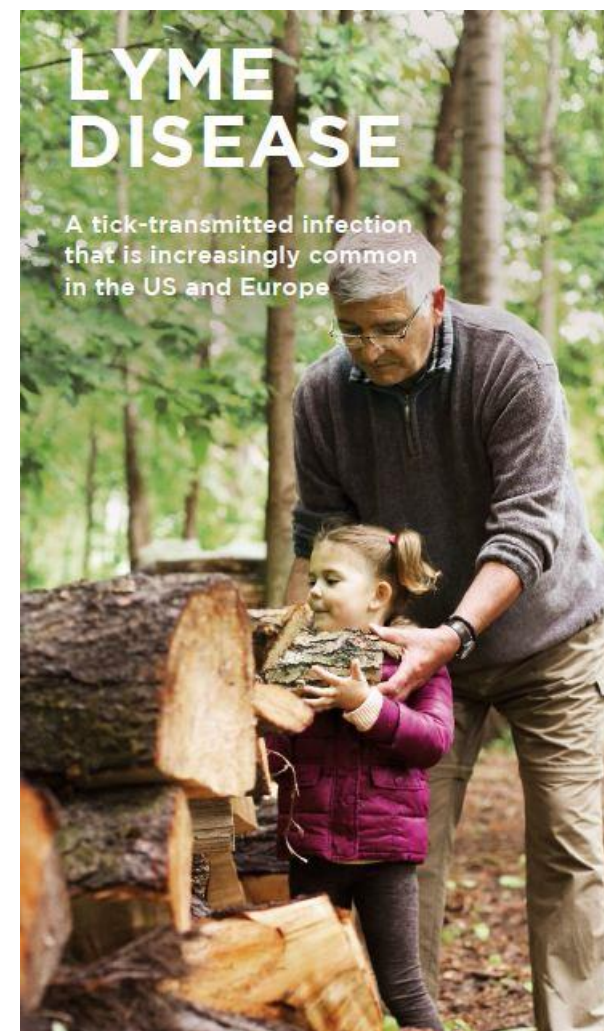


Product sales  
€67.9m

Direct sales  
70.8%

Gross Margin  
59.7%

Cash generated  
€18.3m





## YTD Q3 2017 Profit & Loss (unaudited)

### EBITDA Guidance increase to €10m - €13m

	€m - Nine months ended September 30,	
	2017	2016
<b>Revenues and grants</b>	<b>79.8</b>	<b>70.7</b>
Cost of goods and services	(32.1)	(30.0)
R&D expenses	(15.1)	(18.7)
Distribution and marketing expenses	(12.0)	(11.3)
General and administrative expenses	(11.1)	(10.4)
Other income / (expense)	(0.2)	23
Amortization and impairment	(9.0)	(39.5)
<b>OPERATING PROFIT/(LOSS)</b>	<b>0.2</b>	<b>(39.1)</b>
Finance results and tax	(8.0)	(7.3)
<b>LOSS FOR THE PERIOD</b>	<b>(7.8)</b>	<b>(46.5)</b>
<b>EBITDA*</b>	<b>12.3</b>	<b>3.5</b>

\* Calculated by excluding amortization, depreciation and impairments from the operating profit/loss



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# IXIARO®/JESPECT®

The only JE vaccine approved in the US and Europe

## Japanese encephalitis vaccine

- + Designed to protect travelers and military against Japanese encephalitis (JE)
- + Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older<sup>1</sup>



## Commercial position

- + Currently, **no effective treatment for the disease**<sup>2</sup>
- + Valneva's vaccine is the **only approved vaccine available for US and EU travelers**
- + Supply agreement in place with US military
  - › Only FDA approved JE vaccine
- + Chinese/Asian manufacturers mainly serve local public markets

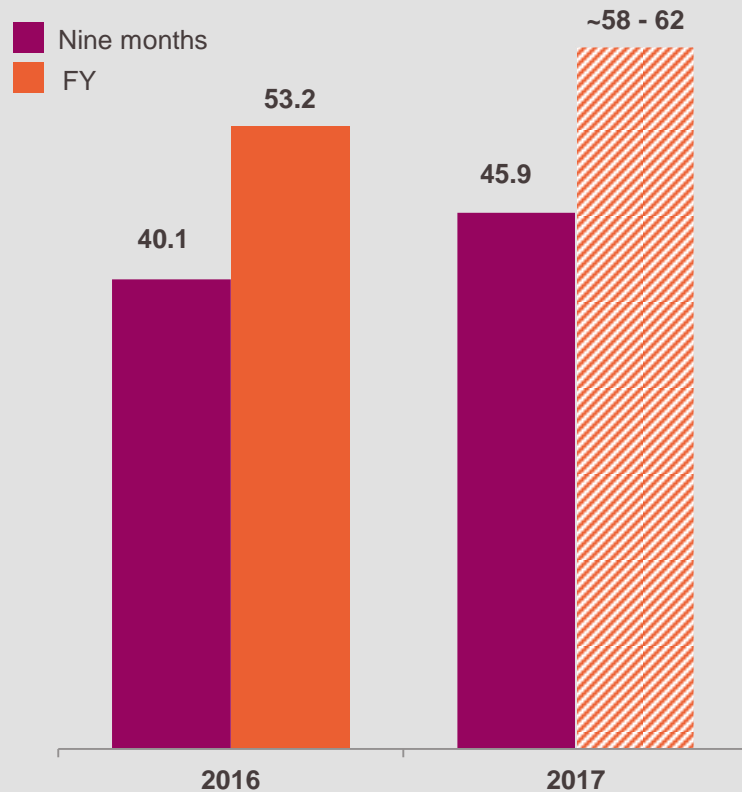
## Market potential

- + **279 million travelers to Asia** in 2015<sup>3</sup>
  - › Travelers to Asia **expected to grow by 4.4% per year**<sup>3</sup>
- + **Global JE vaccines market valued at ~€150-200m**<sup>4</sup>
  - › Traveler 65%, Military 15%, Endemic 20%<sup>4</sup>
- + **Significant growth potential in key markets**

<sup>1</sup> Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years of age. Prior to availability of the new presentation, no attempt should be made to adjust the syringe volume or to administer a 0.25mL/3µg dose in children less than 3 years of age; <sup>2</sup> CDC. MMWR 2010;59:1-27; <sup>3</sup> UNWTO Tourism Highlights 2016; <sup>4</sup> Nomura Code estimates (October 2012) and Valneva Management estimates;



### Product revenues in € million



### IXIARO®/JESPECT® nine month 2017 revenues

**Nine-month 2017 product revenues rose to €45.9m**  
(compared to €40.1m in nine months 2016)

#### Significant growth was driven by:

- + Adoption of JE vaccination policy US DoD & order phasing
- + Increased penetration in key traveler markets including Germany, UK and Canada

### Outlook

- + Approximately 2/3 of JEV sales generated through Valneva commercial infrastructure
- + Valneva confirms its FY 2017 guidance of JEV revenues reaching approximately €60 million (€58 to €62 million)



# DUKORAL® :

## The only cholera (ETEC<sup>1</sup>) vaccine available in EU, Canada & Australia

### DUKORAL®

- + For the prevention of diarrhea caused by *Vibrio cholera* (cholera) and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)<sup>1</sup>
- + In a number of countries including the EU, indicated to protect against cholera only
- + Designed to protect adults and children from two years of age who will be visiting endemic areas



### Commercial position

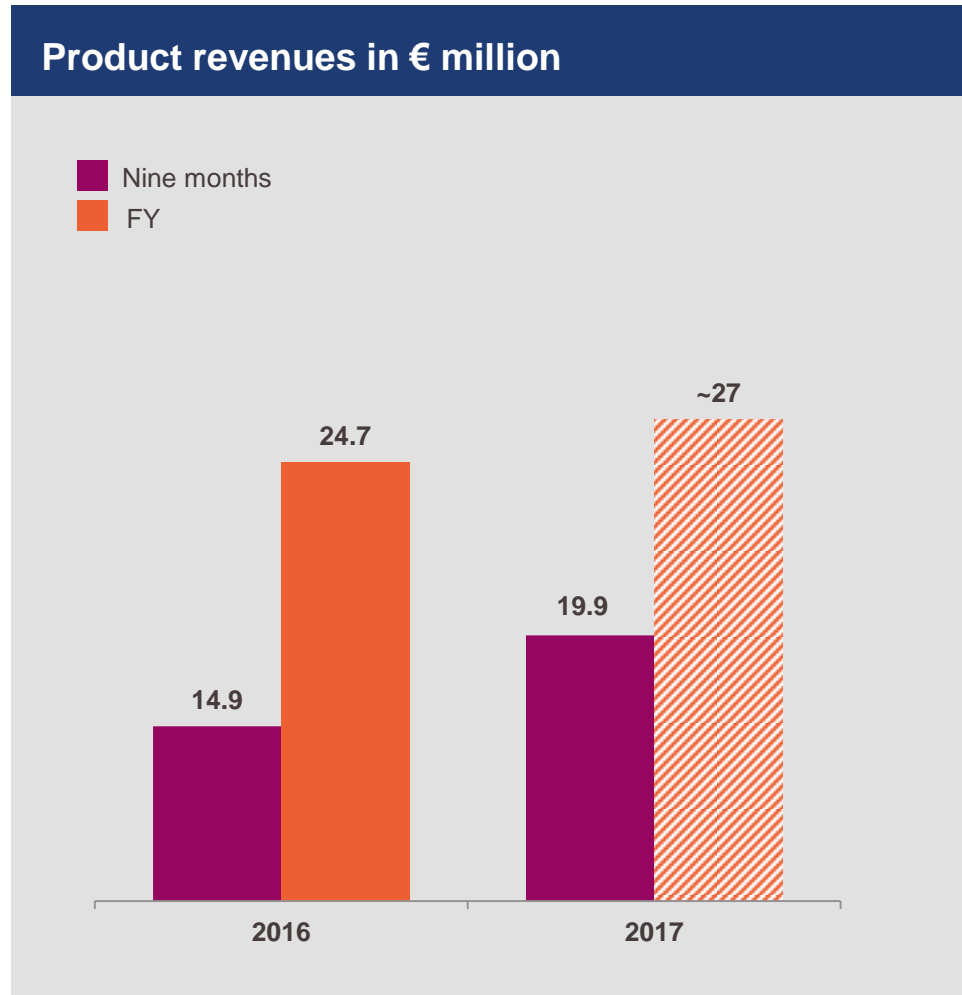
- + Only approved cholera vaccine available for European, Canadian and Australian travelers
  - › WHO pre-qualification widely used in other countries
  - › Asian manufacturers predominantly serve local markets and primarily for cholera only

### Market potential

- + 363 million travelers to Asia/South America/Africa in 2015<sup>2</sup>
- + Global Cholera/ETEC vaccines market valued at €283m<sup>3</sup>
- + Ongoing travel to risk regions, improved awareness and travel recommendation updates to drive growth
- + Canada, Sweden, Australia account for ~75% of Dukoral® sales

<sup>1</sup> Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium. <sup>2</sup> UNWTO Tourism Highlights 2016; <sup>3</sup> ETEC/ Cholera = global predicted demand, source: PATH/bvgh "The Case for Investment in ETEC vaccines", March 2011 and VacZine Analytics TD 2011

## Excellent sales performance in key markets



### DUKORAL® nine month 2017 revenues

**Nine-month product revenues reached €19.9m**  
(compared to €14.9m in nine months 2016)

**Significant growth of 34% was mainly driven by:**  
Strong sales in Canada and in the UK market

### Outlook

- + DUKORAL® nine-month revenues in line to meet guidance of ~€27m product sales in 2017
- + Continued sales growth expected through promotional efforts, geographic expansion and life cycle management

<sup>1</sup> Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli);

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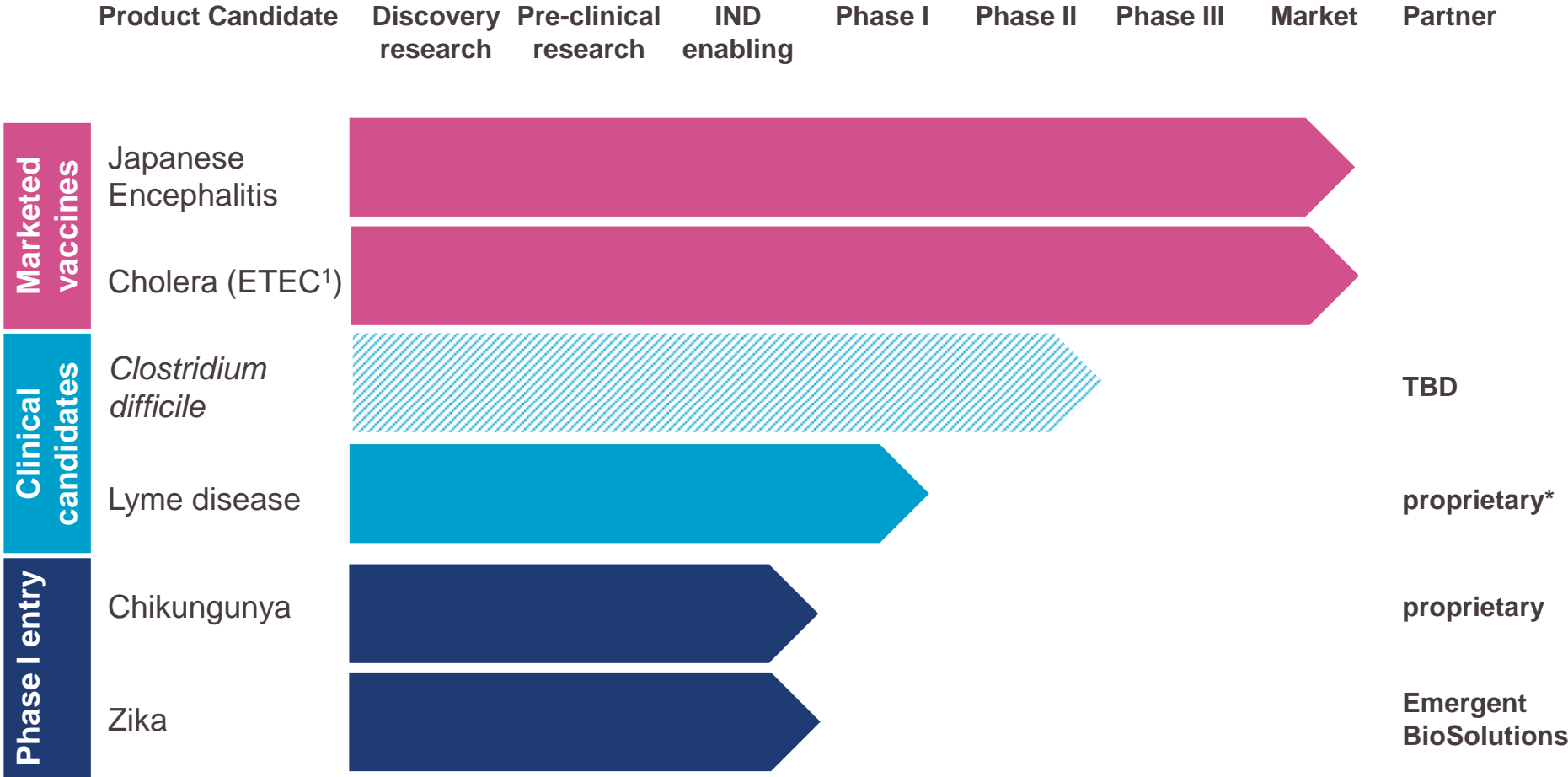


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# Valneva's pipeline

With a focus on urgently needed vaccines



1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium. / \*Potential opt-in by GSK / co-development



## Pre-commercial product: *Clostridium difficile* vaccine

Vaccine targeting healthcare-associated diarrhea, an increasing threat to the elderly in a \$1 billion market<sup>5</sup>

### *Clostridium difficile* (*C. diff*)

- + Single most common pathogen of acute healthcare-associated infections in the US<sup>1</sup> (~ 450,000 cases of annually and ~ 30,000 deaths<sup>2</sup>)
- + ~ 172,000 cases in EU member states per year<sup>3</sup>
- + Targeting primary prevention of *C. difficile*
  - › Current antibiotic treatments have significant limitations with recurrence in ~20% of cases<sup>4</sup>

### Valneva's vaccine candidate VLA84

- + One of three late stage vaccine candidates
- + Modern, recombinant single subunit-toxin antigen (CTAB) expressed in e.coli w/o adjuvants
- + Potential distinct competitive advantages on industrialization/future manufacturing



### Current development status VLA84

- + Phase II completed - Phase III ready
- + Highly immunogenic in all age groups tested (strong immune responses to both *C. diff* toxins A & B)
- + Good safety and tolerability profile confirmed
- + Comparable immunological profile to other CDI clinical programs targeting primary prevention of CDI

### New development & partnering approach

- + Potential partners hesitant about level of Phase III investment required and investment-risk proposition
- + VLA to use first CDI vaccine approval and consider "Head to Head" non inferiority Ph III on immunological correlate
- + New approach expected to substantially improve investment-risk proposition for own or partnered development to market

Source picture: [www.123rf.com](http://www.123rf.com); <sup>1</sup> Magill S, Edwards J R, Bamberg W et al. Multistate Point-Prevalence Survey of Health Care–Associated Infections. *New England Journal of Medicine* 2014;370:1198-208; <sup>2</sup> Lessa et al, Burden of *Clostridium difficile* Infection in the United States. *N Engl J Med* 2015;372:825-34. <sup>3</sup> *Clostridium difficile* infection in Europe. A CDI Europe Report.; <sup>4</sup> Leffler et al, *Clostridium difficile* infection. *N Engl J Med* 2015;372:1539-48; <sup>5</sup> VacZine Analytics *Clostridium difficile* prophylactic vaccines Market View, January; <sup>6</sup> G. de Bruyn et al. *Vaccine* 34 (2016) 2170-2178; \*EOP2 – end of Phase II



# VLA15: the only Lyme disease vaccine in clinical development



Market potential of approximately €700m - €800m<sup>1</sup>

## Lyme disease

- + Transmitted by Ixodes ticks<sup>2</sup>, causing Lyme
- + Most common vector borne illness in the Northern Hemisphere (~400,000 cases in 2015 in US<sup>3</sup> and at least ~200,000 cases per year in Europe<sup>4</sup>)
- + Delayed or inadequate treatment can lead to disabling sequels

## Valneva's vaccine candidate

- + Only active clinical program, no vaccine on the market
- + Multivalent, protein subunit-based vaccine
- + Targets the outer surface protein A (OspA) of Borrelia (proven mode of action)



## VLA15 Phase I trial ongoing in the US & EU

- + Pre-clinical testing completed
  - › Data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans<sup>5</sup>
- + FDA Fast Track Designation received
- + Phase I ongoing - subject enrolment completed

## Acceleration towards Phase II

- + Phase I data expected to be reported in Q1 2018, immediately followed by Phase II initiation
- + Phase II preparations and consultations process initiated
- + Medical need for Lyme vaccine steadily increasing as the disease footprint widens<sup>6</sup>

<sup>1</sup> Company estimate supported by independent market studies; <sup>2</sup> Stanek et al. 2012, The Lancet 379:461–473; <sup>3</sup> As estimated by the CDC based on reported cases in 2015; <sup>4</sup> Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report; <sup>5</sup> <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294>; <sup>6</sup> New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 <https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/>



# VLA1553: Chikungunya vaccine with differentiation potential

## A potential single-shot vaccine against a spreading tropical threat

### Chikungunya virus (CHIKV)

- + Chikungunya virus is a **Togaviridae virus**, transmitted by **Aedes mosquitoes**
- + **Outbreaks in Asia, Africa & Europe**, most recently spread to the Americas (> 180,000 reported cases in 2016)<sup>1</sup>
- + **Disease outbreak with high attack rates**, up to 50% of those infected experience prolonged symptoms or long term sequels

### Valneva's vaccine candidate

- + **Monovalent, single dose, live attenuated virus vaccine** ( $\Delta 5nsP3$ )<sup>2</sup>
- + **Grown on Vero cells**
- + **Protective against various CHIKV outbreak phylogroups & strains**<sup>3</sup>



### Current development status VLA1553 (IND-enabling)

- + **Pre-clinical testing completed**
  - › Data from non-human primates (NHP) have shown that the vaccine has a good safety profile and the potential to provide long term protection against Chikungunya after a single immunization
- + **Program under IND**
- + **Preparations for Phase I initiation completed**

### Phase I to be initiated in early 2018

- + **Phase I initiation (U.S.) in early 2018**
- + **Phase I to evaluate safety and immunogenicity in approx. 120 subjects and to confirm antibody persistence ( $\geq 6m$ )**
- + **Primary target population are travelers to endemic regions and military, public endemic market and emergency stockpiling as secondary target populations**

<sup>1</sup> PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016); <sup>2</sup> CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); <sup>3</sup> Hallengård et al. 2013. J Virology 88:2858–2866.



# VLA1601: vaccine combatting the global threat of Zika

Valneva & Emergent BioSolutions joining forces to accelerate development

## Zika virus

- + Zika virus is a Flavivirus, transmitted by Aedes mosquitoes
- + Most common symptoms are flu-like symptoms lasting between two to seven days. No specific treatment available
- + Scientific consensus that Zika virus causes microcephaly / severe brain defects in newborns / Guillain-Barré syndrom<sup>2</sup> in adults

## Valneva's vaccine candidate

- + Highly purified inactivated vaccine (PIV)
- + Developed using Valneva's proven and licensed inactivated JE vaccine platform



## Current development status VLA1601 (PIV)

- + **Pre-clinical testing** demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to IXIARO<sup>®</sup>
- + **Phase I preparation ongoing**
- + **Co-development deal with Emergent BioSolutions including opt-in post Phase I** (in exchange for a €5m opt-in milestone payment; potential additional milestones of up to €44m\* and royalties on future sales)

## Phase I to be initiated in early 2018

- + **Phase I to evaluate safety and immunogenicity. Data in 2018**
- + **Priority for people traveling to or living in endemic regions, including potential preparedness for stockpiling**

<sup>1</sup> <https://www.cdc.gov/zika/transmission/index.html> <sup>2</sup> <http://www.who.int/mediacentre/factsheets/zika/en/>

\* Related to product development, approval, commercialization, and product sales, and royalties on annual net sales

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## 2017 financial outlook

Continued revenue growth and positive EBITDA trend

	2016 Actual	2017 Outlook	Growth
Revenues	€97.9m	€105 – 115m	up to 17% growth vs. 2016
Product sales	IXIARO <sup>®</sup> €53.2m DUKORAL <sup>®</sup> €24.7m	€58 – 62m €27m	10 – 15% <10%
R&D expenditure	€24.6m	€23 – 25m*	–
EBITDA	€2.8m	€10 – 13m	x3.5 to x4.5 vs. 2016

\* Due to external R&D costs expected later in the year

# Valneva – Exciting Upcoming Newsflow



**+ Further Expansion of Commercial infrastructure to Support Sales Growth**

**+ Chikungunya Phase I commencement in early 2018**

**+ Zika Phase I commencement in early 2018**

**+ Lyme Phase I results in Q1 2018 followed by Phase II**

**+ Lyme R&D/Investor Day(s) end of Q1 2018**

**+ Additional EB66<sup>®</sup> and IC31<sup>®</sup> licensing agreements**

Thank you  
Merci  
Danke  
Tack

