# Valneva – a fully integrated, commercial stage biotech company focused on developing innovative, life-saving vaccines

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# Valneva, a fully integrated, commercial stage biotech company developing innovative vaccines

**Products**

**Commercial Products**
+ Valneva expects total revenues of €105-115m in 2017, with ~€90m product sales

**Portfolio**

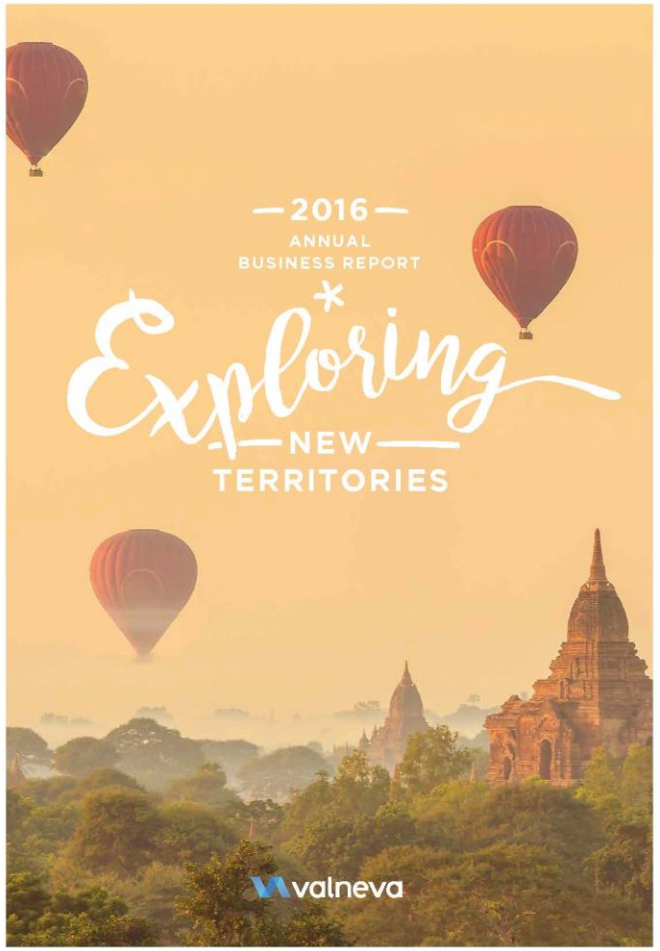
**Vaccine Candidates**
+ Valneva invests ~ 20% of revenues in innovative R&D programs in areas of unmet medical needs
+ Phase I trials in Lyme disease ongoing in US & EU
+ One additional candidate to enter Phase I in 2017

**Platforms**

**Technologies & Services**
+ Valneva offers unique technology platforms (EB66®, IC31®) and services to a broad range of clients
+ Revenues of ~€10m foreseen to come from Technology & Services in 2017

**Partnering**

**Product Partnering & Licensing**
+ Valneva creates near and long-term value through partnering of vaccine candidates
+ C.Difficile (Ph III ready) sought to be partnered in 2017



# 2020 strategy – A journey to success

## Becoming a leading independent pure play vaccine company

***Products***

**Growing revenues from existing and future products to €250m**

***R&D***

**Investing 15-20% of annual revenues in R&D programs delivering patient benefit and long-term value**

***Financials***

**Achieving financial self-sustainability and positive cumulative cash-generation**


***Growth***

**Generating organic growth complemented by opportunistic M&A strategies**

# About Valneva SE

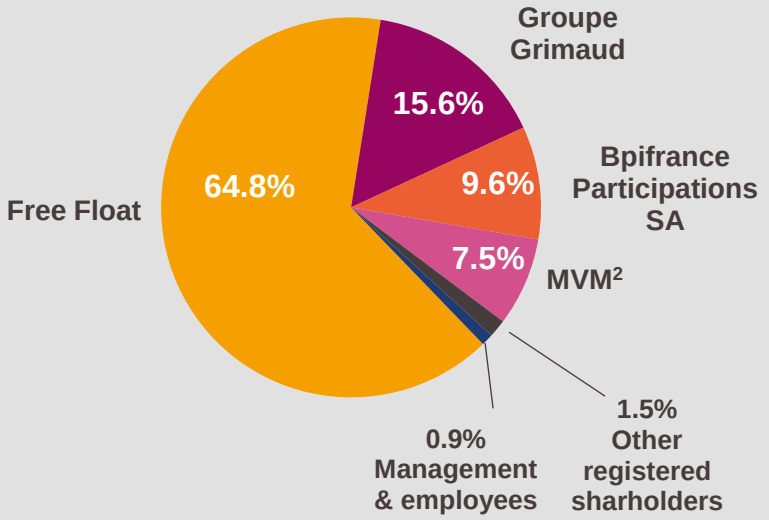
## A fully integrated, commercial stage biotech company

### Corporate profile

+ Created in May 2013 through the **merger of Vivalis SA and Intercell AG**;
+ Expanded business by acquiring a **commercial product from Crucell/Janssen** in February 2015
+ Incorporated in Lyon, France
+ More than **430 employees**[1]
+ Principal sites in:
  - › Vienna, **Austria** (R&D, G&A, QA/QC)
  - › Nantes, **France** (R&D, G&A)
  - › Solna, **Sweden** (Manufacturing)
  - › Livingston, **Scotland** (Manufacturing)
+ **Own commercial presence in:**
  - › US
  - › Canada
  - › UK
  - › Sweden, Norway, Finland, Denmark
  - › Austria

### Stock information

+ Listed on NYSE Euronext Paris, the Vienna Stock Exchange, and Deutsche Börse Xetra® platform
+ Number of ordinary shares: 77,582,714
+ **Market cap**: approx. €230m (June 2, 2017)
+ ISIN: FR0004056851
+ Shareholder structure:




1 Approx. 1/3 Manufacturing & Supply, 1/3 R&D, 1/3 SG&A
2 Funds managed by MVM Life Science Partners

# Leading commercial product: Japanese encephalitis vaccine

## Protecting travelers from the most common encephalitis in Asia[1]

### Japanese encephalitis vaccine

+ **Designed to protect travelers, military and populations in endemic regions against Japanese encephalitis (JE)**
+ Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older[1]


### Commercial position

+ Currently, **no effective treatment for the disease**[2]
+ Valneva's vaccine is the **only approved vaccine available for US and EU travelers** ≥ 2 months old[1]
+ Exclusive supplier agreement in place with US military
+ Asian manufacturers mainly serve local public markets

### Market potential

+ **279 million travelers to Asia** in 2015[3]
  - › Travelers to Asia **expected to grow by 4.4% per year**[3]
+ **Global JE vaccines market valued at ~ €150-200m**[4]
  - › Traveler 65%, Military 15%, Endemic 20%[4]

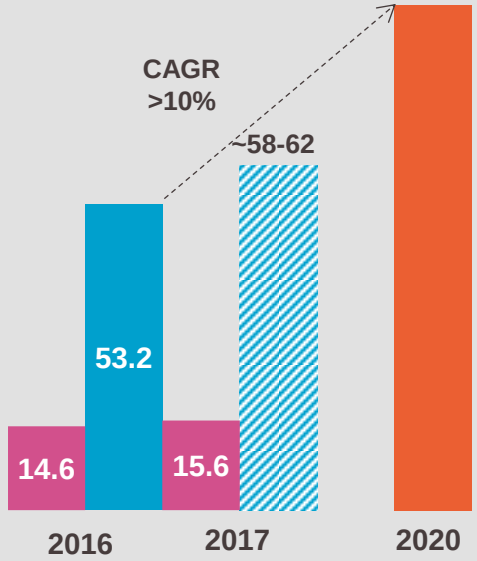
**1** Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years 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; **2** CDC. MMWR 2010;59:1-27; **3** UNWTO Tourism Highlights 2016; **4** Nomura Code estimates (October 2012) and Valneva Management estimates;

# Leading commercial product: Japanese encephalitis vaccine

## Sales and margin growth ahead

Q1[1] FY 2020

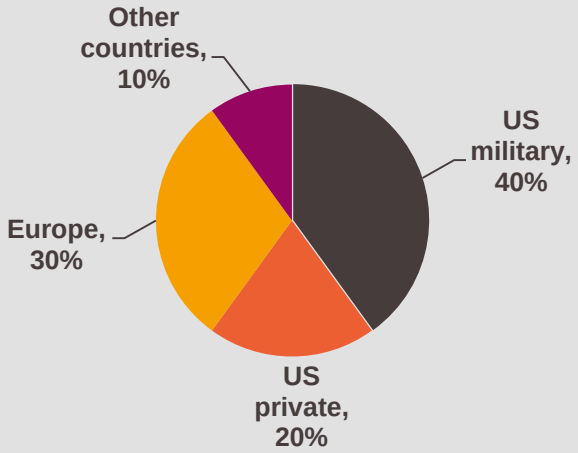
### Valneva product sales in € million




### 10% mid-term annual sales growth expected

+ Increased product adoption in the US (private) and in Europe
+ Geographic expansion

### Geographic split



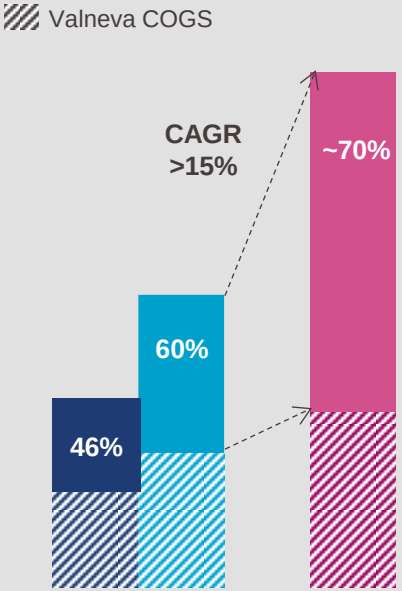

Split of 2016 product sales

### Growth expected in 2017

+ Almost 70% of JEV sales will be generated by Valneva's commercial teams with a 100% revenue recognition

2015 FY 2016 2020

### Gross margin




### Margin to improve by 1.5x in the mid-term

+ Fixed manufacturing cost structure to translate into over-proportional margin growth

**1** unaudited

# Commercial product: Cholera/ (ETEC[1]) vaccine

## Established vaccine in the field of cholera/diarrhea

**DUKORAL®**

+ **For the prevention of diarrhea caused by *Vibrio cholera* (cholera) and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)[1]**
+ In a number of countries including the EU, indicated to protect against cholera only
+ **Designed to protect adults and children** from 2 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[2]
+ Ongoing travel to risk regions, improved awareness and updating travel recommendations
  - › **Significant growth potential in key markets** (penetration rate <1%)[3]
+ Canada, Sweden, Australia account for ~75% of sales

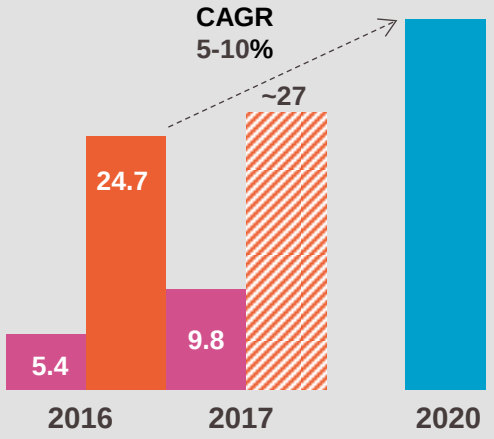
**1** Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium. **2** UNWTO Tourism Highlights 2016;

# Commercial product: Cholera/ (ETEC[1]) vaccine

## Sales and margin growth ahead

Q1[2] FY 2020

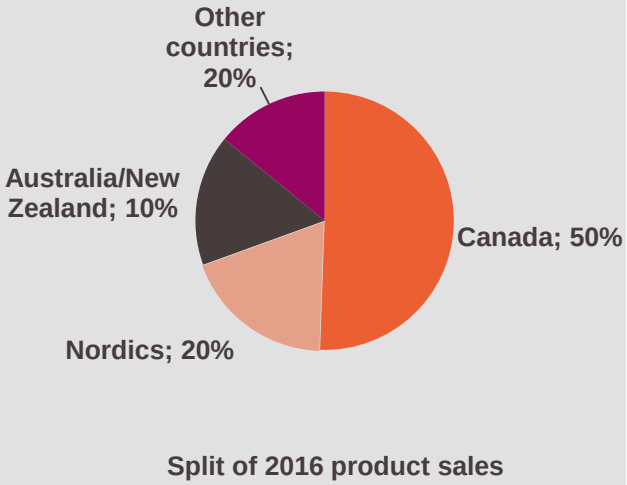
### Product Sales in € million




### 5-10% sales growth expected in 2017

+ Significant growth opportunities outside Canada and through geographic expansion

### Canada remains the most important market




Split of 2016 product sales

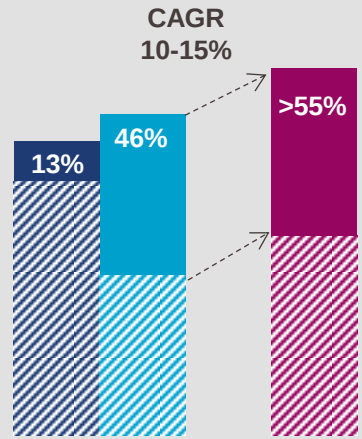
### Key revenue drivers 2017

+ Increased travel to endemic regions
+ Awareness campaigns for HCPs & lay public

2015 FY 2016 2020

### Gross margin

Valneva COGS




### Future margin improvement

+ Increased revenues
+ Fixed cost reduction in product manufacturing

**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 **2** unaudited**; 3** pro-forma sales incl. €5.3m under previous owner;

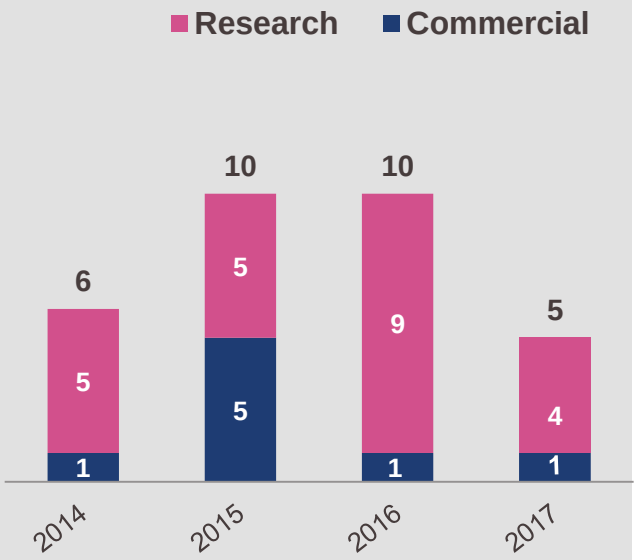
# EB66® platform for efficient large scale vaccine production

## A technology increasingly contributing to the company's profitability

### Revenue generating platform

+ **Fully characterized cell-line** (**avian** embryonic stem cell derived) with **low production costs**
+ **Over 35 agreements with the world's largest pharma cos**
+ **~€34m** in upfront, milestones & research fees **received to date**
+ **Exclusive license to**:
  - › **GSK** for EB66®-based pandemic and seasonal influenza vaccines
  - › **Jianshun Biosciences** to commercializes EB66® in China

### 5 new agreements signed in 2017

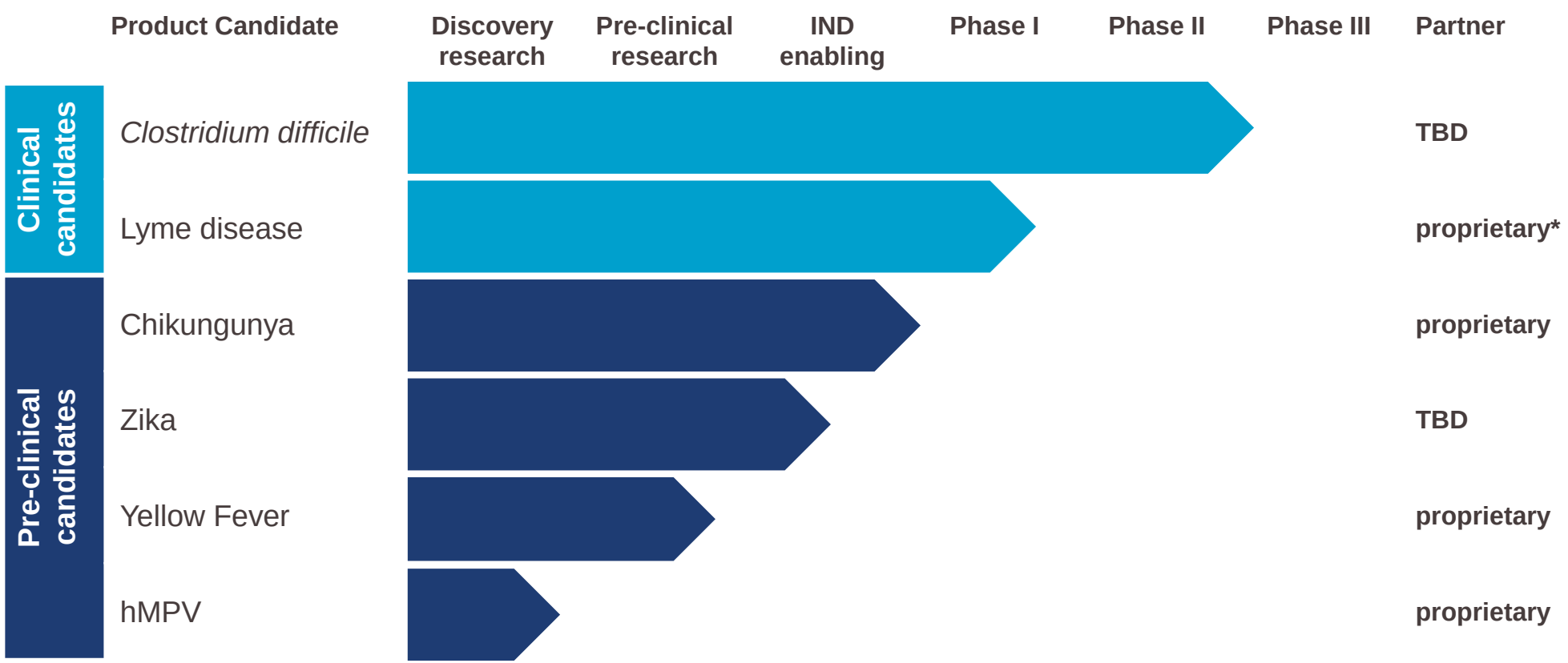



### 2017 Highlights

+ **Commercial agreement with Bavarian Nordic for the development and commercialization of multiple poxvirus-based vaccines on the EB66® cell-line**
  - › **The deal also includes the possibility for Bavarian to transfer some of its existing late-stage products onto EB66® (upon regulatory approval)**
+ **Research agreement with MSD Animal Health (Merck) for the development of new EB66 ®-based veterinary vaccines**

# Valneva's pipeline of vaccine candidates

## With a focus on urgently needed vaccines




~ 20% of revenues invested in research and development of innovative vaccine candidates

*Potential opt-in by GSK at the end of Phase II

# Pre-commercial product: *Clostridium difficile* vaccine

## Vaccine targeting healthcare-associated diarrhea, an increasing threat to the elderly

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

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

### Valneva's vaccine candidate

- **One of three clinical programs**
- **Potentially second to market**
- **Total market estimate of > $1 bn/year target groups[5]**

### Current development status VLA84

- **Successful completion of Phase II study announced in July 2016**
- **Vaccine dose confirmed in older adults and elderly**
- **Highly immunogenic in all age groups tested (strong immune responses to both C. diff toxins A & B)**
- **Good safety and tolerability profile confirmed**

### Valneva aims for a licensing agreement in 2017

- **Ready for Phase III**
- **Comparable immunological profile to the only other EOP2*-stage program targeting primary prevention of CDI (according to published Phase II data[6])**
- **Valneva discussing with interested parties**

Source picture: www.123rf.com; **1** 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; **2** Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34. **3** Clostridium difficile infection in Europe. A CDI Europe Report.; **4** Leffler et al, Clostridium difficile infection. N Engl J Med 2015;372:1539-48; **5** VacZine Analytics Clostridium difficile prophylactic vaccines Market View, January; **6** G. de Bruyn et al. Vaccine 34 (2016) 2170-2178; *EOP2 – end of Phase II

# Pre-commercial product: Lyme disease vaccine

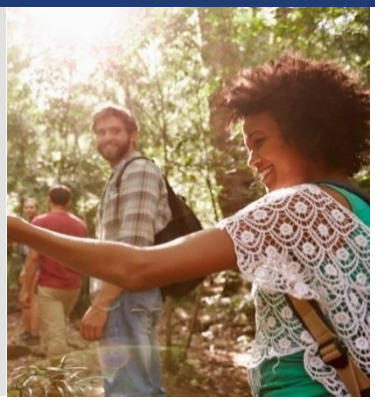
## Market potential of approximately €700m - €800m[5]

### Lyme disease

- **Transmitted by Ixodes ticks[1], causing Lyme**
- **Most common vector borne illness in the Northern Hemisphere (~300,000 cases per year in US[3] and ~85,000 cases per year in Europe[2])**
- **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**



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

- **Patient recruitment for Phase I trials ongoing**
  - Patient recruitment advancing according to study protocol
  - Phase I study will evaluate safety and immunogenicity
- **Pre-clinical testing completed**
  - Data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans[4]

### Acceleration towards Phase II

- **Phase I data expected to be reported early 2018**
- **Phase II preparations and consultations process initiated – Phase II start anticipated H1/2018**
- **Medical need for Lyme vaccine steadily increasing as the disease footprint widens[6]**

**1** Stanek et al. 2012, The Lancet 379:461–473; **2** Estimated from available national data. However, this number is largely underestimated as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed, based on WHO Europe Lyme Report; ECDC tick-borne-diseases-meeting-report; **3** Latest data from the CDC (PR on Aug 19, 2013); **4** http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294; **5** Company estimate supported by independent market studies; **6** 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/

# Pre-clinical candidate: Chikungunya vaccine (VLA1553)

## Targeting Chikungunya, an emerging disease

### Chikungunya virus

- **Transmitted by Aedes mosquitoes, causing Chikungunya disease**
- **Outbreaks in Asia, Africa & Europe, most recently spread to the Americas (> 180,000 reported cases in 2016) [1]**
- **Disease outbreak with high attack rates, up to 50% of those infected experience prolonged or long term symptoms**

### Valneva's vaccine candidate

- **Monovalent, single dose, live attenuated virus vaccine (Δ5nsP3)[2]**
- **Grown on Vero cells**
- **Protective against various CHIKV outbreak phylogroups & strains [3]**

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

- **Pre-clinical testing completed**
  - Data from non-human primates (NHP) has shown that the vaccine has a good safety profile and the potential to provide long term protection against Chikungunya after a single immunization
- **Phase I preparation ongoing**
  - Scientific advice (EU) and pre-IND (US) meetings held

### Phase I to be initiated in H2 2017

- **Phase I expected to evaluate safety and immunogenicity in approx. 120 subjects and to confirm antibody persistence (≥6m)**
- **Priority for travelers to endemic regions, also of interest to military; larger traveler market than JE**
- **Public endemic market and emergency stockpiling as secondary target populations**

Source picture: Sun et al. 2013, eLife 2:e00435; **1** PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016); **2** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase)
**3** Hallengärd et al. 2013. J Virology 88:2858–2866.

# 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® €53.0m<br>DUKORAL® €24.6m | €58 – 62m<br>€27m | 10 – 15%<br>10% |
| **R&D investments (20% of revenues)** | €24.6m | €21 – 23m | – |
| **EBITDA** | €2.8m | €5 – 10m | 80 – 250% growth vs. 2016 |

# Valneva – expected newsflow and outlook

| | |
|---|---|
| **Products** | + IXIARO® /JESPECT® sales expected to grow by 10-15% to €58-62m in 2017<br>+ DUKORAL® sales expected to grow by 10% to €27m in 2017<br>+ Potential upside from additional distribution agreements for third party products |
| **Portfolio** | + Lyme Phase I progression and acceleration towards Phase II<br>+ Phase I entry of at least one additional vaccine candidate<br>+ Ongoing investments in innovative vaccine R&D in areas of unmet medical needs |
| **Platforms** | + Signing of additional EB66® and IC31® licensing agreements<br>+ Significant revenues and increased profitability from technologies & services |
| **Partnering** | + C.difficile vaccine candidate (Phase III ready) sought to be partnered<br>+ Other R&D partnering deals possible<br>+ Active discussions on broadening of commercial portfolio in travel vaccines |

Thank you
Merci
Danke
Tack

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