Valneva – a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs

Company Presentation
January 2019

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. The Valneva shares may not be offered or sold in the USA. The offer and sale of the Valneva shares has not been and will not be registered under the 1933 US Securities Act, as amended.

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 and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of their affiliates, directors, officers, advisors and employees shall bear any liability for any loss arising from any use of this presentation.

Certain information and statements included in this presentation are not historical facts but are forward-looking statements. 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.

Valneva's mid-term strategy

To become the leading commercial stage vaccine biotech

Products

Growing revenues from existing and future products to €200m and beyond

R&D

Investing in innovative R&D programs to meet unmet medical needs

Financials

Use proceeds from Commercial business to invest in promising product candidates

Growth

Generating organic growth complemented by targeted acquisition and licensing strategies

About Valneva

Corporate Profile

+ **Valneva is a biotech company** developing and commercializing vaccines for infectious diseases with major unmet needs
  - › Product sales revenue exceeds **€100m**
  - › Focused-R&D programs including **the most advanced Lyme disease vaccine** in clinical development today

+ **Specializes on important, high value niches**
  - › Travel vaccines
  - › Technological competence on vector-transmitted diseases

+ International footprint with over 450 employees
  - › **US & Canada** (S&M)
  - › **Austria** (R&D, SG&A, QA/QC)
  - › **Sweden** (Manufacturing, S&M)
  - › **UK** (Manufacturing, S&M)
  - › **France** (R&D, SG&A)

+ Developed and launched **IXIARO® in-house**

+ Expanded business by acquiring a **commercial product (DUKORAL®) from Crucell/Janssen** in February 2015

Strengthened shareholder base during 2018 to support future growth

€50m raised in 2018

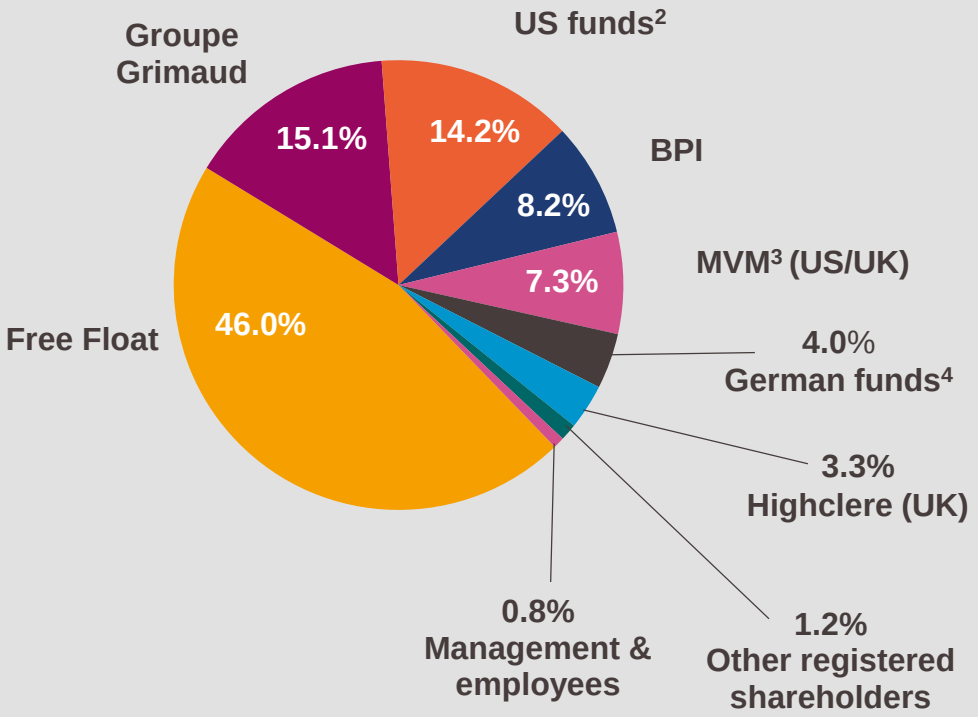
Financing led by blue chip US Life Science investors

Market positioning

US capital markets important for Valneva's future

Stock information

+ Main listing = Euronext (Paris)
+ Shareholder structure[1]:
+ Current **market cap**: ~ €300m
+ Number of ordinary shares: 90.9m

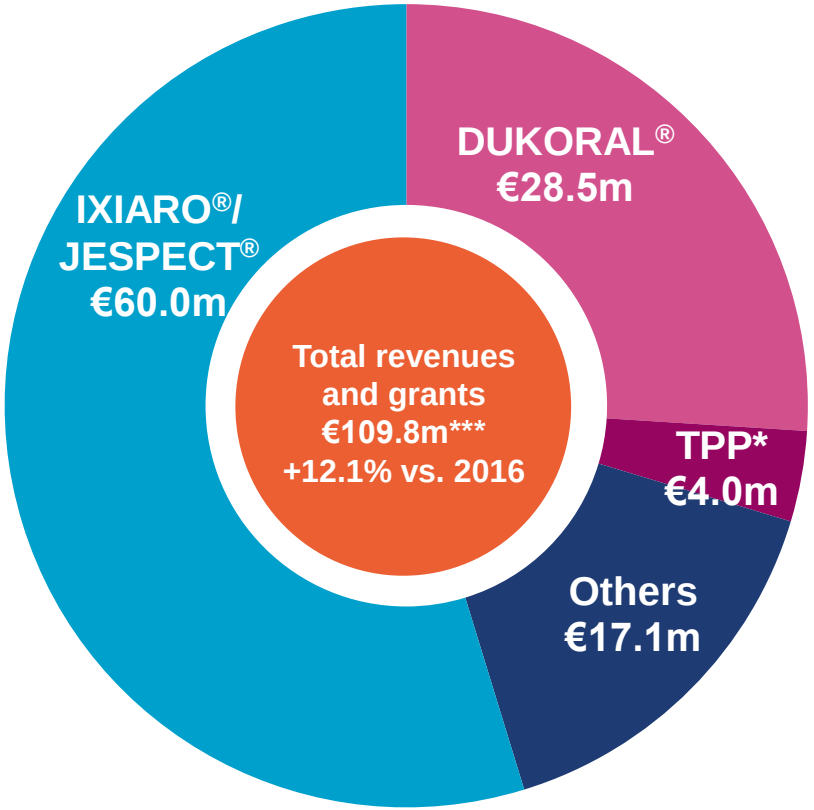


1 Current estimates based on ordinary share capital; **2** Combined positions of 13 US-based funds; **3** Funds managed by MVM Life Science Partners; **4** Combined positions of Apus Capital, Apo Asset Management, Lupus alpha, CD-Ventures, Medical Strategy and Deutsche Apotheker.

Valneva's profitable commercial business funds high-value R&D programs including Lyme; 2018 product sales guidance >€100m

Repeated double digit product sales growth (15% in 2017 vs. 2016)

2017 Full-year results



Product sales
€92.6m

Direct sales
73.5%

Gross
margin**
58%

Cash
generated
€12.8m

*Third party products
**On total revenues
***Totals may not sum to €109.8m due to rounding

A valuable R&D pipeline

IXIARO®/JESPECT® and DUKORAL®

Two unique travel vaccines against Japanese Encephalitis and cholera (ETEC[1])

IXIARO®/JESPECT®

+ **Designed to protect travelers and military against Japanese encephalitis (JE), the leading cause of viral neurological disease & disability in Asia[2]**
+ Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older[3]

Commercial position

+ Currently, **no effective treatment for the disease**[4]
+ Valneva's vaccine is the **only approved vaccine available for US and EU travelers**
+ Supply agreement in place with US military and strong track record of repeat contracts[5]
+ Limited competition; local producers exist in endemic regions and mainly serve public markets

DUKORAL®

+ **For the prevention of diarrhea caused by *Vibrio cholera* and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)[1]**
  - ~3-5 million cholera cases, 100,000-120,000 deaths/year[6]
  - ~5-18 million reported ETEC cases/year[7] (ETEC is the most frequent form of traveler's diarrhea)
+ In several markets, including EU, currently indicated to protect against cholera only
+ **Designed to protect adults and children** of two years of age who will be visiting endemic areas

Commercial position

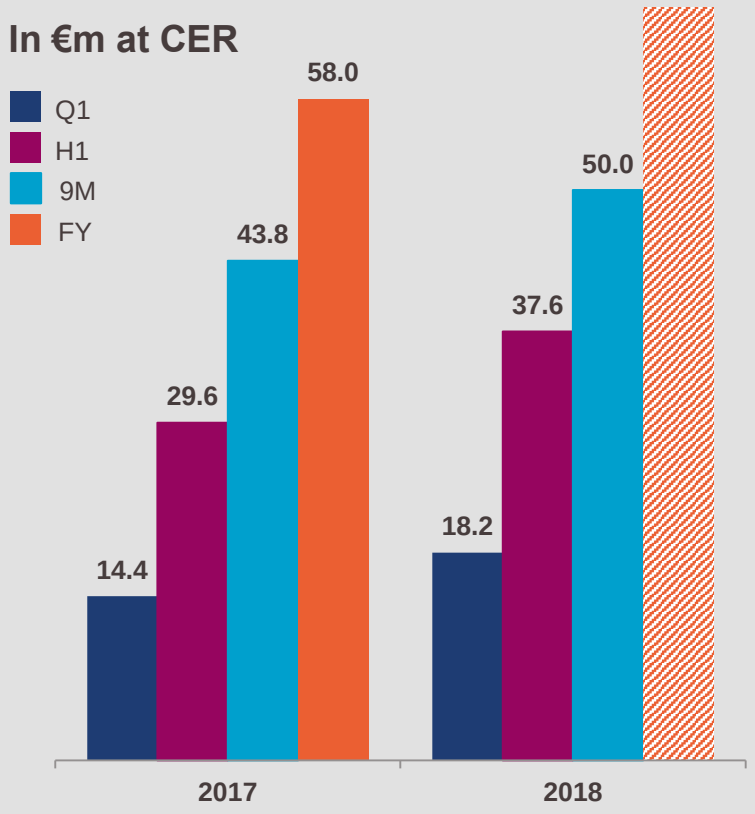
+ **Only approved cholera vaccine available for European, Canadian and Australian travelers**
  - WHO pre-qualification widely used in other countries
  - Asian manufacturers predominantly serve local markets and primarily for cholera only

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** Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; **3** 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; **4** CDC. MMWR 2010;59:1-27; **5** Valneva currently supplies its Japanese encephalitis vaccine IXIARO® pursuant to a one year contract with the US Government's Department of Defense (US DOD) that commenced November 7, 2017. Valneva can provide no assurance that this contract will be renewed or, if renewed, any assurance as to the number of doses, pricing or any other terms of any potential contract renewal to supply Japanese encephalitis vaccine to the US DOD; **6** WHO cholera factsheet February 2014; **7** Lundkvist J, Steffen R, Jonsson B. Cost-benefit of WC/rBS oral cholera vaccine for vaccination against ETEC-caused travelers' diarrhea. J Travel Med 2009; 16(1):28-34

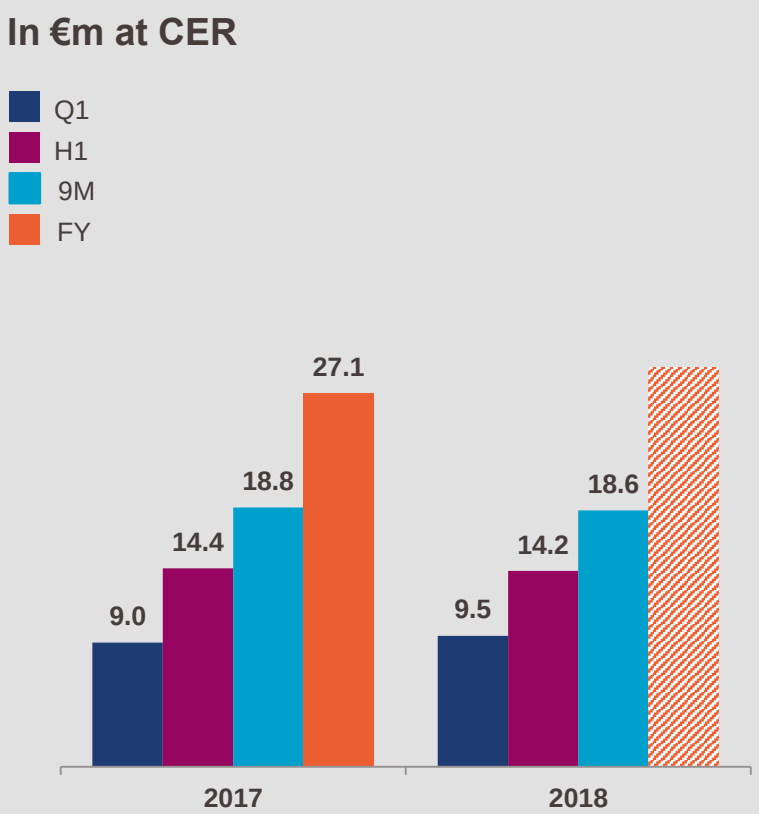
Ongoing product sales growth in line with guidance

2018 9M product sales of €71.1 million[1] (10% CER growth)

IXIARO®: Double digit growth expectations for FY 2018 confirmed



DUKORAL®: A strong fourth quarter will lead to matching FY 2017 sales

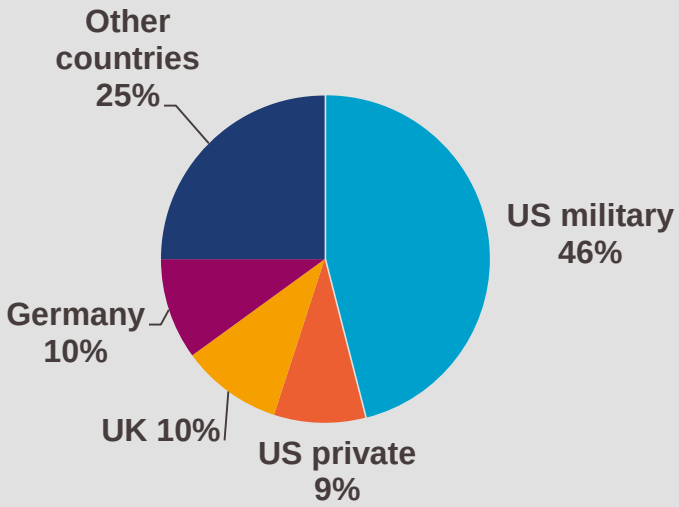


1 Including IXIARO®, DUKORAL® and third-party sales

2018 product sales growth expected to continue in 2019

US and Canada provide the majority of sales revenues

IXIARO®/JESPECT®: US is the biggest market

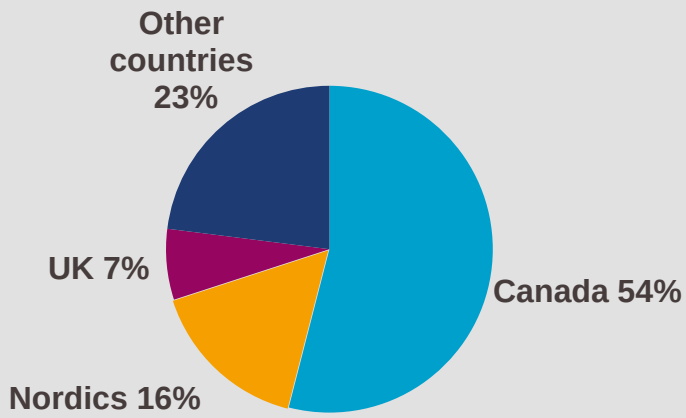


Split of 2017 product sales

Double-digit growth expected in 2018, through:

+ Increased penetration in key markets
+ Development of commercial network, including US private market

DUKORAL®: Canada is the biggest contributor



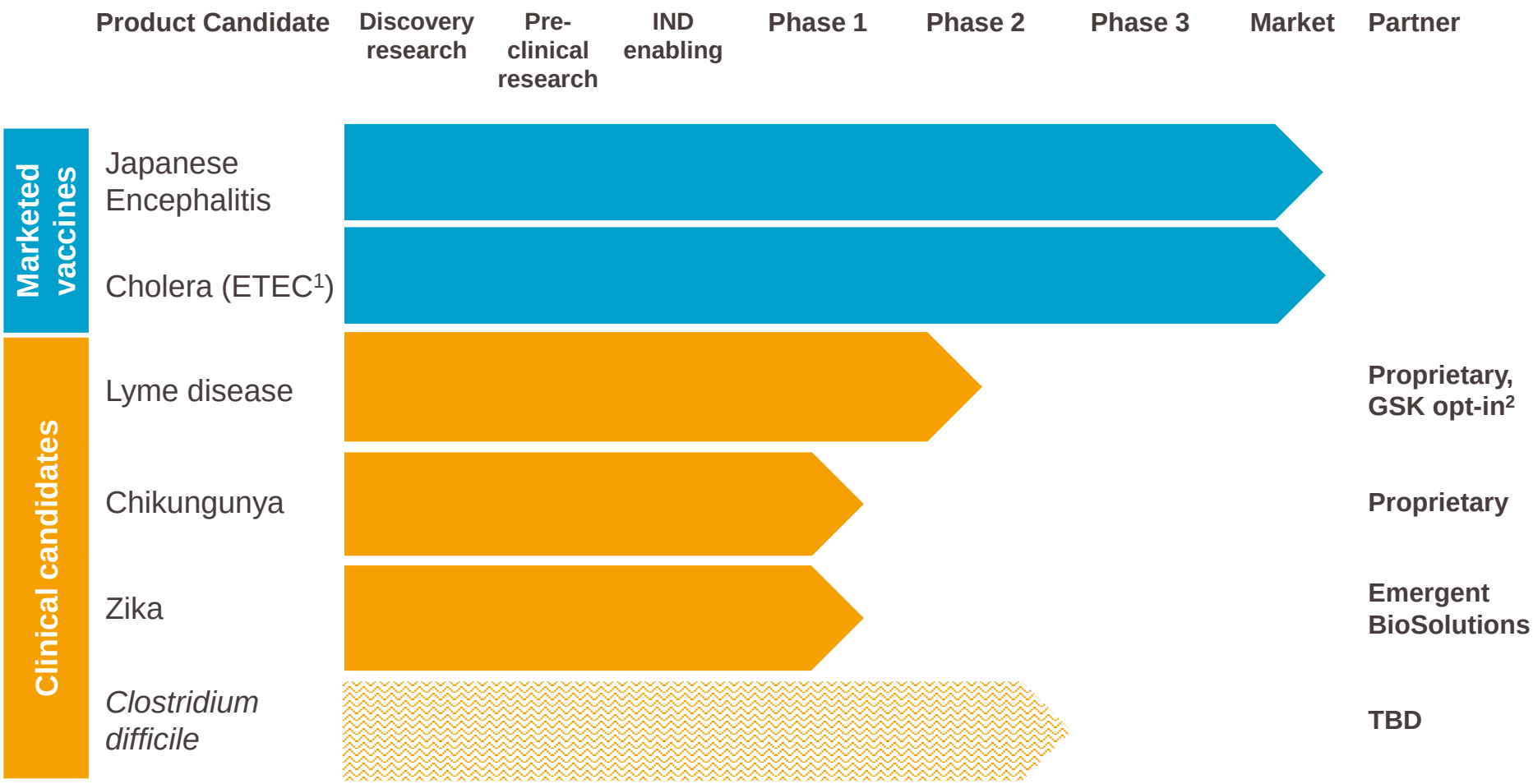
Split of 2017 product sales

Limited growth in 2018 due to H1 supply constraint

+ Existing markets will remain key
+ Possible label extensions / harmonization in the mid-term

Valneva's R&D pipeline

Focusing on vaccines with high unmet medical need



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** Based on a strategic partnership agreement signed in 2007, GSK has an opt-in after Phase 2 on products developed by Valneva Gmbh

Lyme disease
An area of high medical need and major vaccine opportunity

Lack of effective treatment

- **Early symptoms are often overlooked.** The typical fever, headache, fatigue and rash can easily be mistaken for other common illnesses.
- Treatment with antibiotics is usually successful in the early stage of infection[1]**, but there are numerous cases that go undiagnosed or are inadequately treated.**
- **Improperly treated or untreated, the infection can cause serious complications** affecting the joints, heart or central nervous system.[2]
- **Long-term treatment with antibiotics has not been proven effective[3]** for persistent Lyme disease infections.

Significant unmet need

Lyme disease is now present in 100% of the United States, new research suggests[4]

Most-affected regions:

- 95% of cases in 2016 occurred in 14 Northeastern and North Central states[5]
  - Highest incidence rates in Maine, Vermont and Pennsylvania[6]

Key age groups[7]:

- 17.3% of cases in children 5-14 years old
- 36.6% of cases in adults 40-64 years old

Peak seasons[8]: spring, summer

1 https://www.cdc.gov/lyme/treatment/index.html; **2** https://www.cdc.gov/lyme/signs_symptoms/index.html; **3** https://www.cdc.gov/lyme/postlds/index.html;
4 https://questdiagnostics.com/dms/Documents/health-trends/Quest_LymeDiseaseTrendsReport_2018.pdf; **5** https://www.cdc.gov/lyme/stats/index.html;
6 https://www.cdc.gov/lyme/stats/tables.html; **7** http://dx.doi.org/10.15585/mmwr.mm6354a1; **8** https://www.cdc.gov/lyme/stats/graphs.html

VLA15: the only Lyme disease vaccine in clinical development

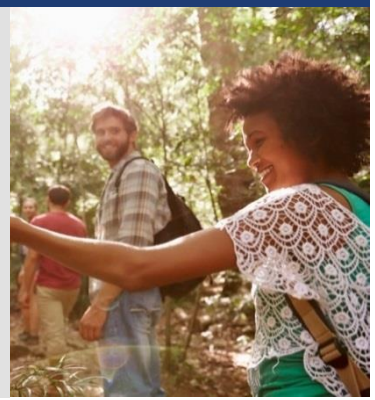
Market potential of up to $1bn[1]

Lyme disease

+ **Transmitted by *Ixodes scapularis* ticks (Northeastern & Midwestern US) and *Ixodes ricinus* ticks (Europe)[2]**
+ **Most common vector borne illness in the Northern Hemisphere (over 300,000 cases per year in US[3] and at least 200,000 cases per year in Europe[4])**
+ **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 1 initial data

+ **Positive Phase 1 initial results showed favorable safety profile and encouraging immunogenicity for VLA15**
+ **FDA Fast Track Designation received mid 2017**
+ Preclinical data showed that the vaccine has the potential to provide protection against the majority of *Borrelia* species pathogenic for humans[5]

Phase 2 initiated

+ **Alignment obtained with FDA and EMA on Lyme vaccine development strategy**
+ **Phase 2 initiated, first data expected mid-2020**
+ **Medical need for Lyme vaccine steadily increasing as the disease footprint widens[6]**

1 Company estimate supported by independent market studies; **2** Stanek et al. 2012, The Lancet 379:461–473; **3** As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article; **4** 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; **5** http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294; **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/

VLA15 (Lyme): Phase 1 study

Positive initial results reported Q1 2018

Conducted in 179 subjects in US and EU (www.clinicaltrials.gov, identifier NCT03010228):

Study primary endpoint met

+ Favorable safety profile
+ No safety concerns arose associated with VLA15 in any treatment group[1]

Encouraging immunogenicity with VLA15

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

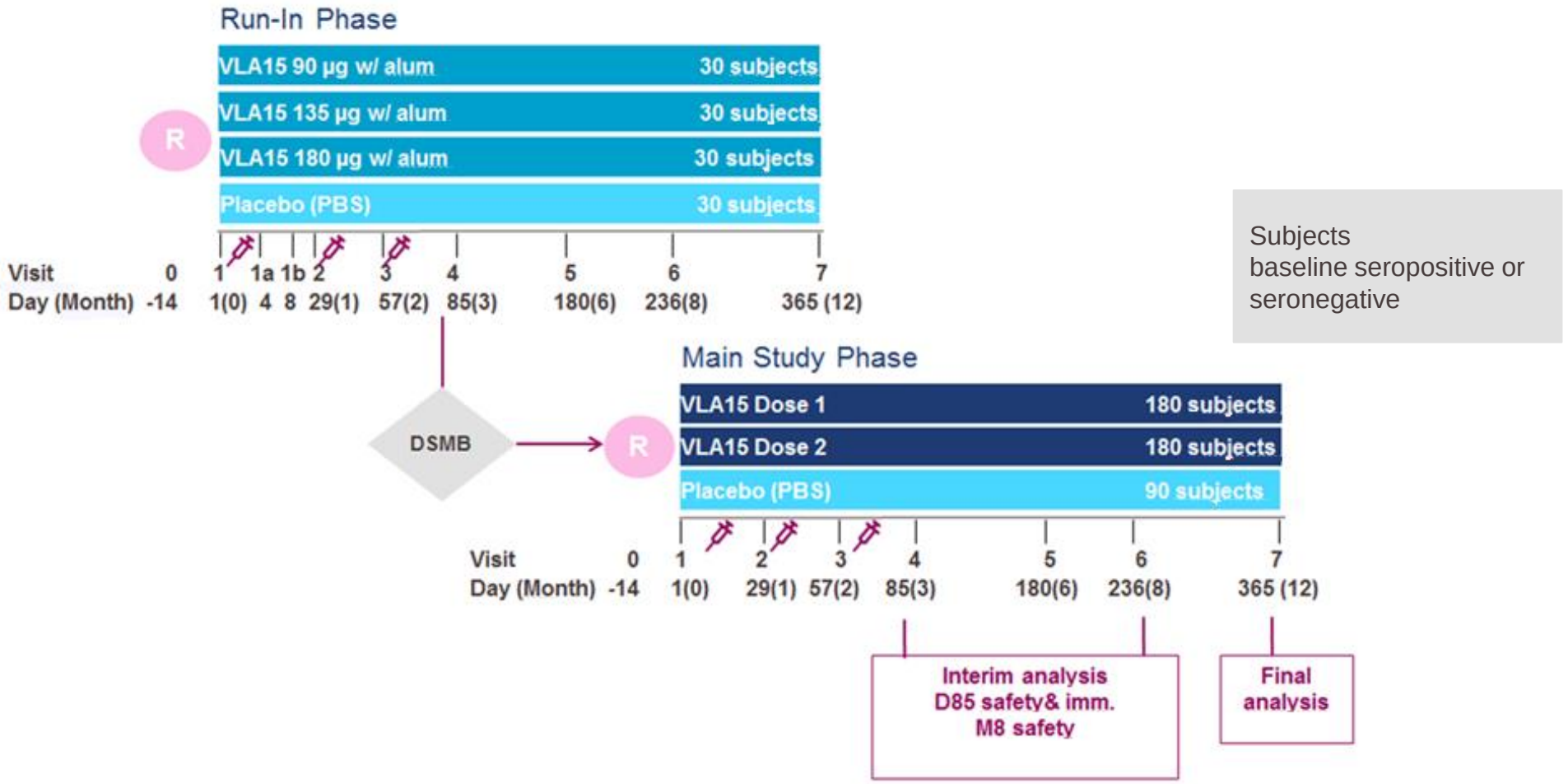
1 No differences in the safety profile were observed for the adjuvanted groups compared to the non-adjuvanted treatment groups.
2 IgG levels were substantially higher after three immunizations (Day 84) compared to after two (Day 56)
3 4-fold use against base-line
4 Preferred for further development / Further dose optimization will be considered.

VLA15 (Lyme): Phase 2 study (VLA15-201)

Observer-blind, randomized, placebo-controlled, multicenter study

Phase 2 study conducted in US and EU

- Four groups, three (2) doses, one formulation
- Run-in Phase: 120 healthy volunteers (18 to 40 years)
- Main Study Phase: 470 healthy volunteers (18 to 65 years)
- Primary objective: Immunogenicity data at Month 3
- Secondary objectives: Immunogenicity and safety data until M12



Lyme (VLA15) – Development
Key milestones

Current Development Assumptions		
▪ Phase 2 initiation (VLA15-201)	end 2018	✓
▪ Phase 1 final data (D365) and initial Booster data	Q1 / 2019	
▪ Run-in Phase (Phase 2) completed	mid 2019	
▪ Second Phase 2 initiation (VLA15-202)	mid 2019	
▪ Phase 2 data (primary)	mid 2020	
▪ Phase 3 initiation	Q4 / 2021	
▪ Phase 3 data*	Q4 / 2022	
▪ 1st possible BLA submission*	Q4 / 2023	
▪ 1st possible licensure*	Q3 / 2024	

*If pivotal field efficacy trial sufficient over one tick season – otherwise +1 year / rolling submission under Fast Track

VLA15: Outlook

Striving towards first BLA submission in 2023[1]

Phase 3 – Current hypothesis[2]

- **Pivotal, double-blind, placebo controlled field efficacy study in endemic countries**
- **Key objective:**
  - › Efficacy against Lyme disease (all serotypes) with vaccine at final dose and schedule
  - › Adults (18-70 yrs)

    Possible inclusion of younger age group (12-17)
- **Likely ~ 16,000 subjects**
  - › US and Europe, possibly also Canada
  - › Study sites in high-risk, endemic areas
  - › Two tick seasons with interim results submitted after the first tick season
    - Subject to data, possible BLA submission based on one season
- **Pediatric studies (Ph2/Ph3) largely in parallel**

1 Assumes licensure with data from one tick season; **2** Based on company assumptions and estimates. No detailed discussions with regulatory authorities have yet taken place.

VLA1553: A differentiated Chikungunya vaccine candidate

Potential single-shot vaccine against a severe, growing threat

Chikungunya

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

Valneva's vaccine candidate

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

Positive Phase 1 interim data

- FDA Fast track Designation received end 2018
- Positive Phase 1 interim results showed excellent immunogenicity with acceptable safety profile[5]
- Long term protection shown in preclinical testing
  Data from non-human primates (NHP) show vaccine's good safety profile and its potential to provide long-term protection after a single immunization[6]

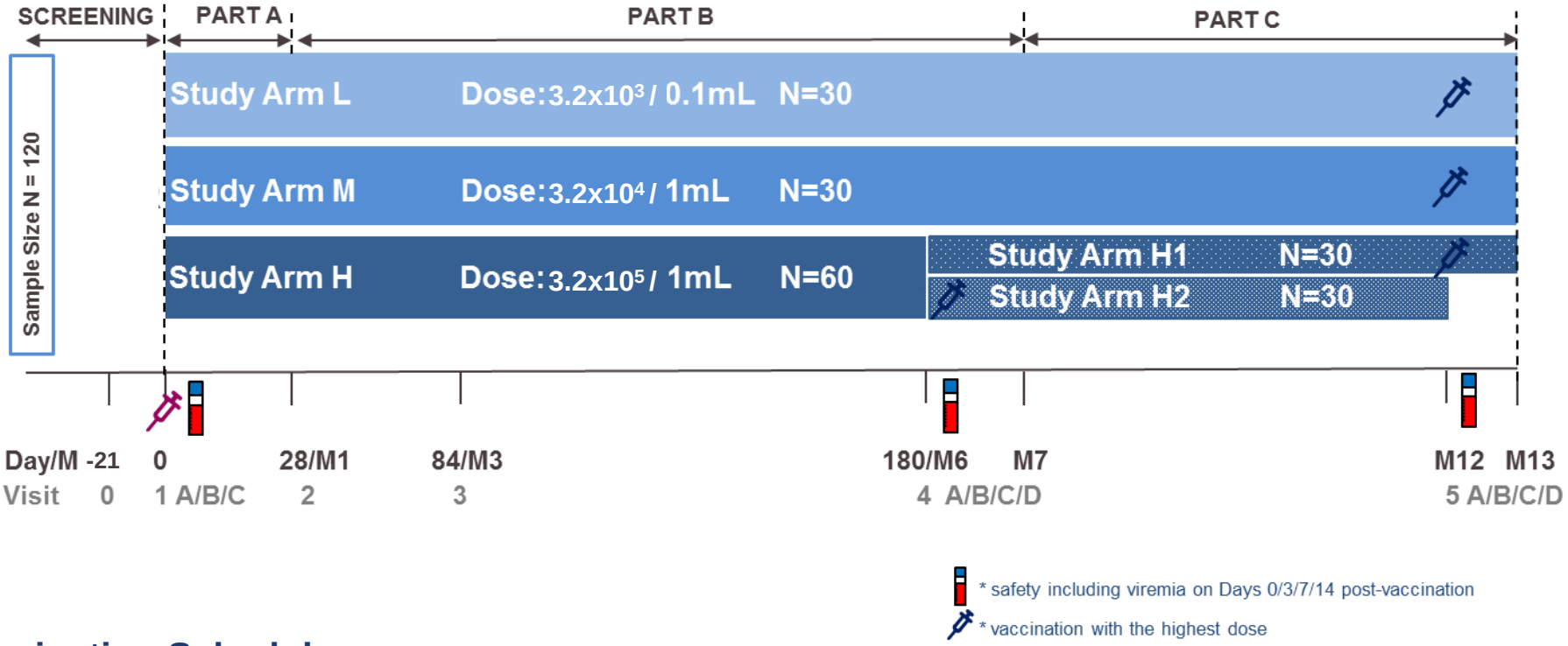
Phase 1 progression on track to conclude early 2020

- Group of study participants being re-vaccinated with highest vaccine dose to provide early intrinsic human challenge
- Chikungunya now eligible for FDA Priority Review Voucher (PRV)[7]
- Target populations include travelers, military personnel and individuals at risk living in endemic regions

1 PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016) https://www.paho.org/hq/dmdocuments/2016/2016-aug-19-cha-chikv-cases-ew-33.pdf ; **2** PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 5 (February 3, 2017) https://www.paho.org/hq/dmdocuments/2017/2017-feb-3-phe-CHIKV-cases-ew-5.pdf ; **3** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **4** Hallengärd et al. 2013. J Virology 88:2858–2866; **5** Pooled analysis of all study groups since study continues with additional vaccination to potentially obtain a first indication for efficacy **6** Roques et al. 2017JCI Insight 2 (6): e83527; **7** As of August 23, 2018 https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm618097.htm

VLA1553: Chikungunya vaccine candidate, Phase 1 study design

Blinded, randomized, dose-escalation study



Vaccination Schedule

+ Single-dose vaccination (Day 0)
+ Re-vaccination with highest dose (Month 6 and 12)

(1) to show that single-shot is sufficient to induce high titer neutralizing antibodies;

(2) to serve as indirect human viral challenge demonstrating that subjects are protected from viremia and thereby indicating early VE

Chikungunya Phase 1 study (VLA1553-101) Interim Results

Excellent immunogenicity with acceptable safety profile[1]

Immunogenicity

- 100% Seroconversion Rate (SCR)[2] at day 28 after single dose[1]
- 96.5% of subjects achieving ≥ 16 fold rise in antibody titres[2]
- High Geometric Mean Titre (GMT) in pooled analysis

Excellent immunogenicity profile after single vaccination

Safety

- No Serious Adverse Events (SAEs) up to day 28[1]
- No Adverse Events of Special Interest (AESIs) up to day 28[1]
- Local tolerability excellent
- Systemic adverse events included short-term fever, headache and fatigue
- Transient cases of reduced levels of neutrophils, lymphocytes or leucocytes w/o clinical symptoms[3]

Safety profile acceptable and supporting further development

1 Pooled analysis across all study groups since study continues with additional vaccination to potentially obtain a first indication for efficacy; **2** SCR defined as proportion of subjects achieving a CHIKV specific neutralizing antibody titre as NT50 ≥ 20; **3** As for other live-attenuated vaccines

Financial Outlook

On track to deliver FY 2018 revenue and EBITDA guidance

	2017 Actual	Initial 2018 Outlook	Updated 2018 Outlook
Product sales revenues	€92.6m	> €100m	✓
R&D investment	€23.4m	€30 – 35m	€25 – 30m
EBITDA	€10.8m	€5 – 10m	✓

Total revenues and grants were €109.8m in 2017. Other revenues (including service revenue and 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 – Upcoming expected newsflow H1 2019

+ Continuing product sales growth

+ New IXIARO® supply contract with US DoD (imminent)

+ VLA 15 Phase 1 final data, including initial Booster data, in Q1 2019
+ Second Phase 2 study initiation, mid-2019

+ 2019 guidance and full 2018 financial results in Q1

+ Valneva to present on Lyme, Chikungunya at the 2019 World Vaccine Congress in April

+ Chikungunya Phase 1 final results for single vaccination expected mid-2019

Appendices

World class leadership team

Thomas Lingelbach

President & CEO

+ CEO of **Intercell** since 2011
+ Managing Director for **Novartis Vaccines** & Diagnostics Germany
+ Vice President of Global Industrial Operations at **Chiron Vaccines**
+ 25 years in vaccine industry

Franck Grimaud

President & CBO

+ CEO and co-founder of **Vivalis** since 1999
+ Responsible for **Groupe Grimaud**'s development in Asia
+ 20 years in Corporate Business Development and life sciences

David Lawrence

CFO

+ CFO of vaccine biotech **Acambis** (FTSE / Nasdaq)
+ VP Finance at **Chiron Vaccines** and GSK
+ Non-executive Board experience
+ 25 years of experience in vaccines and life sciences

Frédéric Jacotot

General Counsel

+ VP Legal & IP and General Counsel of Valneva since September 2013
+ Division Counsel at **Abbott**
+ 25 years as a legal expert in the pharmaceutical industry

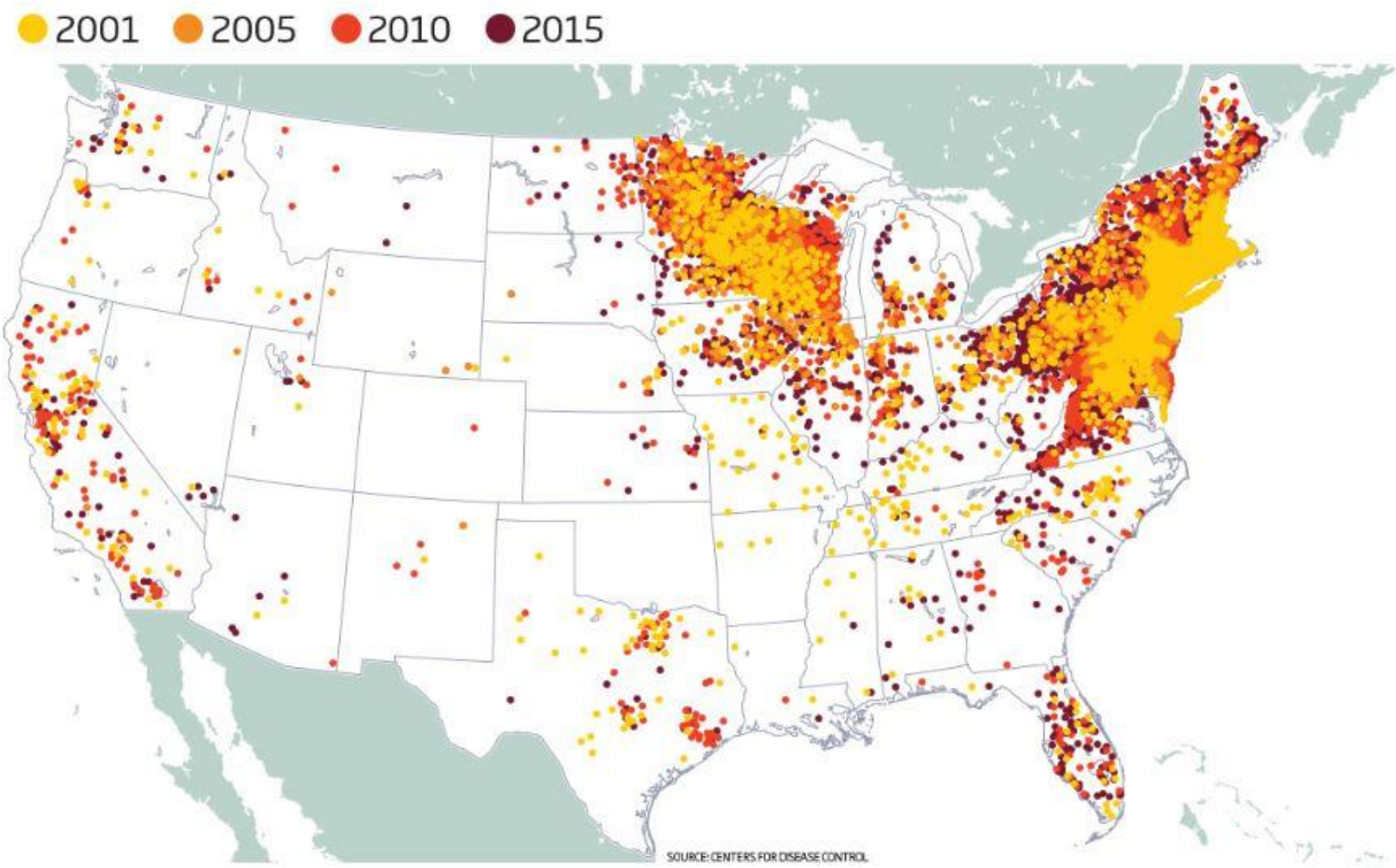
Wolfgang Bender, MD, PhD

CMO

+ Senior international positions at various large pharmas including **Novartis, Takeda, Pfizer** and **Hoechst**
+ Experiences in scientific-medical affairs, drug development and general management of vaccines and pharmaceuticals
+ 30 years of experience

Spread of Lyme across the US

Over 300,000 estimated cases in the US annually – CDC 2017



Source : Centers for Disease Control and Prevention

VLA84: Unpartnered *Clostridium difficile* vaccine candidate

Vaccine targeting healthcare-associated diarrhea, an increasing threat to the elderly in a $1 billion market[5]

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 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**

Phase 2 completed

- **Phase 3 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 Ph3 on immunological correlate**
- **New approval expected to substantially improve investment-risk proposition for own or partnered development to market**

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

VLA1601: Zika vaccine candidate

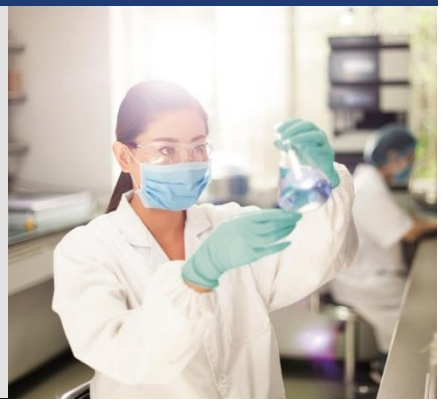
Valneva and Emergent BioSolutions partnership

Zika

- Zika is a mosquito-borne viral disease, a Flavivirus transmitted by *Aedes* mosquitoes[1]
- 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[2] in adults

Valneva's vaccine candidate

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



Positive Phase 1 results (interim)[4]

- Excellent safety profile in all tested doses and schedules – comparable to IXIARO® and other clinical stage ZIKA vaccines
- Immunogenic with doses and schedules dependent kinetics as expected for an inactivated, alum-adjuvanted whole-virus vaccine
- Seroconversion Rates (SCR) up to 85.7%[3]

Phase 1 final data and next decisions expected mid 2019

- Phase 1 final analysis (up to Day 208) after first vaccination expected in Q2 / 2019
- Experts and agencies evaluating potential routes to licensure for ZIKA vaccines including potential preparedness as stockpiling
- Co-development deal with Emergent Biosolutions – Decision on any further development expected by mid 2019

1 https://www.cdc.gov/zika/transmission/index.html **2** http://www.who.int/mediacentre/factsheets/zika/en/; **3** SCR on Day 35 of Interim Analysis of Data up to Day 56;
4 https://www.valneva.com/en/investors-media/news/2018#300

Thank you
Merci
Danke
Tack

valneva