

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

Company Presentation
November 2018





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Strengthening shareholder base and strategic positioning



€50m raised in 2018

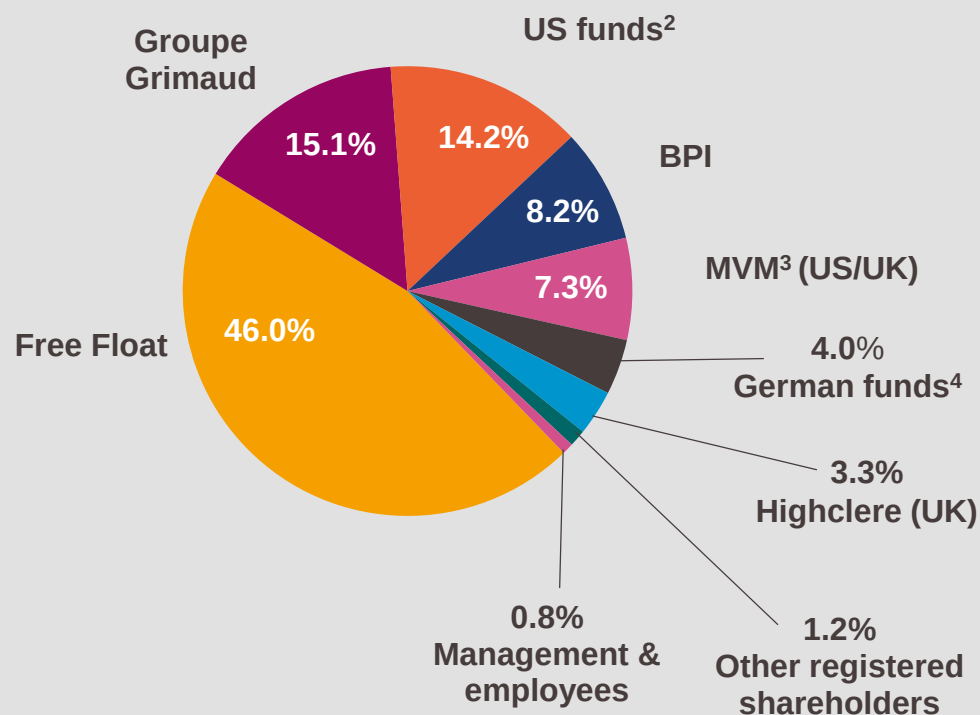
Recent financing led by blue chip US Life Science investors

Market positioning

US capital markets important for Valneva's future

Stock information

- + Main listing = Euronext (Paris)
- + Shareholder structure¹:
- + Current **market cap**: ~ €300m
- + Number of ordinary shares: 90.9m

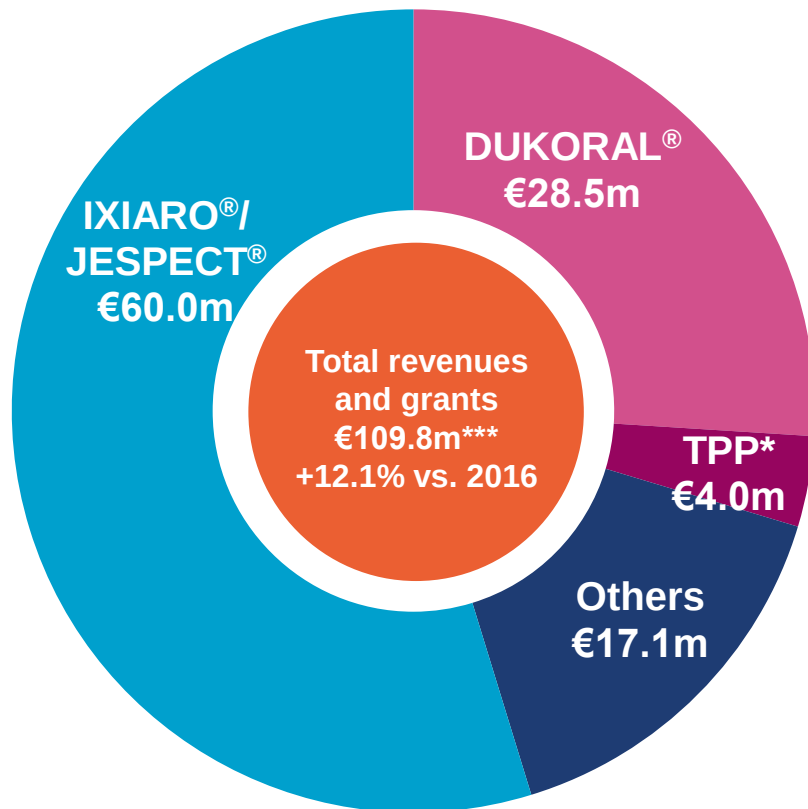


¹ Current estimates based on ordinary share capital; ² Combined positions of 13 US-based funds; ³ Funds managed by MVM Life Science Partners; ⁴ Combined positions of Apus Capital, Apo Asset Management, Lupus alpha, CD-Ventures, Medical Strategy and Deutsche Apotheke.

Valneva's strong commercial business funds its high-value R&D



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



2017 Full-year results

*Third party products

**On total revenues

***Totals may not sum to €109.8m due to rounding

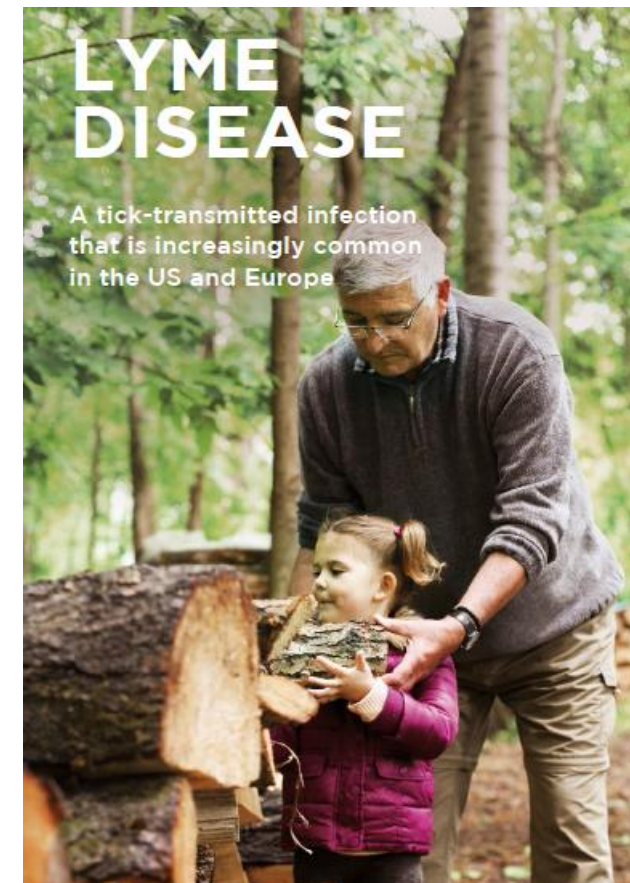
A valuable R&D pipeline

Product sales
€92.6m

Direct sales
73.5%

Gross
margin**
58%

Cash
generated
€12.8m





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

The only JE vaccine approved in the US and Europe

Japanese Encephalitis vaccine

- + Designed to protect travelers and military against JE, the leading cause of viral neurological disease & disability in Asia¹
- + Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older²



Commercial position

- + Currently, **no effective treatment for the disease**³
- + 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 contracts⁴
- + Limited competition; local producers exist in endemic regions and mainly serve public markets

Market potential

- + **308 million travelers to Asia & the Pacific** in 2016⁵
 - › Travelers to Asia expected to **grow 4.4% per year**⁵
- + **Global JE vaccines market valued at ~€150-200m**⁶
 - › Traveler 65%, Military 15%, Endemic 20%⁵
 - › ~68,000 symptomatic cases in Asia each year⁷
- + **Significant growth potential in key markets**

¹ Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; ² 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; ³ CDC. MMWR 2010;59:1-27; ⁴ 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; ⁵ UNWTO Tourism Highlights 2017; ⁶ Nomura Code estimates (October 2012) and Valneva Management estimates; ⁷ WHO. Bull World Health Organ 2011; 89:766-774E

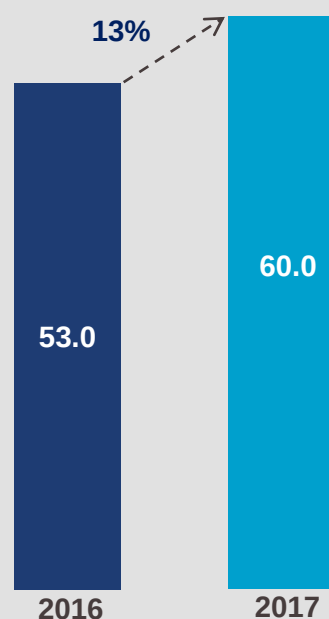


IXIARO®/JESPECT®

Repeated double-digit sales growth and increasing margin

■ 2016 ■ 2017

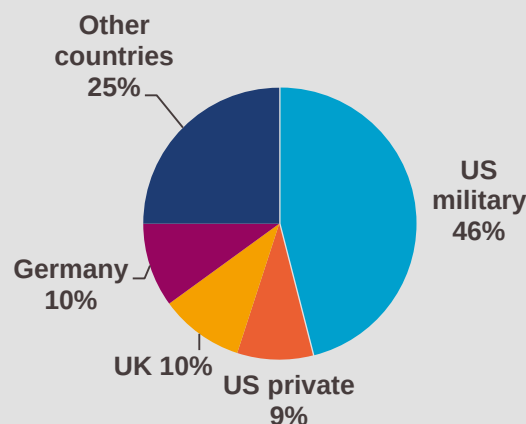
IXIARO®/JESPECT® sales (in €m)



2017 Revenue growth driven by

- + Increased product adoption in the UK, German and Canadian markets
- + US military sales

US is the biggest contributor to top line



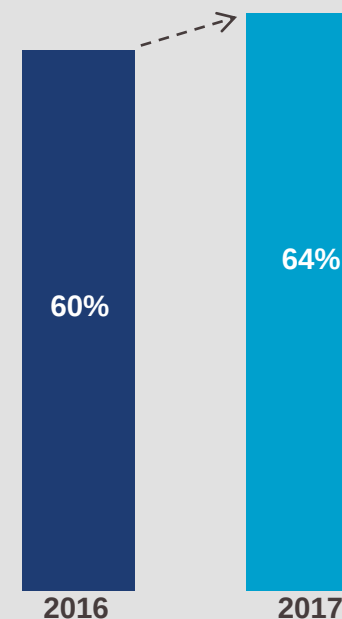
Split of 2017 product sales

Double digit growth expected in 2018 through

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

■ 2016 ■ 2017

Gross margin



Further margin improvement expected

- + Fixed manufacturing cost structure to translate into margin growth

The only cholera (ETEC¹) vaccine available in EU, Canada & Australia

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/year²
 - › ~5-18 million reported ETEC cases/year³ (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

Market potential

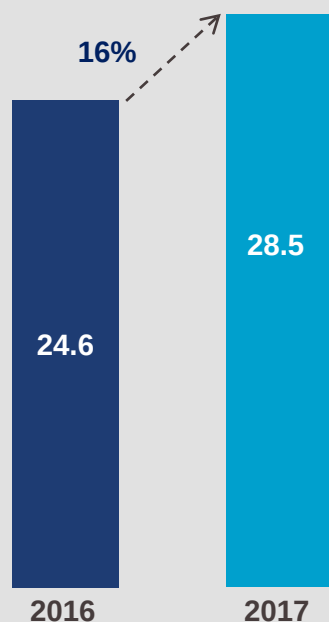
- + **435 million travelers** to Africa, Asia, the Caribbean and Central & South America in 2016⁴
- + **Global cholera/ETEC vaccines market valued at €283m⁵**
- + Ongoing travel to risk regions, improved awareness and travel recommendation updates to drive growth
- + **Canada, Sweden, Australia account for ~75% of Dukoral® 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 WHO cholera factsheet February 2014; ³ 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; ⁴ UNWTO Tourism Highlights 2017; ⁵ ETEC/Cholera = global predicted demand, source: PATH/bvgh "The Case for Investment in ETEC vaccines", March 2011 and VacZine Analytics TD 2011

Excellent sales growth in key markets

■ 2016 ■ 2017

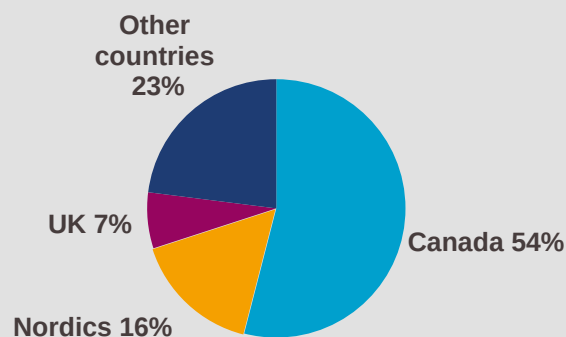
DUKORAL® sales (in €m)



Double-digit sales growth in 2017 driven by

- + Increased market penetration in Canada and the UK

Canada is the biggest contributor



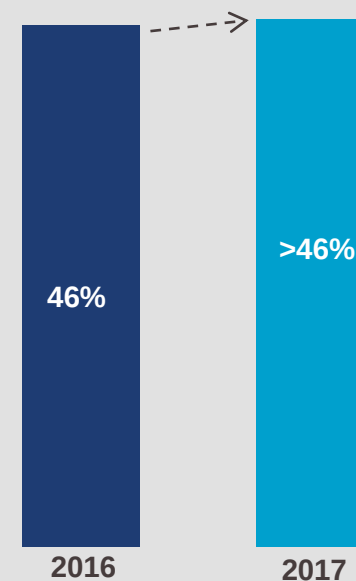
Split of 2017 product sales

FY 2018 sales expected to match 2017

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

■ 2016 ■ 2017

Gross margin



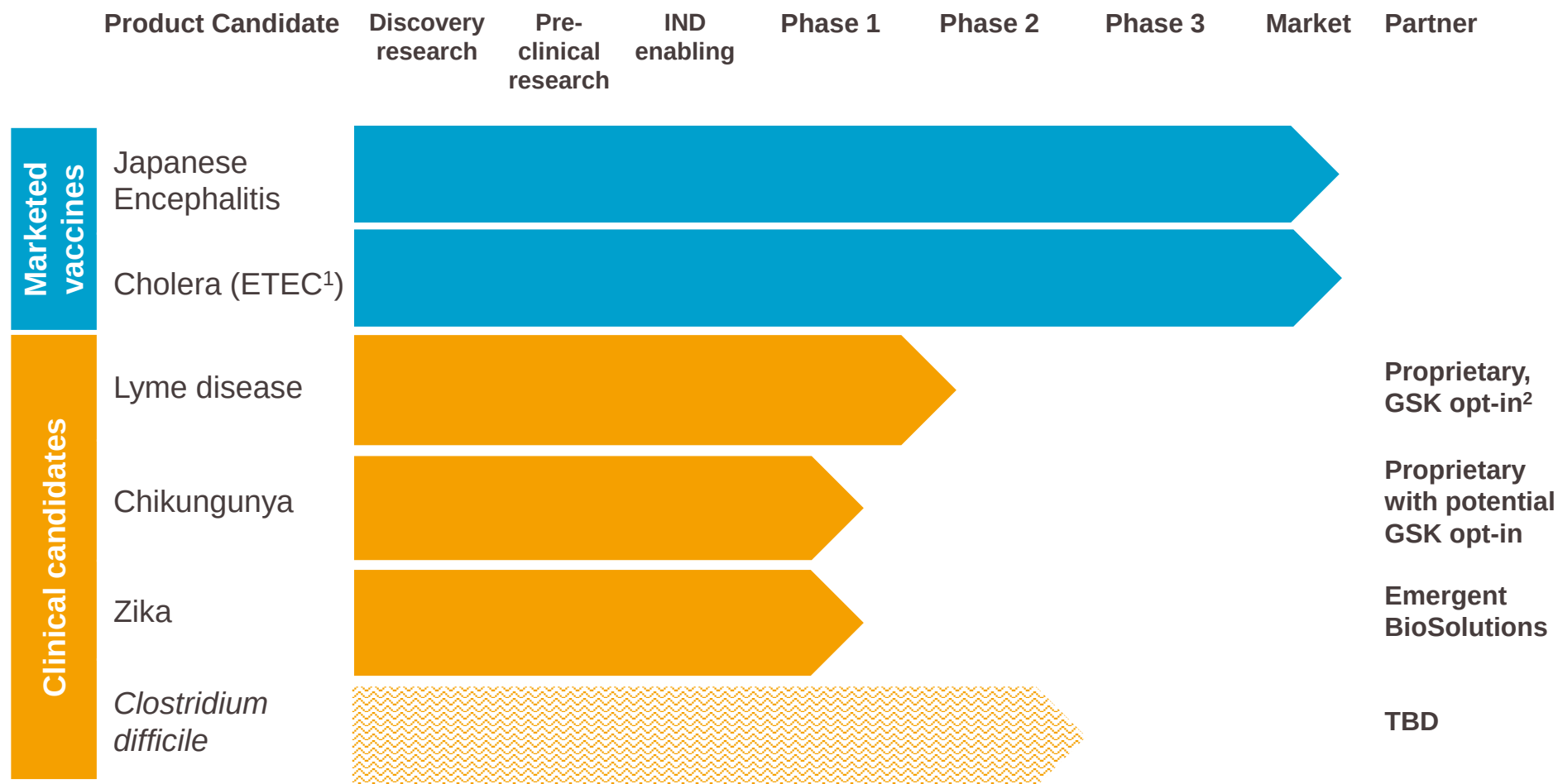
Further margin improvement expected

- + Fixed manufacturing cost structure



Valneva's 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: Why is a vaccine needed?

Lack of effective treatment, significant unmet medical need

Existing treatments not always effective

- › **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 infection¹, **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 effective³** for persistent Lyme disease infections.

Risk of Lyme disease in the United States

Lyme disease is now present in 100% of the United States, new research suggests⁴

Most-affected regions:

- › 95% of cases in 2016 occurred in 14 Northeastern and North Central states⁵
 - › Highest incidence rates in Maine, Vermont and Pennsylvania⁶

Key age groups⁷:

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

Peak seasons⁸: 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>

Lyme disease in the media



The New York Times

Lyme Disease Is Spreading Fast. Why Isn't There a Vaccine?

By Karen Zraick

Aug. 14, 2018



The Laconia Daily Sun

Doctors needed to treat epidemic of Lyme disease

By Judith Weeg Sep 5, 2018 0

healthline.

HEALTH NEWS

✓ Fact Checked

How Lyme Disease Can Hurt Your Heart

- healthline.com, Aug 20 2018

THE WALL STREET JOURNAL.

U.S. | THE NUMBERS

Lyme Disease: An Even Bigger Threat Than You Think

A look at why cases of the tick-borne illness are undercounted



By Jo Craven McGinty

Updated June 22, 2018 12:05 p.m. ET

135 COMMENTS

Fresno mother on a mission after daughter dies from Lyme Disease



By Amanda Venegas

Thursday, August 23, 2018

Avril Lavigne on her Lyme disease battle: 'I had accepted death'

By News.com.au

September 7, 2018 | 1:58pm

- Page Six, Sep 07 2018

Source: Various news sources from June to September 2018.

VLA15: the only Lyme disease vaccine in clinical development



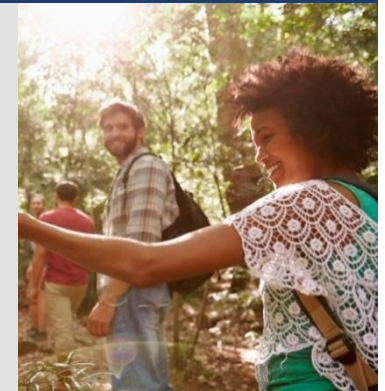
Market potential of approximately €700m - €800m¹

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 US³ and at least 200,000 cases per year in Europe⁴)
- + 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 humans⁵

Phase 2 initiation on track to commence end 2018

- + Alignment obtained with FDA and EMA on Lyme vaccine development strategy
- + Phase 2 initiation expected at end of 2018, subject to regulatory clearances
- + Medical need for Lyme vaccine steadily increasing as the disease footprint widens⁶

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 group¹

Encouraging immunogenicity with VLA15

- + VLA15 immunogenic in all doses and formulations
- + Good OspA-specific IgG antibody responses against all OspA serotypes²
- + Clear dose responses seen between the lowest / higher doses, adjuvanted / non-adjuvanted groups
- + Highest, adjuvanted dose group - Seroconversion Rates³ (SCR) from 71.4% to 96.4% for different OspA serotypes⁴

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

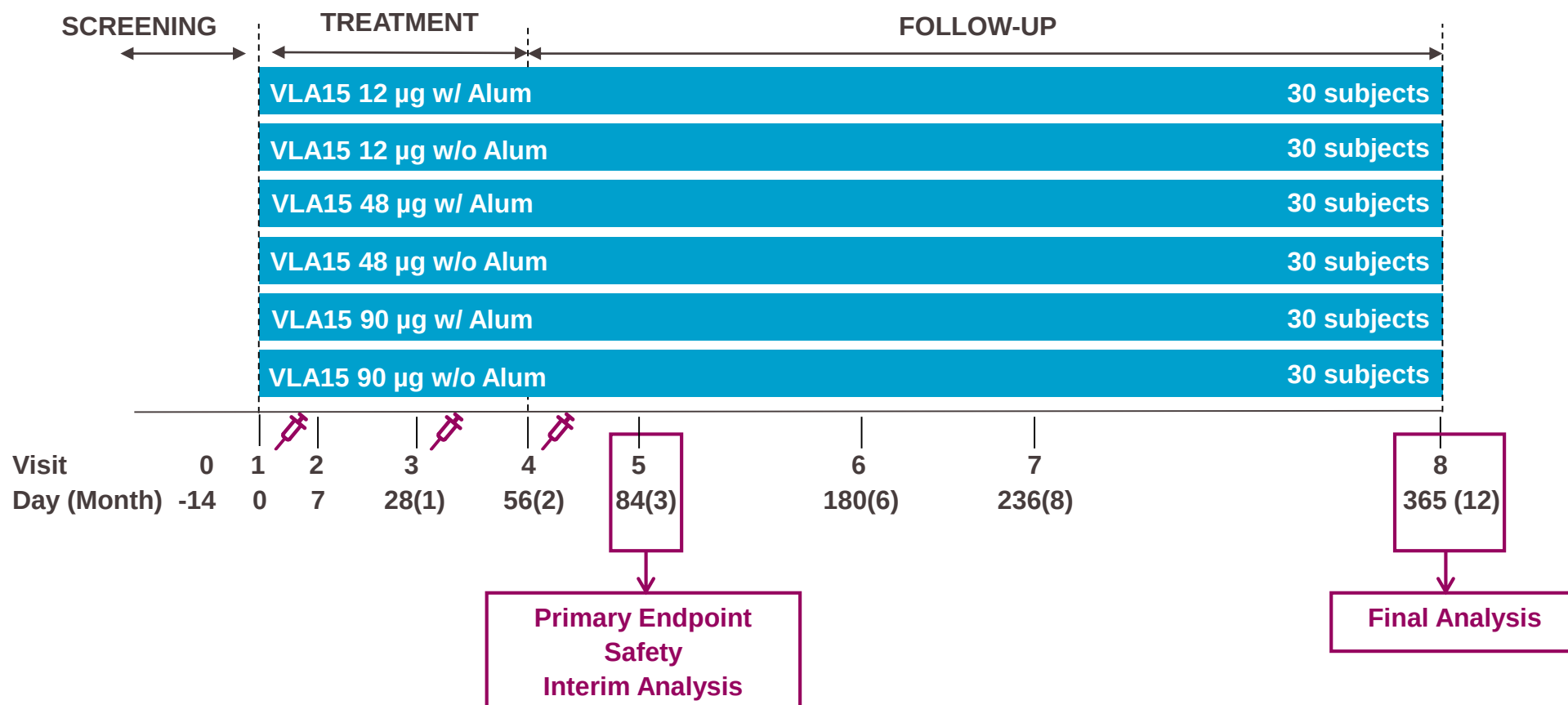
⁴ Preferred for further development / Further dose optimization will be considered.

VLA15 (Lyme): Phase 1 study

Observer-blind, partially randomized, dose escalation study

Phase 1 study conducted in US and EU

- 6 groups, 3 doses, 2 formulations
- 179 subjects aged 18-<40 years
- Primary objective: Safety and tolerability to Month 3
- Secondary objectives: Safety and tolerability until M12; Immunogenicity





Lyme Phase 1 study (VLA15-101): Safety

Favorable 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:

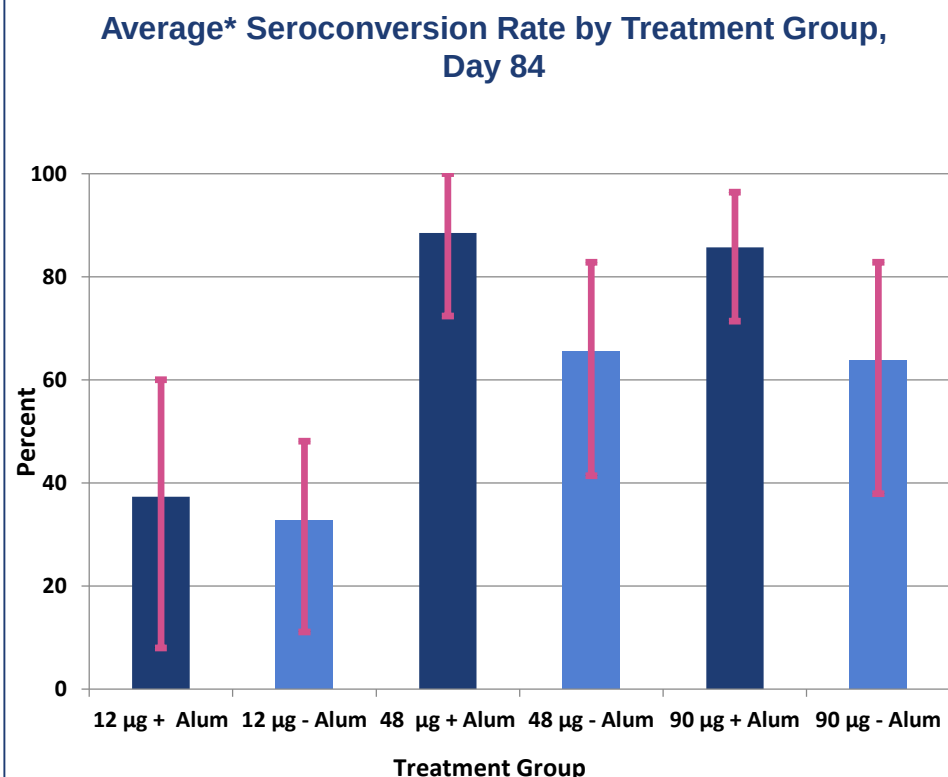
- + Total of 8 subjects with severe, related AEs, from different treatment groups
- + All were solicited AEs (i.e., volunteer-reported, by default considered related to vaccination)
- + Study investigators considered AEs as related in 4 subjects:
 - › 2 Subjects with severe local Pain/Tenderness
 - › 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



Lyme Phase 1 study (VLA15-101): Immunogenicity

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

Sero Conversion Rates (SCR)



*Average = Arithmetic Mean of SCRs against individual Serotypes 1-6 (Rate of subjects with ≥ 4 -fold increase in OspA-specific IgG)

** Error Bars represent highest / lowest individual Serotype SCR for treatment group

Key results

- OspA specific IgG antibody responses induced in all treatment groups and against all OspA serotypes
- Significant difference in response between the lowest adjuvanted dose group and the two highest ones
- 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***

*** Further dose optimization will be considered



VLA15: Status update

Progression into Phase 2 Program at end 2018 on track

Recent progress

- **Phase 1 (initiated early 2017)**
 - › Interim data (March 2018):
 - Study primary endpoint met (safety)
 - Encouraging immunogenicity data
 - › Study extension for Booster (Month 13)
 - ~ 60 subjects (EU only), fully recruited
 - Safety & Immunogenicity read-out (Month 19)
 - Data expected H1/2019
 - › End of Phase 1 (EOP1) process with FDA successfully concluded (July 2018)
 - FDA and EMA alignment on Phase 2 strategy
- **Continuous CMC² development for further industrialization**
- **Increasing investments in in-house capabilities and capacity to support ongoing progress**

Phase 2 Program – Current assumptions¹

- **Key objectives**
 - › Dose optimization / final dosage³
 - Further doses will be included
 - › Confirmation of final schedule
 - Alternative schedule will be tested
- **Primary endpoint: Immunogenicity**
 - › GMTs (Geometric Mean Titers) for IgG against OspA ST1-ST6 (1 month after primary immunization)
- **~ 800 subjects**
 - › Conducted in US and EU (split tbc)
 - › >10 study sites
 - › In endemic areas
 - Including seropositive subjects
 - › Extended age range (18-65 years)

¹ Study protocol(s) subject to regulatory approval(s); ² Chemistry Manufacturing & Control; ³ Only adjuvanted formulations in Phase 2



VLA15: Outlook

Striving towards filing for licensure in 2023¹

Phase 3 – Current hypothesis²

- **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 incidence-driven interim analysis results submitted for after the first tick season
- **Pediatric studies (Ph2/Ph3) largely in parallel**

Key expected upcoming milestones

▪ Phase 2 initiation	→ End 2018
▪ Phase 1 final data (including booster results)	→ H1 2019
▪ Run in phase completion	→ H1 2019
▪ Phase 2 initial data	→ Mid-2020
▪ Phase 3 initiation	→ H2 2021
▪ First filing for licensure	→ H2 2023

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: Chikungunya vaccine candidate

A 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 impairments¹
- + 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 vaccine³
- + Aims for long-lasting protection of individuals > 1 year of age
- + Protective against various CHIKV outbreak phylogroups & strains⁴



Phase 1 fully recruited

- + Phase 1 to evaluate safety & immunogenicity in ~120 subjects and to confirm antibody persistence (≥6m) with potential early indication of efficacy
- + 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 immunization⁵

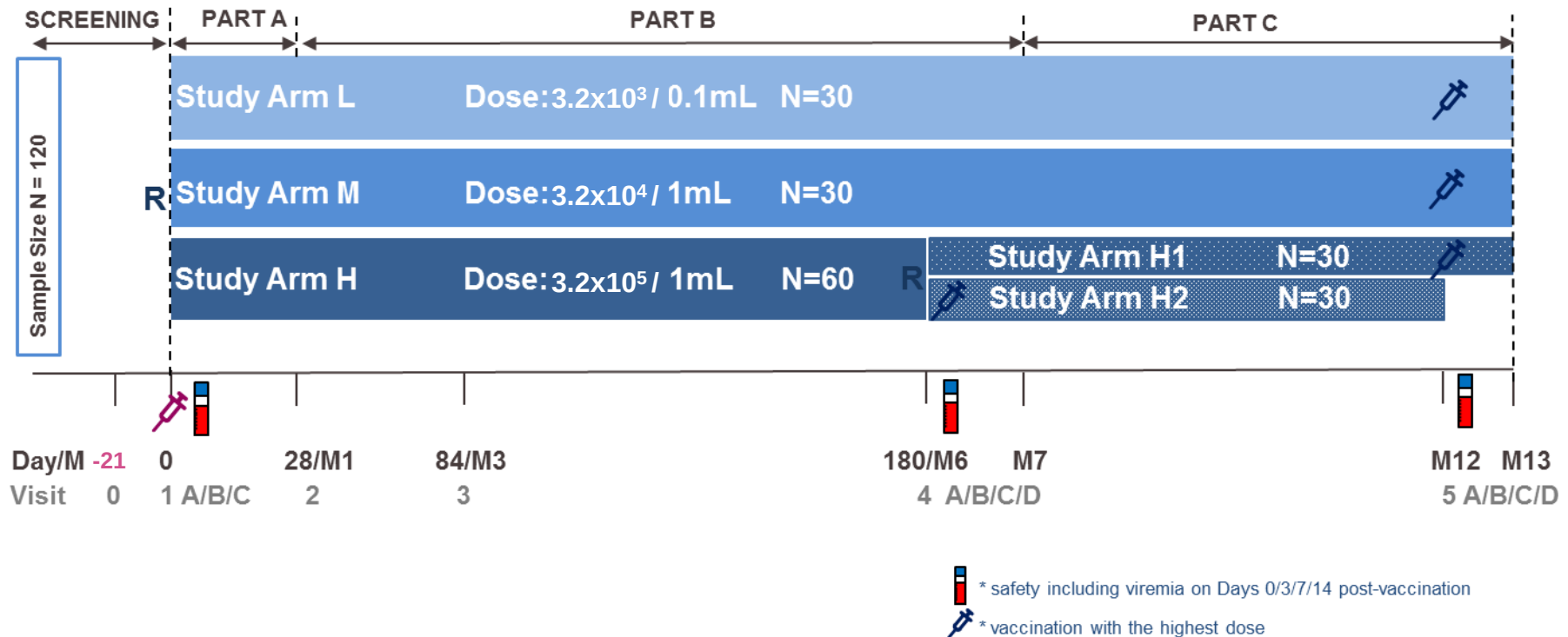
Phase 1 first data⁷ expected by end of 2018

- + 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)⁶
- + 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 Hallengård et al. 2013. J Virology 88:2858-2866; ⁵ Roques et al. 2017JCI Insight 2 (6): e83527; ⁶ As of August 23, 2018 <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm618097.htm>; ⁷ primary and first secondary endpoint data

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



2018 Financial Outlook

On track to deliver against FY revenues 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 – Exciting upcoming newsflow



+ Continuing product sales growth

+ New IXIARO® supply contract with US DoD expected

+ Lyme Phase 2 initiation expected at the end of 2018

+ Phase 1 booster dose initial data expected late January 2019

+ Chikungunya Phase 1 execution with first data at the end of 2018

+ Zika Phase 1 execution with first data within the next few months

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



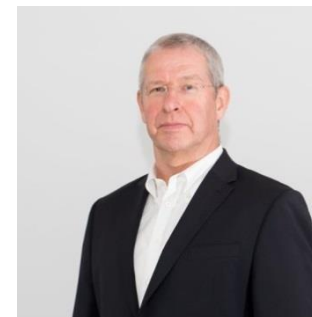
David Lawrence
CFO

- + 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

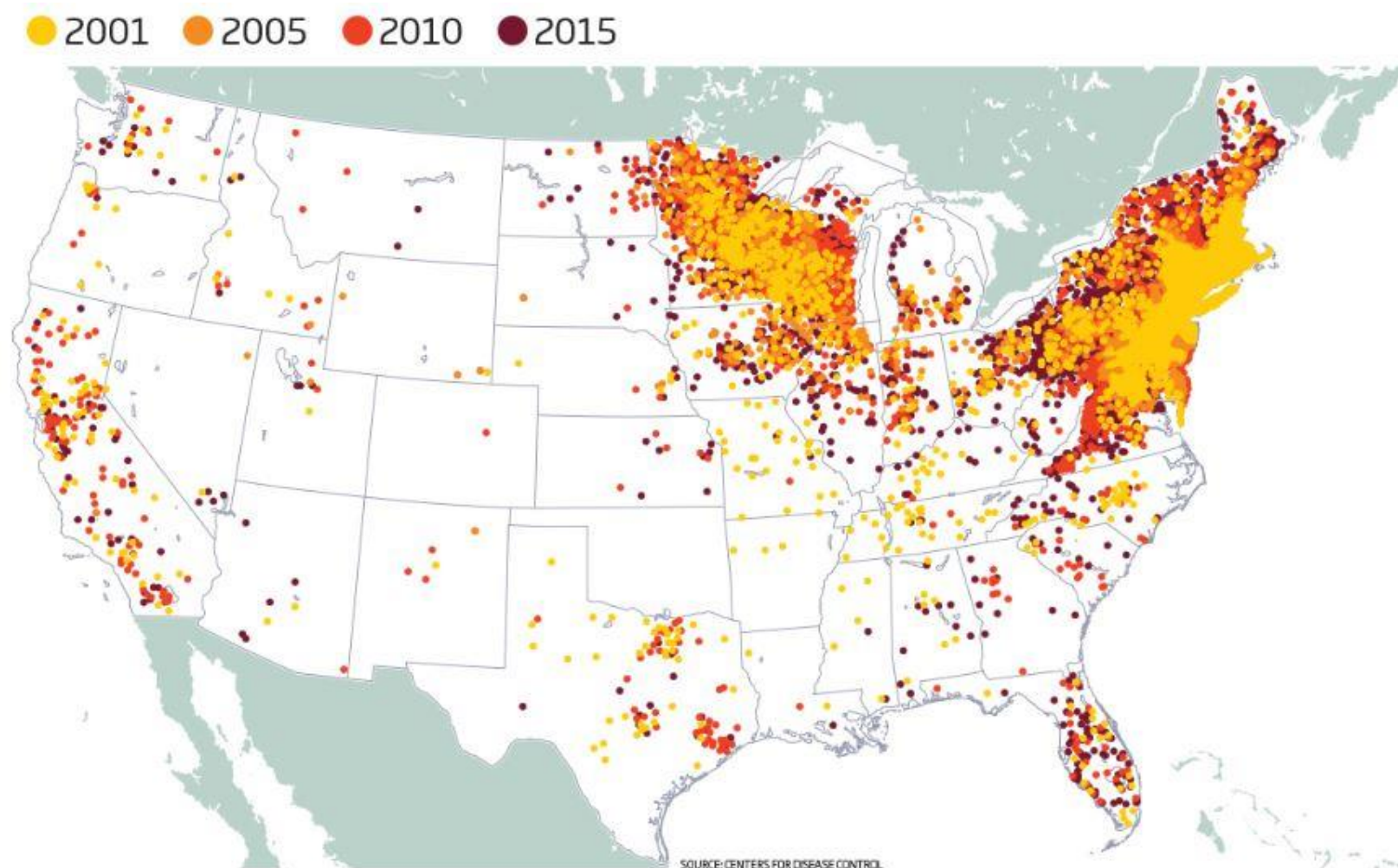


Wolfgang Bender, MD, PhD
CMO

- + 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

VLA1601: Zika vaccine candidate

Valneva and Emergent BioSolutions partnership

Zika

- + Zika is a mosquito-borne viral disease, a Flavivirus transmitted by *Aedes* mosquitoes¹
- + 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 syndrom² 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 1 initiated in February 2018

- + Recruitment completed for Phase 1, initiated in Feb 2018
- + **Pre-clinical testing** demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to IXIARO®
- + **Co-development deal with Emergent BioSolutions**

Phase 1 data expected late 2018 / early 2019

- + Phase 1 to evaluate safety and immunogenicity in ~65 subjects at different dose levels and schedules
- + Priority for people traveling to or living in endemic regions, including potential preparedness for stockpiling
- + Emergent is a strong partner for emergency stockpiling

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



VLA84: Unpartnered *Clostridium difficile* vaccine candidate

Vaccine targeting healthcare-associated diarrhea, an increasing threat to the elderly in a \$1 billion market⁵

Clostridium difficile (C. diff)

- + Single most common pathogen of acute healthcare-associated infections in the US¹ (~ 450,000 cases of annually and ~ 30,000 deaths²)
- + ~ 172,000 cases in EU member states per year³
- + Targeting primary prevention of *C. difficile*
 - › Current antibiotic treatments have significant limitations with recurrence in ~20% of cases⁴

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

Thank you
Merci
Danke
Tack

