Valneva presents its Q2/H1 2017 financial results

Analyst Presentation
August 31, 2017

valneva

Forward-looking statements

This presentation contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this presentation, those results or developments of Valneva may not be indicative of their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this presentation and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this presentation, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Agenda

1. Introduction – News flow – Thomas Lingelbach

2. Financial report Q2/H1 2017 – David Lawrence, Manfred Tiefenbacher

3. Commercialized products, Technology & Services – Franck Grimaud

4. R&D programs – Thomas Lingelbach

5. 2017 outlook – Thomas Lingelbach

6. Q&A

Expansion of Valneva‘s Management Board

Strengthening for future growth

David Lawrence, CFO

Experienced CFO with strategic and business development skills

+ Over 25 years of experience
+ Former CFO of vaccine biotech company Acambis
+ VP Finance at Chiron Vaccines and GSK
+ CEO experiences & Non-Executive Board experience

Wolfgang Bender, CMO
MD, PhD

Global life sciences leader in product development and medical affairs

+ Over 30 years of experience
+ International, senior positions in various big pharmas including Novartis, Takeda, Pfizer and Hoechst
+ Experiences in scientific-medical affairs, drug development and general management of vaccines & pharmaceutics

Valneva's 2017 news flow YTD

Strong commercial performance and R&D progress

August 2017

+ Valneva strengthens its Management Board to support future growth

July 2017

+ Valneva and Emergent BioSolutions join forces to develop a vaccine against the Zika virus
+ Valneva receives FDA Fast Track Designation for its Lyme Disease vaccine

May 2017

+ Q1 2017 product sales up to 26.7% compared to Q1 2016

April 2017

+ Valneva signs New EB66® Commercial License with Bavarian Nordic

March 2017

+ IXIARO/JESPECT revenues grow 73.1% in FY 2016

January 2017

+ Valneva signs New Research License Agreement with MSD Animal Health for the Development of Vaccines using the EB66® Cell Line

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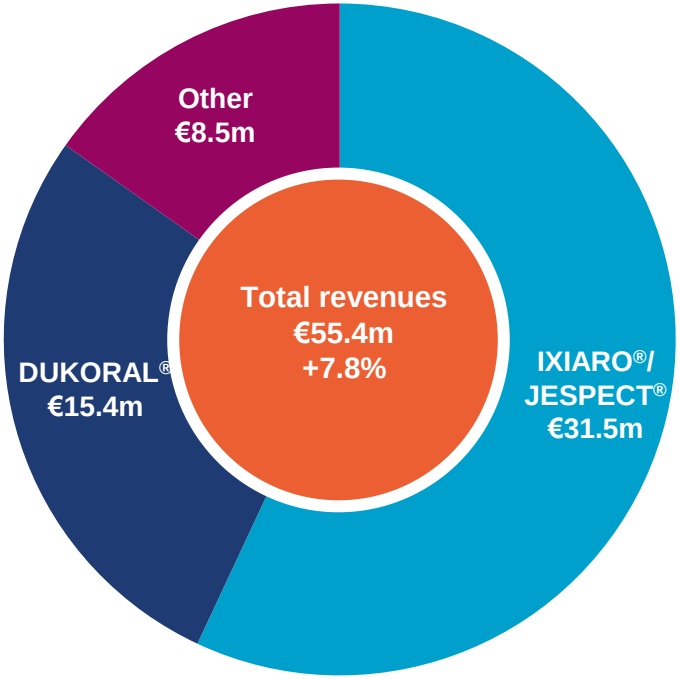
Valneva H1 2017 results

Overview on revenues, +7.8% to H1/2016

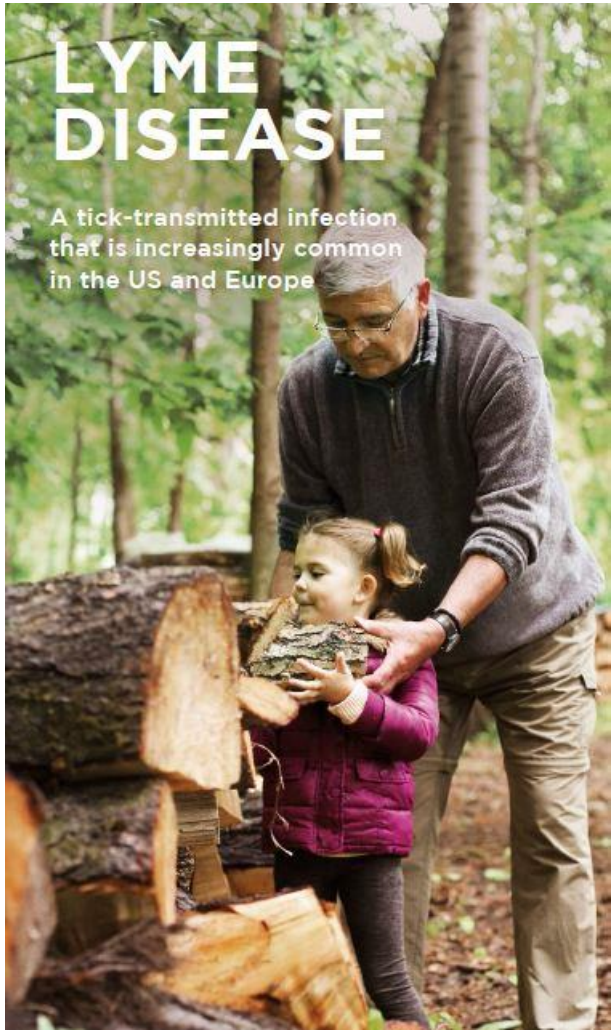


Product sales
€48.1m

Direct sales
74.3%

Gross
Margin
55.9%

Cash
generated
€16.6m



Q2/H1 2017 profit & loss (unaudited)

€000

	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Revenues and grants	**26,248**	**26,700**	**55,370**	**51,387**
Cost of goods and services	(11,119)	(8,770)	(24,441)	(21,691)
R&D expenses	(4,520)	(6,658)	(9,731)	(12,457)
Distribution and marketing expenses	(3,897)	(4,061)	(8,187)	(7,356)
General and administrative expenses	(3,399)	(3,558)	(7,411)	(7,323)
Other income / (expense)	(175)	(48)	(192)	43
Amortization and impairment	(1,797)	(35,939)	(3,592)	(37,658)
OPERATING PROFIT/(LOSS)	**1,341**	**(32,334)**	**1,816**	**(35,054)**
Finance results and tax	(4,046)	(2,089)	(6,178)	(4,406)
LOSS FOR THE PERIOD	**(2,705)**	**(34,422)**	**(4,362)**	**(39,460)**
EBITDA*	**4,196**	**4,658**	**7,555**	**4,672**

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

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Leading commercial product: Japanese encephalitis vaccine

Designed to protect 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®: Ongoing sales growth and gross margin development

Product sales revenues in € million

IXIARO®/JESPECT® Q2/H1 2017 sales analysis

H1 2017 product revenues rose to €31.5m
(compared to €30.1m in H1 2016)

Q2 2017 product sales reached €16.0m
(compared to €15.6m in Q2 2016)

Significant growth was driven by:

+ Adoption of JE vaccination policy US DoD & order phasing
+ Increased penetration in key traveler markets including Germany, UK and Canada

Outlook

+ **Approximately 2/3 of JEV sales generated through Valneva commercial infrastructure (= 100% revenue recognition)**
+ **Valneva confirms its FY 2017 guidance, reaching approximately €60 million (€58 to €62 million)**

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

Established vaccine in the field of cholera/diarrhea

DUKORAL®

+ **For the prevention of diarrhea caused by *Vibrio cholera* (cholera) and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)[1]**
+ In a number of countries including the EU, indicated to protect against cholera only
+ **Designed to protect adults and children** from 2 years of age who will be visiting endemic areas

Commercial position

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

Market potential

363 million travelers to Asia/South America/Africa in 2015[2]

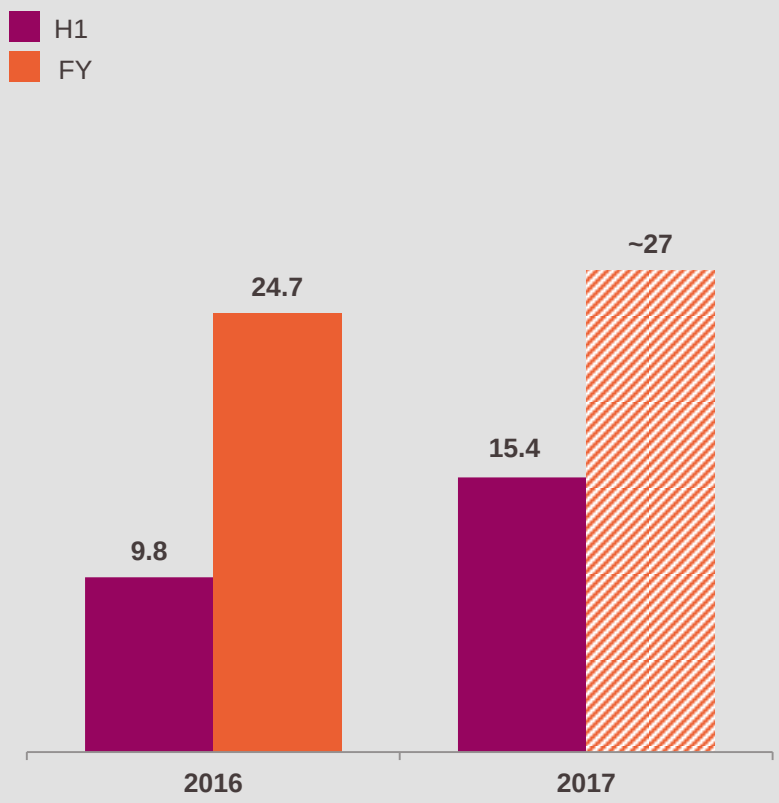
+ Ongoing travel to risk regions, improved awareness and updating travel recommendations
  - › **Significant growth potential in key markets** (penetration rate <1%)[3]
+ Canada, Sweden, Australia account for ~75% of sales

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

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

Excellent H1 sales development in key countries

Product sales revenues in € million



DUKORAL® Q2/H1 2017 sales analysis

H1 product revenues reached €15.4m in H1 2017
(compared to €9.8m of Valneva sales in H1 2016)
+ representing substantial growth of 57%

Q2 2017 sales amounted to €5.6m
(compared to €4.4m in Q2 2016)
Increased product utilization in key travel markets (e.g. Canada and UK) following targeted promotional efforts

Outlook

+ **Product sales in line to meet Company expectations of ~€27m product sales in 2017**

+ **Continued sales growth expected through promotional efforts, geographic expansion and life cycle management**

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);

Technology & Services continues to contribute to revenues

EB66®

+ **Fully characterized cell-line** (avian embryonic stem cell derived)
  - in suspension
  - chemically defined media
  - high productivity
+ **>€34m** in upfront, milestones & research fees **received to date**
+ **Potential** for further milestones and royalties on future product sales

+ **3** approved veterinarian vaccines
+ **2** approved human vaccines
+ Several candidates currently in clinical development
+ **Potential upside** from switching poxvirus vaccines in development to EB66® (Bavarian Nordic)

IC31®

+ A novel **synthetic vaccine adjuvant** to enhance immune responses
  - Tall like argonist
  - T-cell specific enhancements
+ **> €30m** in upfront, milestones & research fees **received to date**
+ **Potential** for further milestones and royalties on future product sales

+ **4** clinical trials including IC31® currently ongoing
+ Hep B (Altimmune)
+ Tuberculosis (Aeras / SSI, Sanofi)

ZIKA co-development & license

+ Zika vaccine (VLA 1601) on IXIARO® platform technology (ZIKV)
+ Exclusive worldwide license to Emergent, Option fee: **€1 million**
+ Co-development / Co-financing until end of Phase I
+ Opt-in for Emergent post Phase I:
  - €5 million initial milestone
  - Potential additional milestones of up to €44 million (product development, approval, product sales)
  - Royalties on annual net sales
  - Agreement includes tech transfer to Emergent for future production

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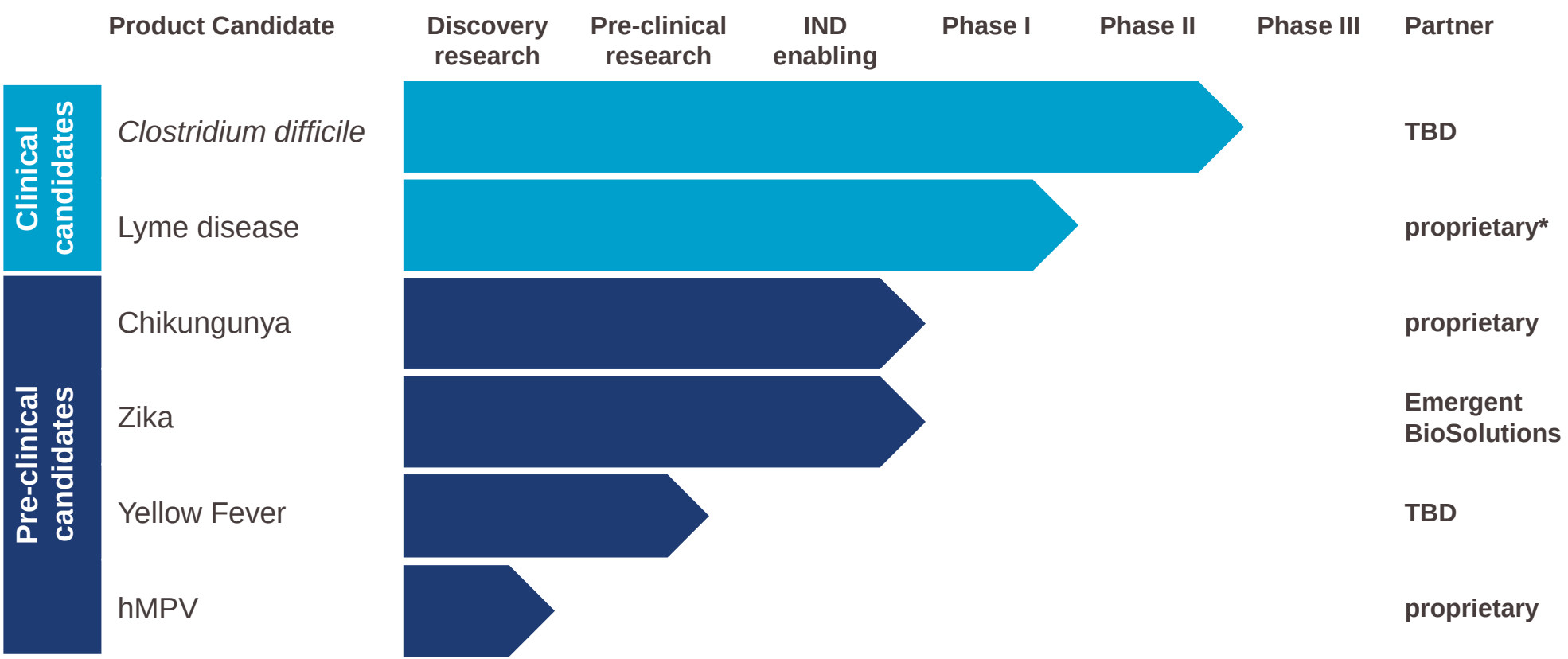
Valneva's pipeline of vaccine candidates

With a focus on urgently needed vaccines



*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 two other CDI clinical programs targeting primary prevention of CDI**
- **Valneva seeking a partner and 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

Clinical product: Lyme disease vaccine

Market potential of approximately €700m - €800m[1]

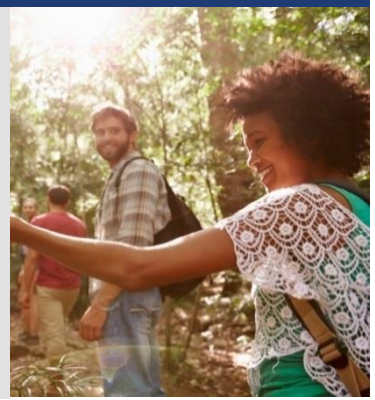
Lyme disease

- Transmitted by Ixodes ticks[2], 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[4])
- 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

- Pre-clinical testing completed
  - Data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans[5]
- Phase I ongoing - subject enrolment completed
- FDA Fast Track Designation received

Acceleration towards Phase II

- Phase I data expected to be reported Q1 2018, immediately followed by Phase II initiation
- Phase II preparations and consultations process initiated
- 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** Latest data from the CDC (PR on Aug 19, 2013); **4** 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; **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/

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) have shown that the vaccine has a good safety profile and the potential to provide long term protection against Chikungunya after a single immunization
- **Program under IND**
- **Phase I initiation preparations completed**

Phase I to be initiated in late 2017 or early 2018

- **Phase I initiation (U.S.) in late 2017 or early 2018**
- **Phase I to evaluate safety and immunogenicity in approx. 120 subjects and to confirm antibody persistence (≥6m)**
- **Primary target population are travelers to endemic regions and military, 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.

Pre-clinical candidate: Zika vaccine (VLA1601)

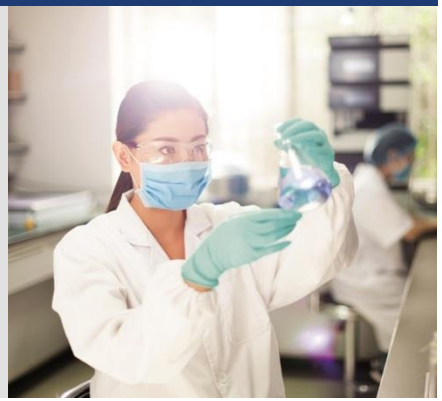
Joint forces with Emergent Biosolutions to combat a global threat

Zika virus

- **Transmitted by Aedes mosquitoes, also causing Chikungunya disease[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 vaccine (PIV)**
- **Developed using Valneva's proven and licensed inactivated JE vaccine platform**



Current development status VLA1601 (PIV)

- **Pre-clinical testing**
  Demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to the commercially produced JE vaccine
- **Phase I preparation ongoing**
- **Co-development with Emergent BioSolutions including opt-in post Phase I** (in exchange for a €5m opt-in milestone payment; potential additional milestones of up to €44m* and royalties on future sales)

Phase I to be initiated in late 2017/early 2018

- **Phase I (U.S). in late 2017 or early 2018 - Phase I data anticipated within six months after trial initiation**
- **Phase I to evaluate safety and immunogenicity**
- **Priority for people traveling to or living in endemic regions, including potential preparedness through stockpiling**

Source picture: Sun et al. 2013, eLife 2:e00435;**1** https://www.cdc.gov/zika/transmission/index.html **2** http://www.who.int/mediacentre/factsheets/zika/en/
* Related to product development, approval, commercialization, and product sales, and royalties on annual net sales

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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® €53.2m DUKORAL® €24.7m	€58 – 62m €27m	10 – 15% >10%
R&D expenditure	€24.6m	€23 – 25m*	–
EBITDA	€2.8m	€5 – 10m	80 – 250% growth vs. 2016

* Due to external R&D costs expected later in the year

Valneva – expected news flow and outlook

Products	+ Ongoing double digit sales growth
Portfolio	+ Lyme Phase I progression and acceleration towards Phase II + Zika & Chikungunya Phase I start in late 2017/early 2018 + Ongoing investments in innovative vaccine R&D in areas of unmet medical needs
Platforms	+ Additional EB66® and IC31® licensing agreements
Partnering	+ Zika deal with Emergent - working towards ZIKV opt-in + Targeted approach on broadening of commercial portfolio in travel vaccines + C. difficile vaccine candidate (Phase III ready) sought to be partnered

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Thank you.

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