Valneva presents its Q1 2017 financial results

Analyst Presentation
May 11, 2017

valneva

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Agenda

1. Introduction – Newsflow Q1 – Thomas Lingelbach

2. Financial Report Q1 2017 – Manfred Tiefenbacher

3. Commercialized Products & EB66® – Franck Grimaud

4. R&D Programs – Thomas Lingelbach

5. 2017 Outlook – Thomas Lingelbach

6. Q&A

Valneva reports strong Q1 revenue growth & positive EBITDA

Reaffirms financial guidance and pipeline outlook for 2017

Newsflow 2017 Year-To-Date

April 2017

+ Valneva Shares now Tradable on Deutsche Börse XETRA® Platform
+ Valneva Announced Signing of a New EB66® Commercial License with Bavarian Nordic
+ Valneva Presented at the 17th World Vaccine Congress in Washington D.C.

March 2017

+ Valneva Reported Best FY Results in the Company's History with its First Year of Positive EBITDA in 2016

February 2017

+ Valneva Reported Strong Q4, FY 2016 Business Performance and 2017 R&D Guidance

January 2017

+ Valneva Announced a New Research License Agreement with MSD Animal Health for the Development of Vaccines in the EB66® Cell Line

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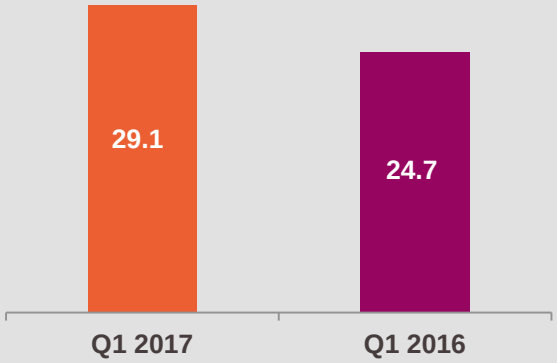
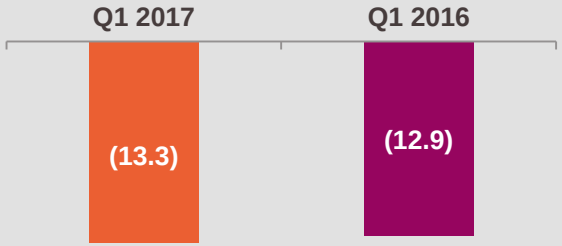
Q1 2017 financial results

Compared to Q1 2016 (IFRS, € million, unaudited)

Revenues & Grants



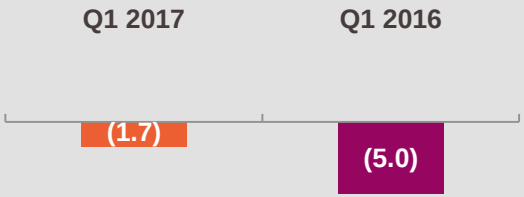
COGS



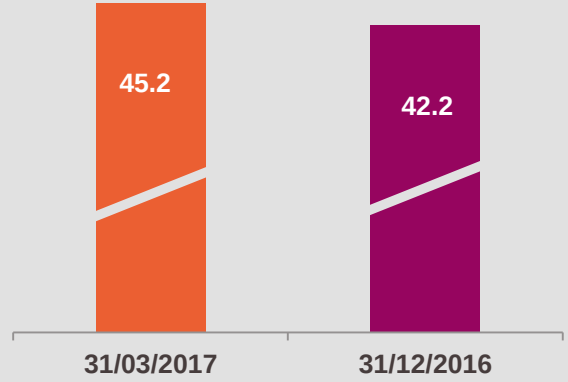
R&D Expenses

EBITDA*

Net profit/loss



Cash position



*Calculated by excluding Q1 2017 amortization, depreciation and impairment of €2.9m from the Q1 2017 operating profit of €0.5m

Q1 2017 profit & loss (unaudited)

€ in thousand

	3 months ended Mar 31,	
	2017	2016
Revenues and grants	**29,122**	**24,687**
Cost of goods and services	(13,322)	(12,921)
R&D expenses	(5,211)	(5,798)
Distribution and marketing expenses	(4,290)	(3,295)
General and administrative expenses	(4,012)	(3,765)
Other income / (expense)	(17)	91
Amortization and impairment	(1,795)	(1,720)
OPERATING PROFIT / (LOSS)	**476**	**(2,721)**
Finance results and tax	(2,133)	(2,317)
LOSS FOR THE PERIOD	**(1,657)**	**(5,037)**
EBITDA*	**3,359**	**14**

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

Financial analysis Q1 2017

Product sales	26.7% increase to €25.9m Driven by strong DUKORAL® sales (up 80.1% compared to Q1 2016) and IXIARO® sales
Total revenues & grants	€29.1m (up 18.0% compared to Q1 2016) - on track to meet €105-115m revenue goal for FY 2017
COGS	€13.3m total COGS yielding 54.3% gross margin, including 55.6% gross margin on commercial products
R&D expenses	€5.2m – decreasing from €5.8m in Q1 2016 as spending on late stage programs was diminished
Distribution & marketing expenses	Increase to €4.3m (vs. €3.3m in Q1 2016) resulting from establishment of own sales & marketing organization
G&A expenses	€4.0m – moderate increase vs Q1 2016 spending of €3.8m

Financial analysis Q1 2017 (continued)

Amortization of intangible assets	€1.8m non-cash amortization charges on acquired intangible assets
EBITDA	Seasonally strong Q1 with positive EBITDA of €3.4m (vs. balanced EBITDA in Q1 2016) driven by solid Q1 sales performance
Net loss	€1.7m net loss compared to €5.0m net loss in Q1 2016; Operating loss improved in line with EBITDA improvement
Cash	€45.2m net cash at quarter-end; Q1 cash-in flow driven by positive EBITDA and positive working capital effects
Debt *	Re-payment of loan to Pharmakon LLC underway

* No drawings from available EIB facility performed in Q1-2017

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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

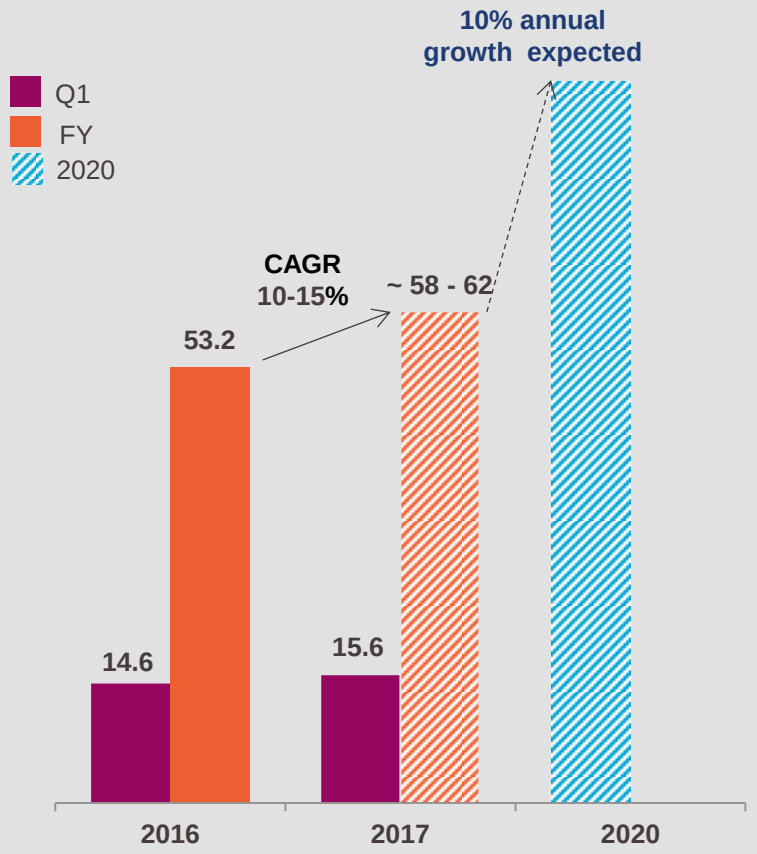
+ **279 million travelers to Asia** in 2015[3]
  - › Travelers to Asia **expected to grow by 4.4% per year**[3]
+ **Global JE vaccines market valued at ~ €150-200m**[4]
  - › Traveler 65%, Military 15%, Endemic 20%[4]

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

IXIARO®/JESPECT®: Strong sales growth in Q1 2017

Revenues in € million



Q1 2017 sales analysis

IXIARO®/JESPECT® product sales increased to €15.6m

+ Compared to €14.6m (Q1 2016)

Growth mainly driven by strong sales to the US military

+ US Navy: update on medical guidance

Outlook

Product sales are expected to grow to 10-15% in 2017 through:

+ Continued marketing and sales activities and increase in product adoption by travelers
+ Reinforced product awareness and improved usage with rapid immunization schedule
+ Improved national recommendations
+ Geographical expansion

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

Established vaccine in the field of cholera/ETEC

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

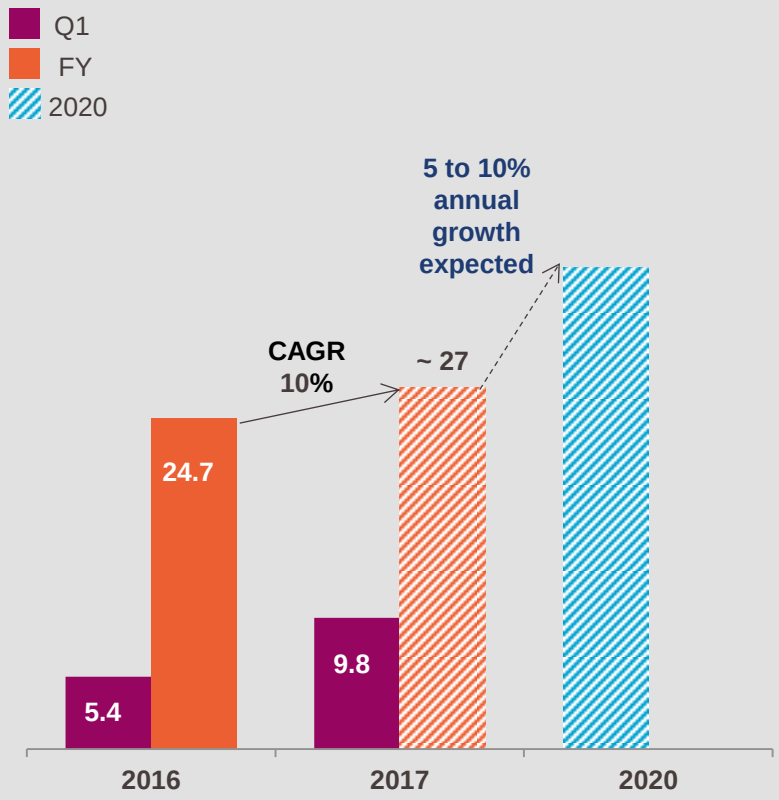
+ **363 million travelers** to Asia/South America/Africa in 2015[2]
+ Ongoing travel to risk regions, improved awareness and updating travel recommendations
  - › **Significant growth potential in key markets** (penetration rate <1%)[3]
+ Canada, Sweden, Australia account for ~75% of sales

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

DUKORAL®: Strong sales performance in Q1 2017

Revenues in € million



Q1 2017 sales analysis

DUKORAL® product sales reached €9.8m

+ Compared to €5.4m (Q1 2016)

Growth mainly driven by strong sales in Canada (accounts for more than 50% of global revenue), UK and Nordics

Outlook

Q1 sales in line to meet Company expectations of 10% product revenue growth in 2017, through:

+ Awareness campaigns directed at healthcare professionals and lay public
+ Increased travel to endemic regions
+ Improved national recommendations
+ Label harmonization across all key countries

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);

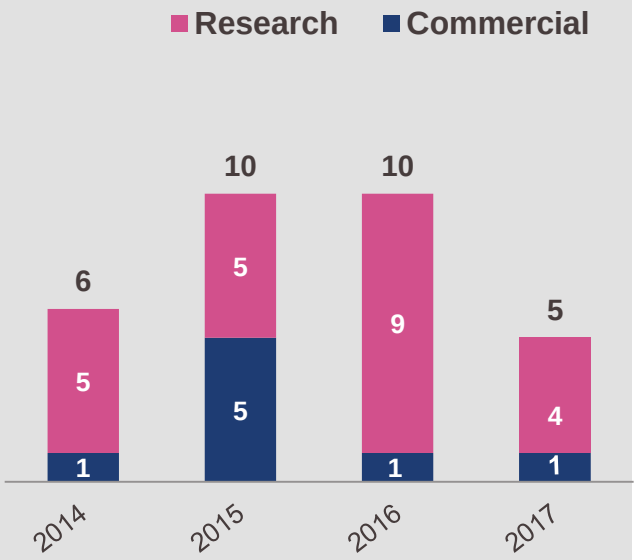
EB66® platform for efficient large scale vaccine production

A technology increasingly contributing to the company's profit line

Revenue generating platform

+ Fully characterized cell-line, growing in suspension with chemically defined media, providing high yield and low production costs
+ **Over 35 agreements**
+ **~€34m** in upfront, milestones & research fees **received to date**
+ **Exclusive licenses 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**

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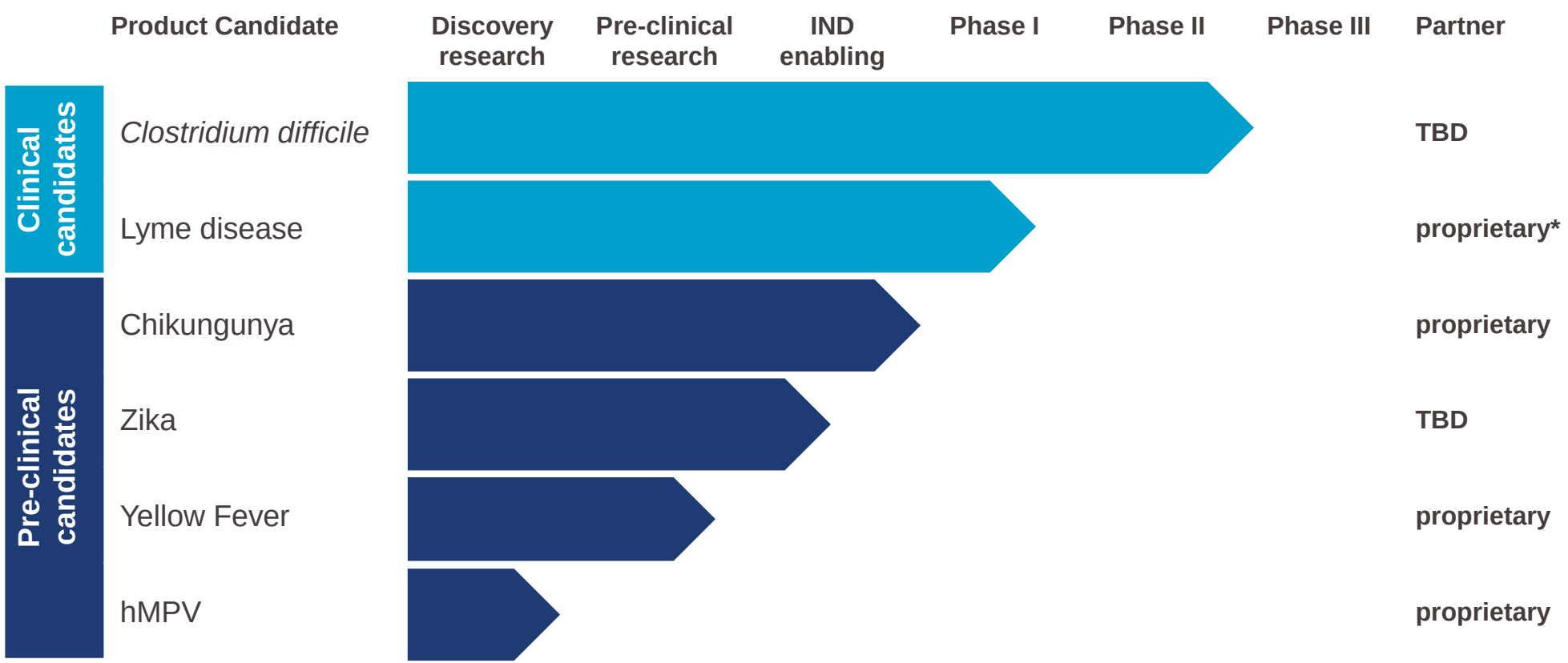
Valneva's pipeline of vaccine candidates

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

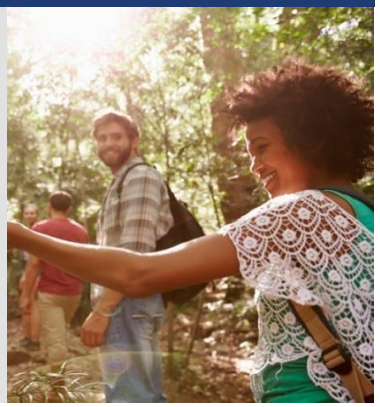
Market potential of approximately €700m - €800m[5]

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 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.

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Valneva – expected newsflow and outlook

Guidance 2017 confirmed

Products	+ IXIARO® /JESPECT® sales expected to grow by 10-15% to €58-62m in 2017 + DUKORAL ® sales expected to grow by 10% to €27m in 2017 + Potential upside from additional distribution agreements for third-party products
Portfolio	+ Lyme Phase I progression and acceleration towards Phase II + Phase I entry of at least one additional vaccine candidate + Ongoing investments in innovative vaccine 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 vaccine candidate (Phase III ready) sought to be partnered + Other R&D partnering deals possible + Active discussions on broadening of commercial portfolio in travel vaccines

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

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Thank you
Merci
Danke
Tack

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