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

Company Presentation
January 2017

valneva

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

Products

Commercial products
+ Valneva expects total revenues of €95-100m in 2016, coming mainly from its two proprietary travel vaccines

Portfolio

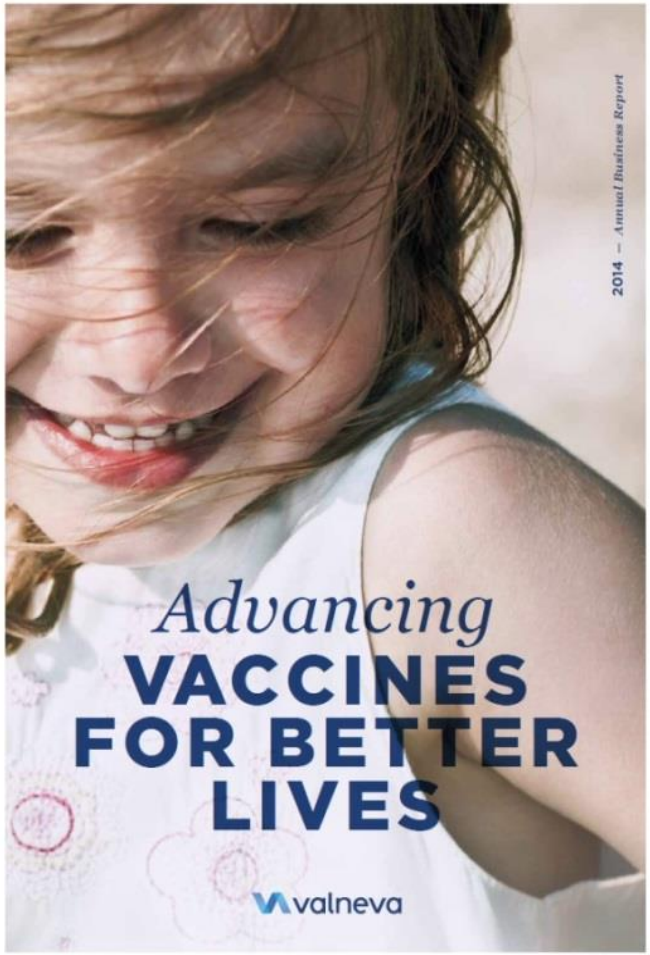
Vaccine candidates
+ Valneva invests in innovative R&D programs in areas of unmet medical needs
+ Phase I trial against Lyme disease initiated

Platforms

Technologies & services
+ Valneva offers unique technology platforms (EB66®, IC31®) and services to a broad range of clients
+ Total revenues of approx. €20m in 2016

Partnering

Product partnering & licensing
+ Valneva creates short and long-term value through partnering of vaccine candidates
+ C.Diff (Ph III ready) expected 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 its 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

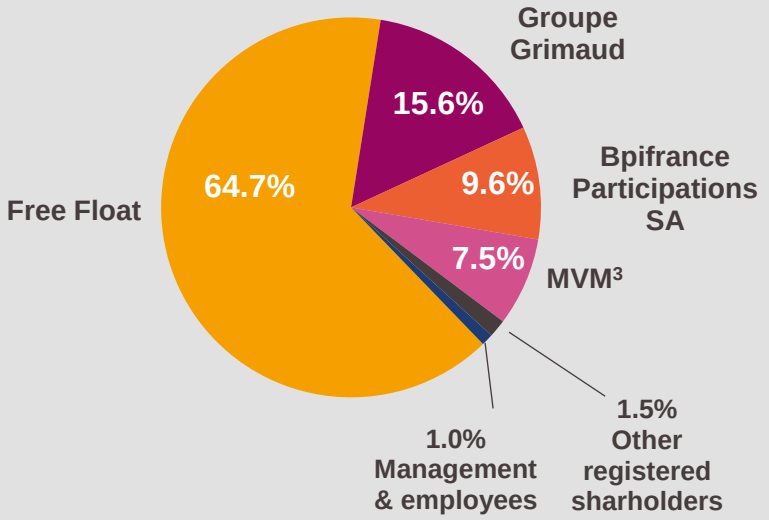
A fully integrated, commercial stage biotech company

Corporate profile

+ Created in May 2013 through the **merger of Vivalis SA and Intercell AG**;
+ Expanded its business by acquiring a **commercial product from Crucell/Janssen** in February 2015
+ Incorporated in Lyon, France
+ More than **400 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 and Vienna Stock Exchange
+ Number of ordinary shares: 77,582,714
+ **Market cap**: approx. €240m (January 5, 2017)
+ ISIN: FR0004056851
+ Shareholder structure[2]:



1 Approx. 1/3 Manufacturing & Supply, 1/3 R&D, 1/3 SG&A
2 from December 15, 2016
3 Funds managed by MVM Life Science Partners

Valneva's management board and supervisory board

Dedicated and committed to the future growth of Valneva

Thomas Lingelbach

President & CEO

Président du Directoire

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

Franck Grimaud

Deputy CEO

Directeur Général

+ CEO and co-founder of Vivalis since 1999
+ Formerly responsible for Groupe Grimaud's development in China, Malaysia and Thailand
+ More than 20 years in Business Development and Life Sciences

Reinhard Kandera

CFO

Directeur financier

+ CFO of Intercell since 2009
+ Formerly at Deutsche Bank
+ More than 20 years in Financial Management and Life Sciences

Supervisory Board

Alexander v. Gabain,
Frédéric Grimaud (Chairman),
Maïlys Ferrere,
Ralf Clemens,
Alain Munoz,
Lisa Shaw-Marotto,
Jim Sulat,
Anne-Marie Graffin

(From left to right)

Valneva's unique business model dedicated to Vaccines

Marketed products, R&D portfolio and technology platforms

Commercial Products

IXIARO®

Japanese encephalitis vaccine

> €50m sales expected in 2016

DUKORAL®

Cholera and ETEC Diarrhea Vaccine

~ €23m sales expected in 2016

Third Party products

Leverage marketing & distribution infrastructure

R&D and Technologies

Portfolio – Vaccine candidates

- **C.Diff (Phase III ready)**
- **Lyme disease (Phase I)**
- **Chikungunya, Zika (IND-enabling)**
- **Research & pre-clinical candidates**

Cell-based platform EB66®

GlaxoSmithKline Biologicals, MERIAL, KAKETSUKEN, JSB 健顺生物 IOSCIENCES, farvet

IC31® adjuvant / Other laboratory services

AERAS Global TB Vaccine Foundation, EU-TBVAC, LUMC, National Institutes of Health, Statens Serum Institut, SANOFI, altimmune, Johnson & Johnson, GlaxoSmithKline Biologicals

1 expected for 2016; net sales revenues to Valneva (differ from in-market sales)

Japanese encephalitis and cholera
Two life-threatening diseases

Japanese encephalitis

+ **The leading cause of viral neurological disease & disability in Asia[1]**

+ **A rare disease, but associated with high individual morbidity and mortality rate[2]**
  - › Estimated 68,000 symptomatic cases in Asia each year[3]
  - › Between 0.1% and 4% of infections lead to clinical disease[4]
  - › Fatal in 20-30% of symptomatic cases[1]
  - › Half of the survivors are left with neurological sequelae[1]

Cholera and ETEC

+ **Cholera is the most severe form of diarrhea**
  - › Estimated 3 – 5 million cases and 100,000 to 120,000 deaths per year[5]

+ **ETEC is the most frequent form of traveler's diarrhea**
  - › Estimated 5 – 18 million reported cases per year[6]

+ **Cholera and ETEC transmission through ingestion of contaminated food or water**

1 Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; **2** CDC. MMWR 2010;59:1-27; **3** WHO. Bull World Health Organ 2011; 89:766–774E; **4** van den Hurk AF et al. Annu Rev Entomol 2009;54:17-35; **5** WHO cholera factsheet February 2014; **6** Lundkvist J, Steffen R, Jonsson B. Cost-benefit of WC/rBS oral cholera vaccine for vaccination against ETEC-caused travellers' diarrhea. J Travel Med 2009; 16(1):28-34;

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 month of age[1]
+ Exclusive supplier agreement in place with US military
+ Asian manufacturers mainly serve local public markets

Market potential

+ **248 million travelers to Asia** in 2013[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]

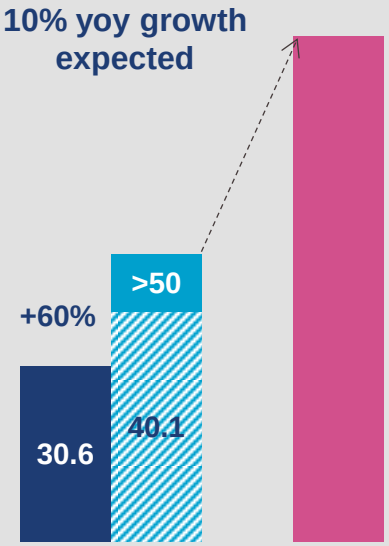
1 Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years of age. 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 2014; **4** Nomura Code estimates (October 2012) and Valneva Management estimates;

Leading commercial product: Japanese encephalitis vaccine

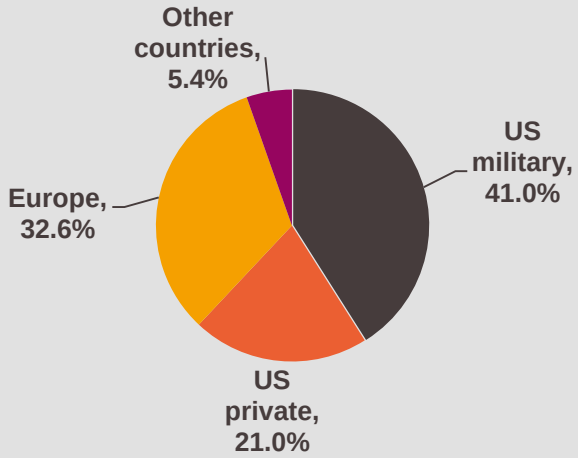
Strong growth led by new commercial network and continued improved usage

2015 9M 2016 FY 2016[1] 2020

Valneva sales in € million

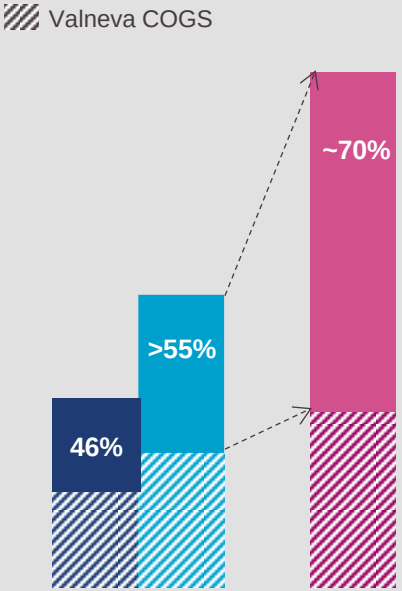


US military sales already secured



Expected split of 2016 product sales

Gross margin



10% yoy sales growth expected

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

60% yoy growth expected in 2016

+ 60% of sales will be generated by Valneva's commercial teams with a 100% revenue recognition

Margin to improve by 1.5x in the mid-term

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

1 expected;

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

+ **347 million travelers** to Asia/South America/Africa in 2014[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

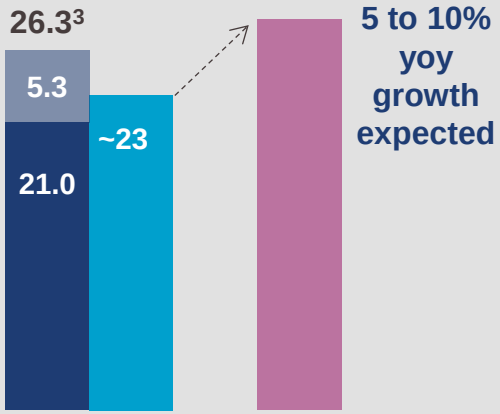
1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium. **2** UNWTO Tourism Highlights 2015;

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

Significant growth potential through geographic expansion

2015 2016[2] 2020[2]

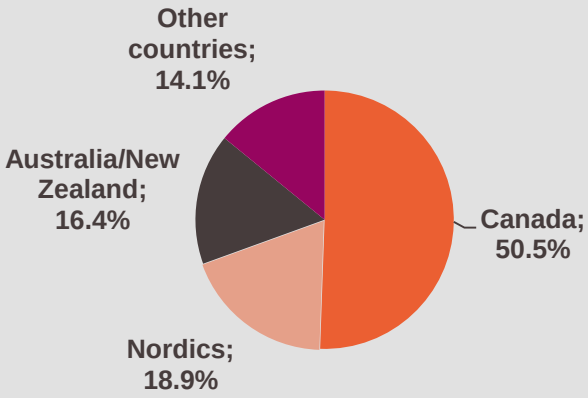
Sales in € million



€23m sales target for 2016

+ Sales only slightly impacted by label change in Canada

Canada remains the most important market



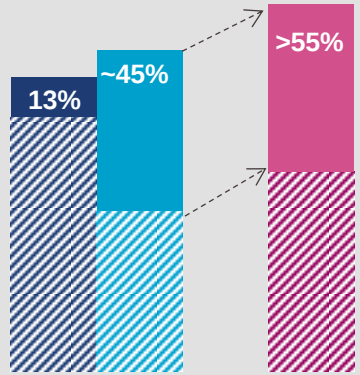
Expected split of 2016 product sales

5 to 10% yoy growth expected

+ Significant growth opportunities outside Canada and through geographic expansion

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

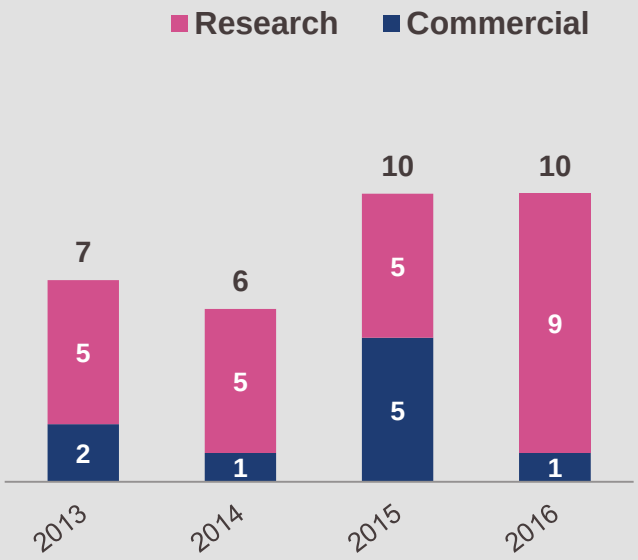
EB66® platform for efficient large scale vaccine production

A technology becoming increasingly profitable

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** commercialize EB66® in China

10 new agreements signed in 2016

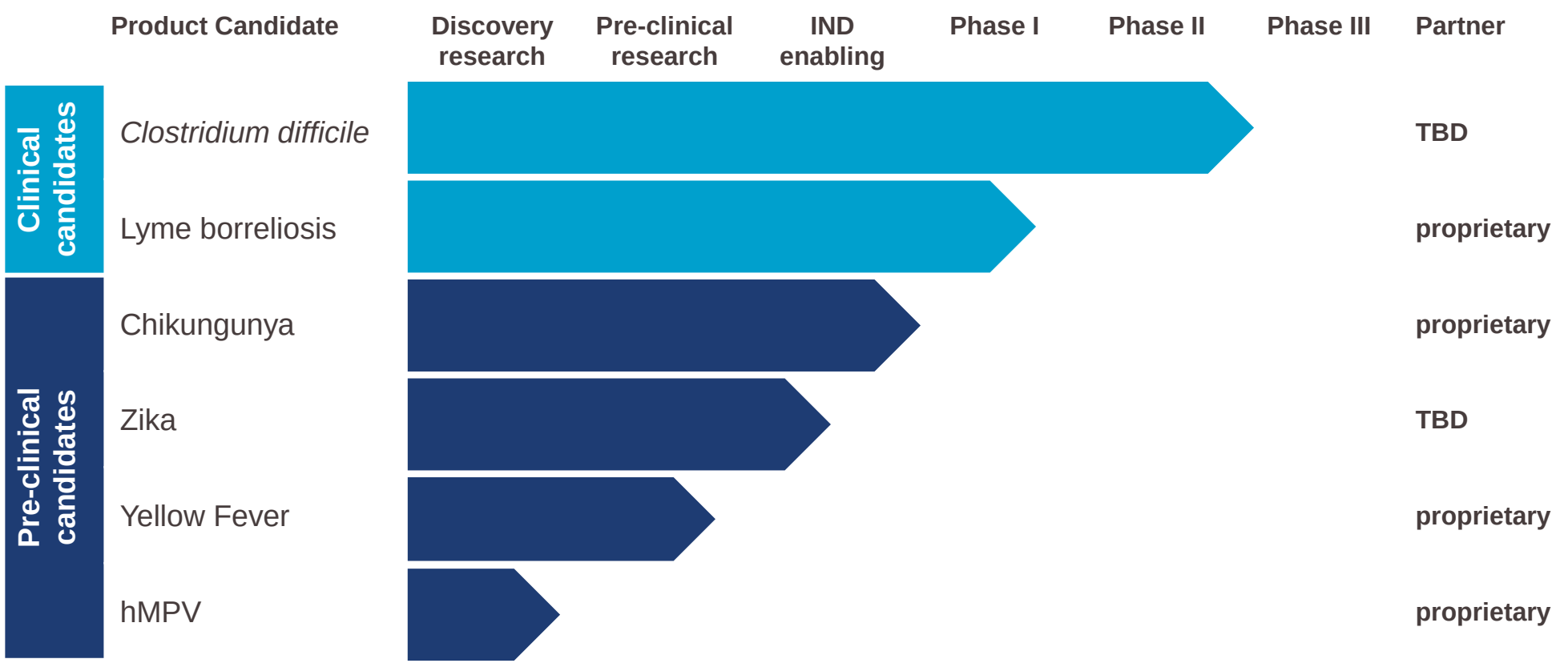


Recent highlights

+ **New research agreement with Merck - MSD Animal Health for the development of veterinary vaccines in the EB66® cell line**
+ **Collaboration between GE Healthcare and Valneva delivers optimized cell culture medium for vaccine production in EB66® cells**
+ **EMA decision in Q4 2016 to allow production of live vaccines in cell-lines such as EB66® will open new markets for the technology**

Valneva's pipeline of vaccine candidates

With a focus on urgently needed vaccines



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**
- **Expected to enter market as number two**
- **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: study design was agreed with regulators in Europe and the US**
- **Comparable immunological profile to the only more advanced vaccine program targeting primary prevention of CDI (according to published Phase II data[6])**
- **Valneva is in discussions with several potential partners**

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

Pre-commercial product: Lyme borreliosis vaccine

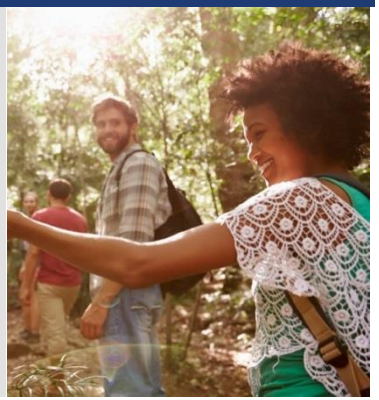
Targeting Lyme borreliosis with market potential of above €500m[4]

Lyme borreliosis

- **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**



Current development status VLA15 (Phase I)

- **IND clearance in US and CTA approval in EU received**
  VLA15 progressing into clinical testing
- **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]

Progression into Phase I development

- **Priority in EU markets where high awareness on tick transmitted diseases exists**
- **Expected penetration rates of up to 10% in high-incidence territories given likely reimbursement status**
- **The single-blind, partially randomized, dose escalation Phase I study will evaluate safety and tolerability**

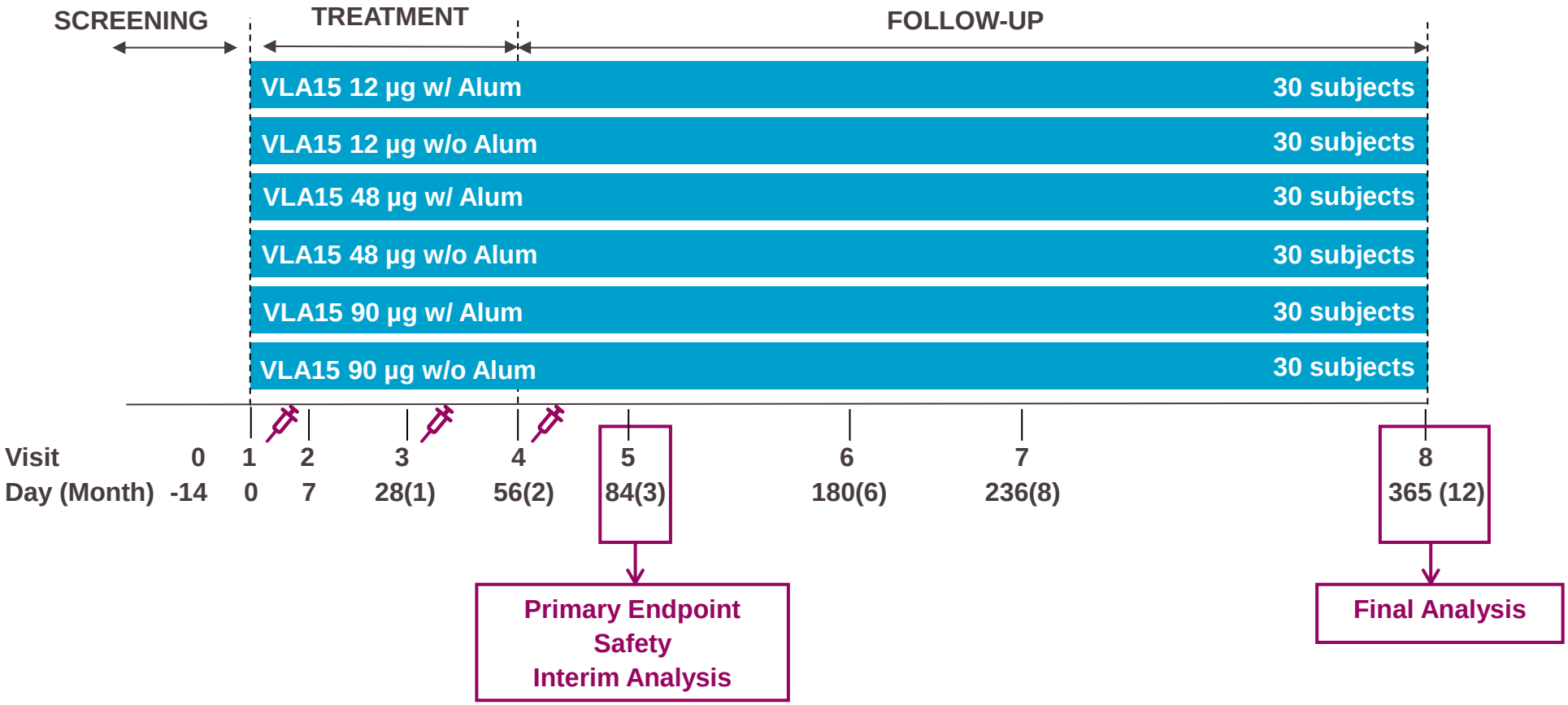
Source picture: PHIL – Public Health Photo Library; **1** Stanek et al. 2012, The Lancet 379:461–473; **2** Estimated from available national data. However, this number is largely underestimated as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed, based on WHO Europe 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

VLA15 – Phase I Study

Observer-blind, partially randomized, dose escalation study

Phase I study to be conducted in US and EU

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



Pre-clinical candidate: Chikungunya vaccine (VLA1553)

Targeting Chikungunya, an emerging disease outbreak

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**
- **Grown on Vero cells**
- **Protective against various CHIKV outbreak phylogroups & strains [2]**

Current development status VLA1553 (Pre-clinical)

- **Pre-clinical testing completed**
  - Data from non-human primates (NHP) showed that the vaccine was safe and has the potential to provide long term protection against Chikungunya after a single immunization
- **Pre-clinical development initiated**

Phase I to be initiated in H2 2017

- **Priority for travelers to endemic regions, also interesting for military; larger traveler market than JE**
- **Public endemic market and emergency stockpiling as secondary target populations**

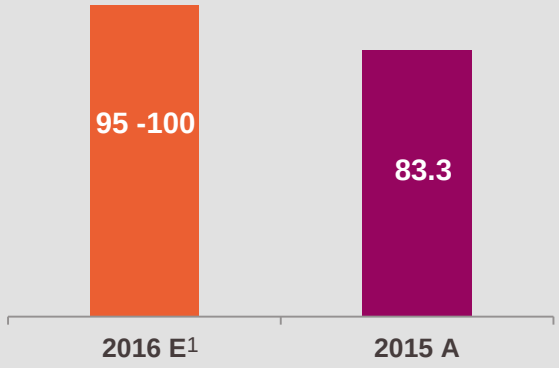
Source picture: Sun et al. 2013, eLife 2:e00435; **1** PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016); **2,** Hallengärd et al. 2013. J Virology 88:2858–2866.

Financial Profile: $100m revenue, EBITDA positive

Financially sustainable – future R&D fully funded

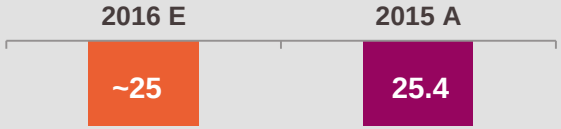
million euros

Revenues & Grants

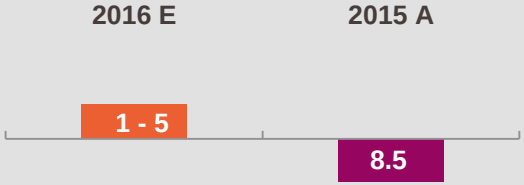


Gross Margin

R&D Expenses



EBITDA*



2016 Highlights & Outlook

+ Total revenues €95-100m
+ Commercial product sales expected to grow at 10% organically
+ First year of positive EBITDA in 2016
+ ~€20m collaboration, licensing & grant revenue (2016) – near-term upside from licensing deals on C. Difficile and other R&D
+ ~€25m R&D expenses – R&D shift to earlier stage programs

1 estimated by Valneva

* EBITDA was calculated by excluding depreciation, amortization and impairment charges from operating loss as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase in the calculation for the comparator period of the previous year.

Valneva – expected newsflow and outlook

Products	+ €75-80m product sales expected for FY 2016 , bringing total revenues to €95-100m + 10% annual sales growth expected until 2020
Portfolio	+ Lyme Phase I execution and Phase II acceleration + Chikungunya vaccine Phase I entry + Ongoing investments in innovative vaccines R&D in areas of unmet medical needs
Platforms	+ Signing of additional EB66® and IC31® licensing agreements + Significant revenues and increased profitability from technologies & services
Partnering	+ C.Diff (Phase III ready) expected to be partnered + Other R&D partnering deals possible + Active discussions on broadening of commercial portfolio in travel vaccines

Thank you
Merci
Danke
Tack

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