

# Valneva presents its FY 2017 financial results

Analyst Presentation  
March 22, 2018



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# Agenda



- 1. Introduction – Highlights – Thomas Lingelbach**
2. Financial report FY 2017 – David Lawrence
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# Valneva 2017 performance at a glance

A strong year for Valneva

	<b>Delivered on financial targets</b>	<ul style="list-style-type: none"><li>+ Sales +15% vs. 2016</li><li>+ EBITDA €10.8m vs. €2.8m in 2016</li></ul>
	<b>Executed well on key growth drivers</b>	<ul style="list-style-type: none"><li>+ Increased product adoption in main markets</li><li>+ Additional IXIARO<sup>®</sup> supply contract with U.S. government</li><li>+ Took over direct commercial control in U.S. private market</li></ul>
	<b>Advanced R&amp;D pipeline</b>	<ul style="list-style-type: none"><li>+ FDA Fast Track for Lyme, Phase I fully recruited</li><li>+ Signed collaboration agreement for Zika vaccine</li><li>+ Prepared Zika &amp; Chikungunya Phase I for initiation in 2018</li></ul>
	<b>Strengthened the management</b>	<ul style="list-style-type: none"><li>+ Appointment of David Lawrence as CFO</li><li>+ Appointment of Wolfgang Bender, MD, PhD as CMO</li></ul>



## Recent Key R&D newsflow in 2018

**February 26, 2018**

**Zika: Emergent BioSolutions and Valneva Initiate Phase I Clinical Study to evaluate their vaccine candidate VLA1601**

**March 13, 2018**

**Chikungunya: Valneva initiates Phase I clinical study to evaluate its single-shot vaccine candidate VLA1553**

**March 19, 2018**

**Lyme disease: Valneva reports positive Phase I interim results for its Lyme vaccine candidate VLA15**

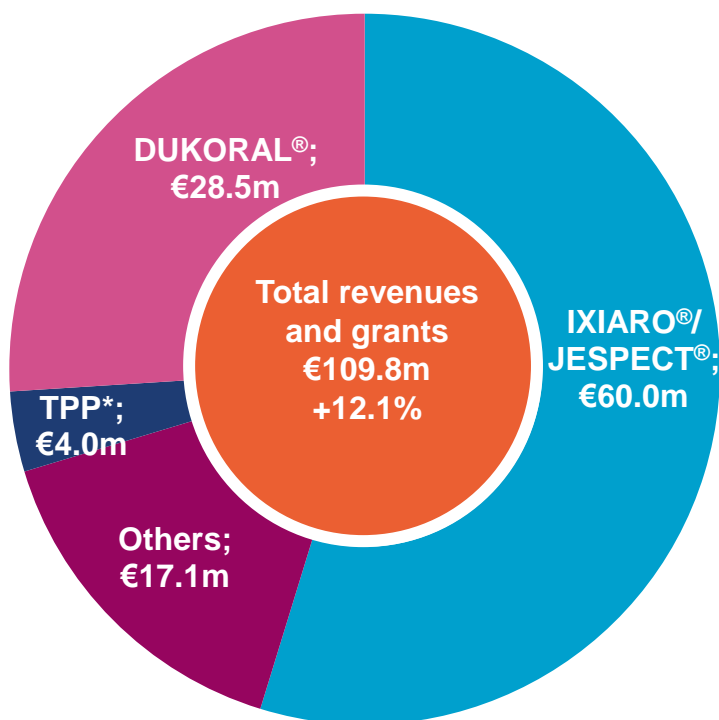
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# Valneva's Two Main Value Drivers

Product sales revenues growth of 15% and R&D progression

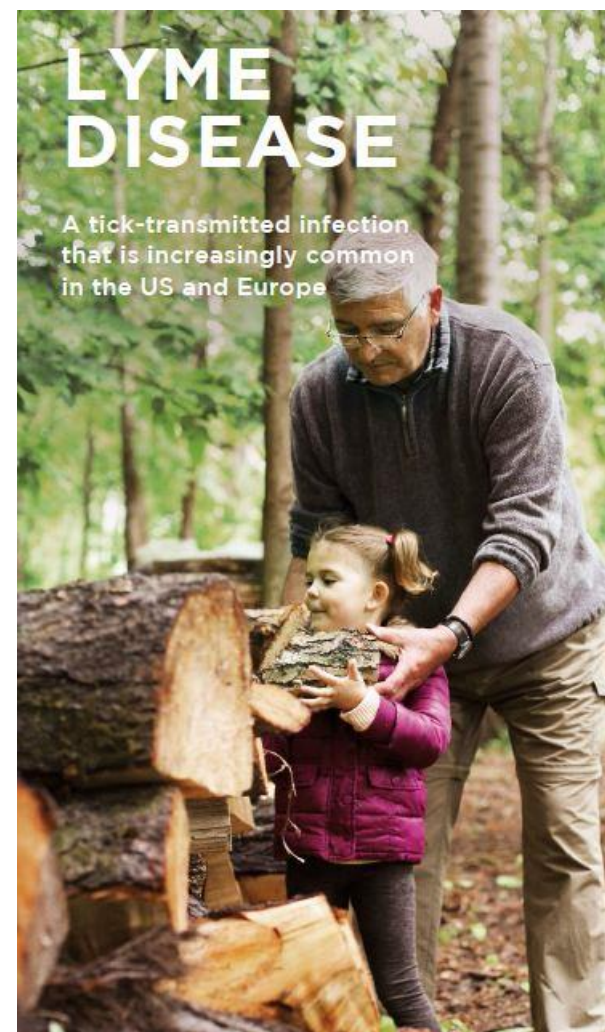


Product sales  
€92.6m

Direct sales  
73.5%

Gross Margin  
58%

Cash generated  
€12.8m



\* Third party products



## Full Year 2017 Profit & Loss

Strong sales and EBITDA performance

€m	12 months ended December 31	
	2017	2016
<b>Revenues and grants</b>	<b>109.8</b>	<b>97.9</b>
Cost of goods and services	(46.0)	(43.1)
R&D expenses	(23.4)	(24.6)
Distribution and marketing expenses	(17.9)	(16.6)
General and administrative expenses	(15.5)	(14.4)
Other income / (expense)	(0.2)	(0.5)
Amortization and impairment	(10.7)	(41.2)
<b>OPERATING PROFIT/(LOSS)</b>	<b>(4.0)</b>	<b>(42.6)</b>
Finance results and tax	(7.5)	(6.6)
<b>LOSS FOR THE PERIOD</b>	<b>(11.5)</b>	<b>(49.2)</b>
<b>EBITDA*</b>	<b>10.8</b>	<b>2.8</b>

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

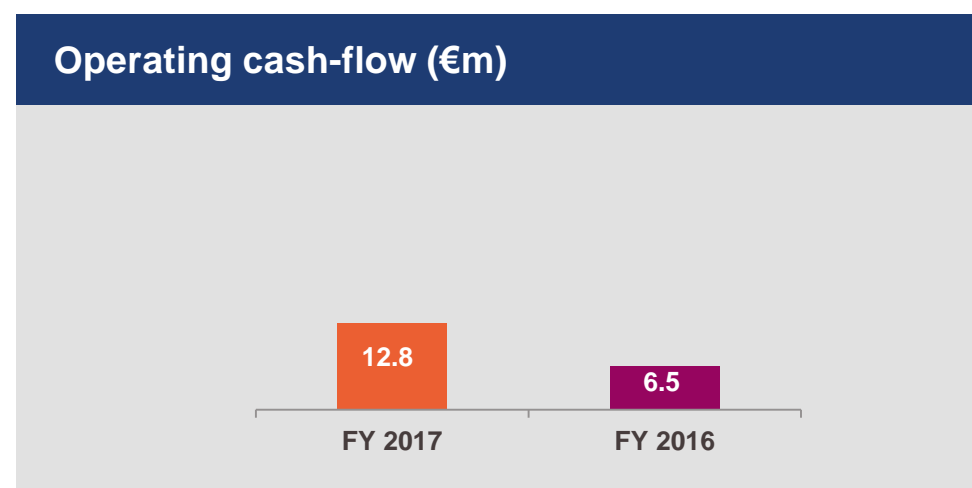
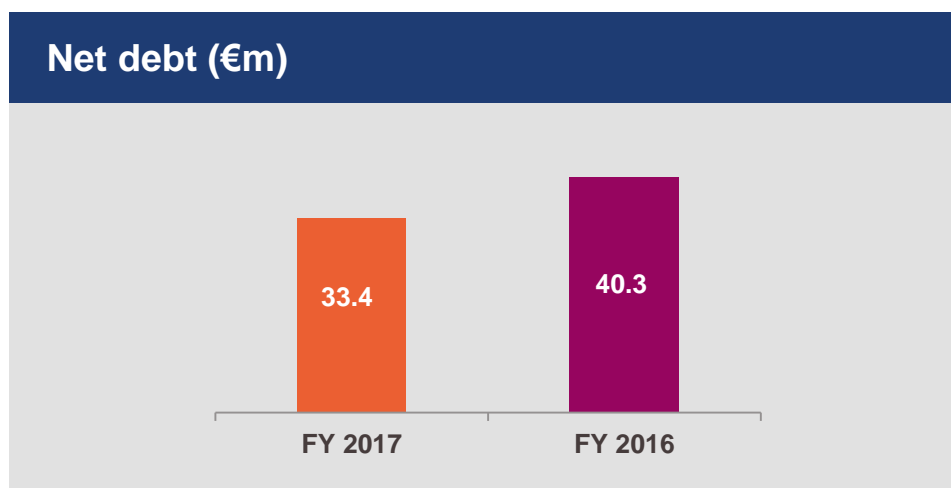
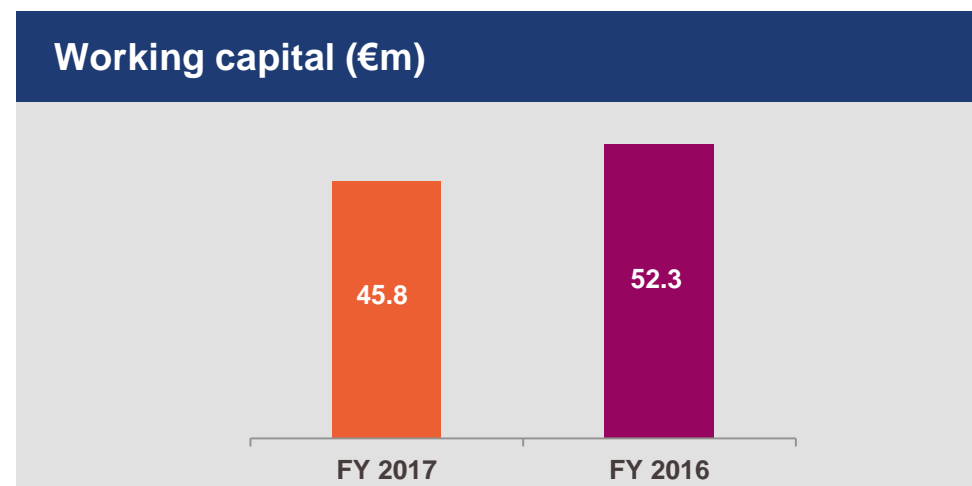
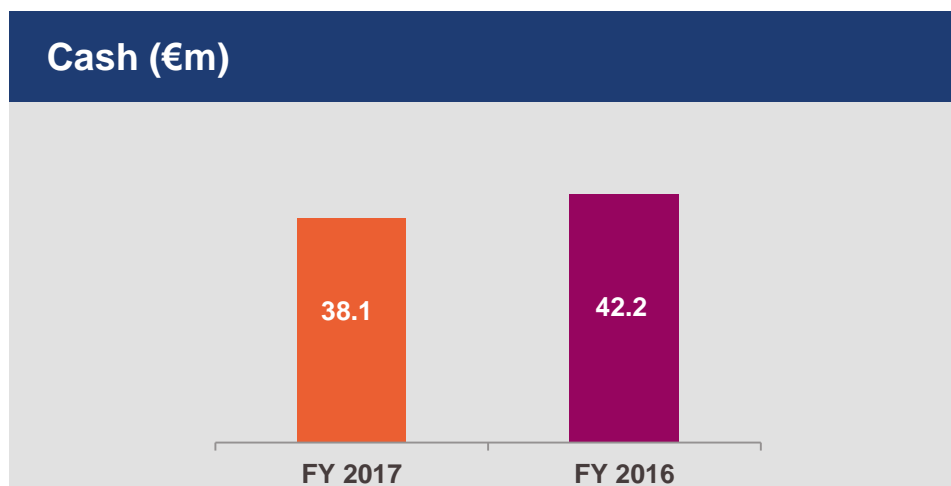


# Full Year Revenue analysis 2015 - 2017



€m	2015	2016	2017	2018 Guidance
<i>Product sales revenues</i>				
IXIARO®/JESPECT®	30.6	53.0	60.0	
DUKORAL®	21.0	24.6	28.5	
Third party products	9.9	2.9	4.0	
<b>Total products</b>	<b>61.5</b>	<b>80.4</b>	<b>92.6</b>	<b>&gt; 100</b>
Other revenues	16.8	13.6	12.7	
Grants / R&D tax credits	5.0	3.8	4.5	
<b>Total revenues &amp; grants</b>	<b>83.3</b>	<b>97.9</b>	<b>109.8</b>	<b>110 - 120</b>

# Strong cash position at end of 2017 boosted by positive cash flow



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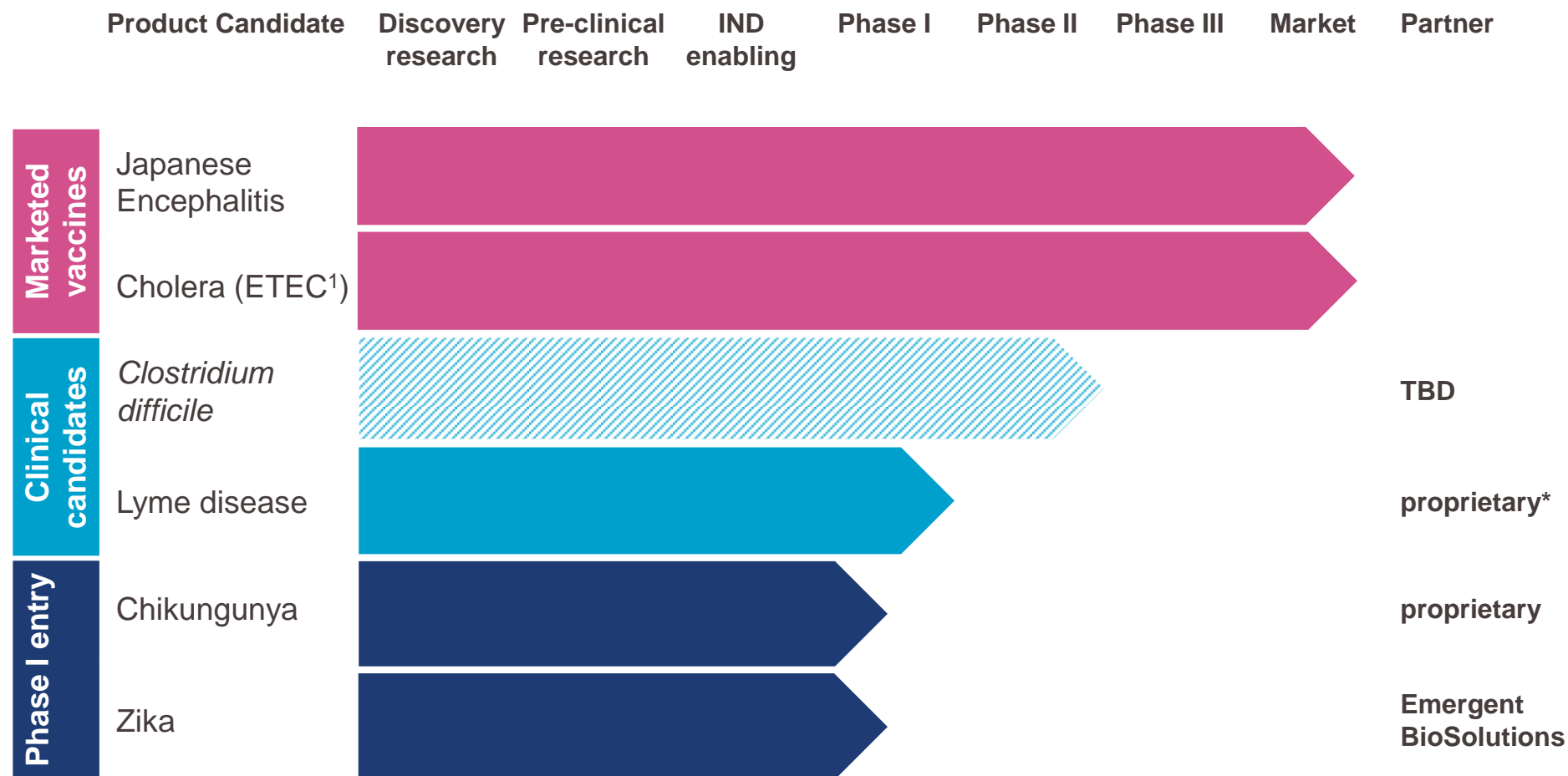


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# Valneva's pipeline

Focusing on vaccines with high unmet medical need



<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. / \*Potential opt-in by GSK / co-development

# VLA15: the only Lyme disease vaccine in clinical development



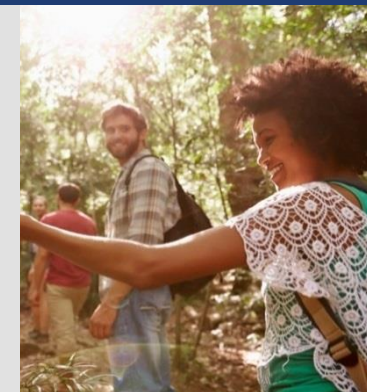
Market potential of approximately €700m - €800m<sup>1</sup>

## Lyme disease

- + Transmitted by Ixodes ticks<sup>2</sup>, causing Lyme
- + Most common vector borne illness in the Northern Hemisphere (~300,000 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 sequelae

## 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)



## Positive Phase I Interim data

- + Positive Phase I interim results showed favorable safety profile and encouraging immunogenicity for VLA 15
- + FDA Fast Track Designation received in H2 2017
- + Preclinical data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans<sup>5</sup>

## Acceleration towards Phase II

- + Phase II preparations and consultations process initiated; Phase II initiation expected in H2 2018
- + 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/>



# Phase 1 study (VLA15-101)

## Positive Interim Results Reported

**Conducted in 179 subjects in US and EU** ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), identifier NCT03010228):

### Study primary endpoint met

- Favourable safety profile
- No safety concerns associated with VLA15 in any treatment group<sup>1</sup>

### Encouraging immunogenicity with VLA15

- VLA15 immunogenic in all doses and formulations
- Good OspA-specific IgG antibody responses against all OspA serotypes<sup>2</sup>
- Clear dose responses seen between the lowest / higher doses, adjuvanted /non-adjuvanted groups
- Highest, adjuvanted dose group - Seroconversion Rates<sup>3</sup> (SCR) from 71.4% to 96.4% for different OspA serotypes<sup>4</sup>

<sup>1</sup> No differences in the safety profile were observed for the adjuvanted groups compared to the non-adjuvanted treatment groups.

<sup>2</sup> IgG levels were substantially higher after three immunizations (Day 84) compared to after two (Day 56)

<sup>3</sup> 4-fold use against base-line

<sup>4</sup> Preferred for further development / Further dose optimization will be considered.



## VLA15-101 - Safety

Favourable safety profile and no associated safety concerns

### **No associated safety concerns:**

- No Serious Adverse Event considered related to VLA15 immunization
- No cases of Arthritis or Rheumatoid Arthritis

### **Very few severe, related AEs:**

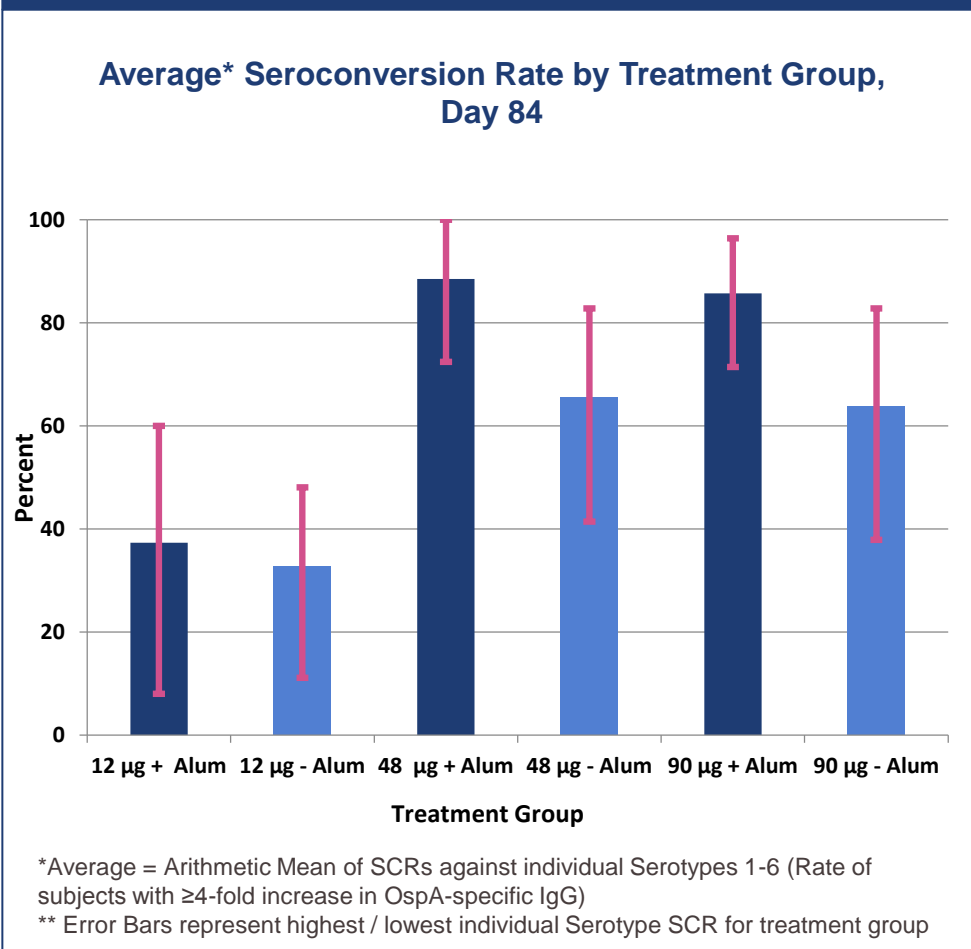
- Total of 8 subjects with severe, related AEs, from different treatment groups
- All were solicited AEs (i.e., volunteer-reported, by default considered related to vaccination)
- Study investigators considered AEs as related in 4 subjects:
  - 2 Subjects with severe local Pain/Tenderness
    - Both not medically attended, one treated with a single Paracetamol dose
  - 1 Subject with Nausea, not medically attended, no treatment
  - 1 Subject with Headache, not medically attended, treated with a single Paracetamol dose
- Severe Arthralgia and Myalgia seen in one subject, considered unrelated to vaccination by study investigator, following an ultramarathon 100 km walk



## VLA15-101 - Immunogenicity

SCR for Highest Adjuvanted Dose Group between 71.4% and 96.4%

### SeroConversion Rates (SCR)



### SeroConversion Rates (SCR)

- OspA specific IgG antibody responses induced in all treatment groups and against all OspA serotypes
- Significant dose response in between lowest and two higher groups
- Alum-adjuvanted treatment groups more immunogenic compared to non-adjuvanted groups in same dose levels
- No significant dose response between 48µg and 90µg. Day 56 data indicate better kinetics of immune response at higher dose levels
- Highest dose considered for further development





# VLA1553: Chikungunya vaccine candidate

A potential single-shot vaccine against a spreading tropical threat

## Chikungunya

- + Mosquito-borne viral disease caused by the Chikungunya virus (CHIKV), a *Togaviridae* virus transmitted by *Aedes* mosquitoes
- + Causes a clinical illness in 72-92% of infected humans who can potentially develop serious, long-term health impairments<sup>1</sup>
- + Outbreaks in Asia, Africa, Europe & the Americas (as of 2017, > 1 million reported cases in the Americas)<sup>2</sup>
- + No preventive vaccines or effective treatments exist

## Valneva's vaccine candidate

- + Monovalent, single dose, live attenuated prophylactic vaccine<sup>3</sup>
- + Aims for long-lasting protection of individuals > 1 year of age
- + Protective against various CHIKV outbreak phylogroups & strains<sup>4</sup>



## VLA1553 Phase I ongoing

- + Phase I initiated in March 2018 in the US
- + Long term protection shown in preclinical testing
  - › 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<sup>5</sup>

## Phase I data expected by early 2019

- + Phase I to evaluate safety and immunogenicity in approx. 120 subjects and to confirm antibody persistence ( $\geq 6m$ ) with potential early indication of efficacy
- + The target population segments are travelers, military personnel and individuals at risk living in endemic regions.

<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.

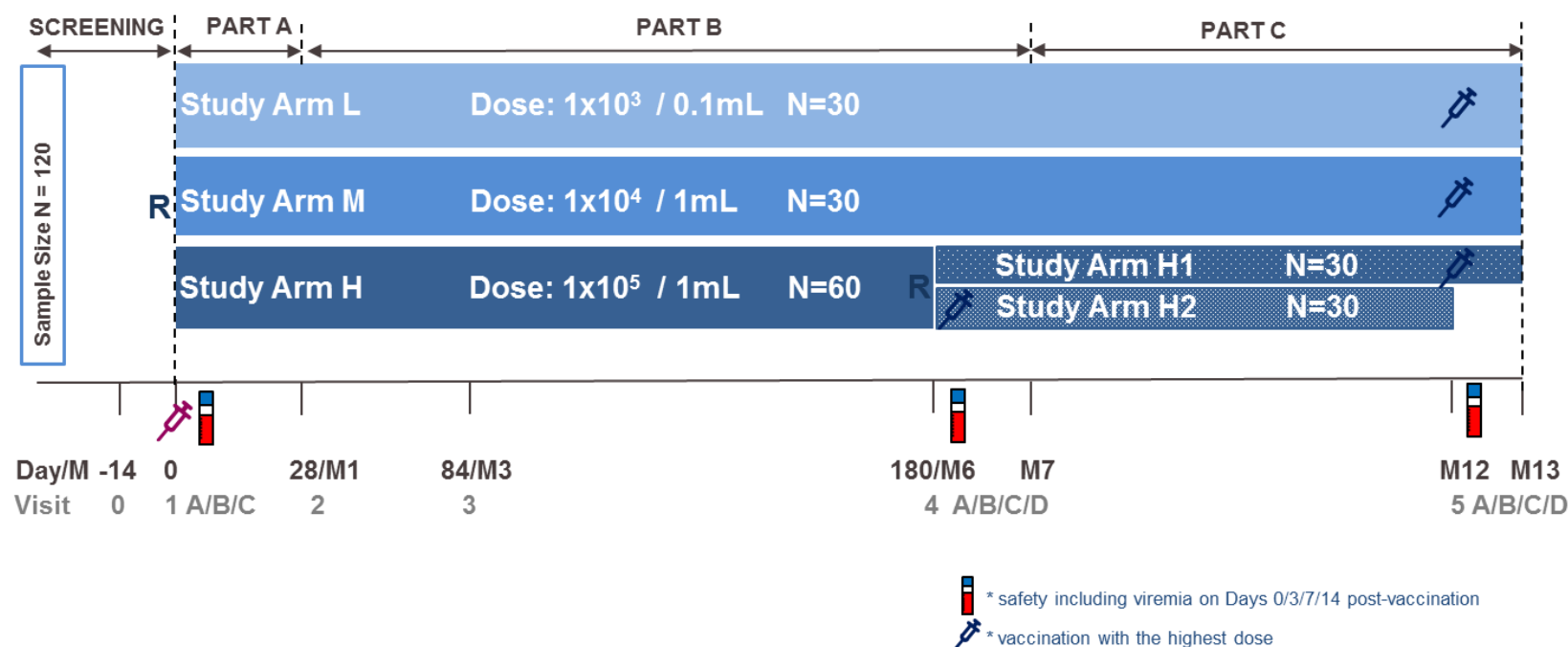


# VLA1553 - Chikungunya vaccine - Phase I Study

## Blinded, Randomized, Dose-Escalation Study

### Phase I study conducted in US (multi-center)

- 120 healthy CHIKV-naïve subjects aged 18 - 45 years
- Objectives: Safety and Immunogenicity



### Vaccination Schedule

- + Single-dose vaccination (Day 0); 3 dose levels (3.2x10<sup>3</sup>/3.2x10<sup>4</sup>/3.2x10<sup>5</sup> TCID<sub>50</sub>/dose)
- + Re-vaccination with highest dose (Month 6 and 12)
  - › to serve indirectly as human viral challenge demonstrating that subjects are protected from viremia and thereby indicating early VE.



# VLA1601: Zika vaccine candidate

## Valneva & Emergent BioSolutions joining forces to accelerate development

### Zika

- + Zika is a mosquito-borne viral disease caused by the Zika virus (ZIKV), a Flavivirus transmitted by Aedes mosquitoes<sup>1</sup>
- + 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 whole-virus vaccine (PIV)
- + Developed using Valneva's proven and licensed inactivated JE vaccine platform



### Phase I initiated in February 2018

- + **Pre-clinical testing** demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to IXIARO<sup>®</sup>
- + **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 data expected late 2018/early 2019

- + **Phase I to evaluate safety and immunogenicity in approximately 65 subjects at different dose levels and schedules**
- + **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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## 2018 Financial Outlook

Continued double-digit sales growth and positive EBITDA, higher R&D investment driven by clinical development progression

	2017 Actual	2018 Outlook	Growth
Product sales	€92.6m	> €100m	> 10%
R&D investment	€23.4m	€30 – 35m	N/A
EBITDA	€10.8m	€5 – 10m	N/A

Total revenues and grants were €109.8m in 2017. Other revenues, (including R&D tax credits, grants, service revenue, royalties) which tend to fluctuate from year to year, are expected to bring the company's overall revenue to between €110m and €120m for the year 2018.

# Valneva 2018 – Exciting upcoming newsflow



+ Further product sales growth during the year

+ Lyme Phase II initiation expected in H2

+ Execution of Chikungunya Phase I Study in the US

+ Execution of Zika Phase I Study in the US

Thank you  
Merci  
Danke  
Tack

