Valneva presents its Q3/9M 2016 financial results

Analyst Presentation
November 9, 2016

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 – Newsflow – Thomas Lingelbach

2. Financial report Q3/9M 2016 – Reinhard Kandera

3. Commercialized products & EB66® – Franck Grimaud

4. R&D programs – Thomas Lingelbach

5. 2016 outlook – Thomas Lingelbach

6. Q&A

Strong business performance confirms the Company's successful development into financial self-sustainability

9M 2016 Highlights

Strong financial performance in 9M 2016

+ Total revenues grew to €70.7 million (17% increase compared to 9M 2015)
+ Positive EBITDA of €3.5 million (vs. an EBITDA loss of €4.3 million in 9M 2015)
+ Positive operating cash flow of €8.0 million brought cash position to €40.3 million at end of Sep. 2016

Valneva raises its FY 2016 operating guidance

+ The Company now expects a positive EBITDA of €1-5 million in FY 2016
+ Valneva narrows revenue guidance to reach between €95 and €100 million
+ Valneva also expects a gross margin on product sales higher than 50%

Commercialized products

+ Successful establishment of new global marketing and distribution network
+ $42 million IXIARO® supply contract with US Government
+ Marketing & Distribution agreement for Seqirus' flu vaccines in Austria
+ Approval of Japanese encephalitis vaccine in Taiwan through commercial partner Adimmune

Strong business performance confirms the Company's successful development into financial self-sustainability

9M 2016 Highlights

Vaccine development

+ Successful completion of Phase II for *Clostridium difficile* vaccine candidate
+ Successful generation of a highly-purified Zika vaccine candidate using Valneva's FDA-EMA Approved Japanese encephalitis platform

Technologies & Services

+ GE Healthcare and Valneva deliver optimized cell culture medium for vaccine production
+ First sales of flu vaccines produced on Valneva's EB66® cell line
+ Signing of 6 new EB66® agreements including a commercial agreement with the Canadian subsidiary of IDT Biologika GmbH;

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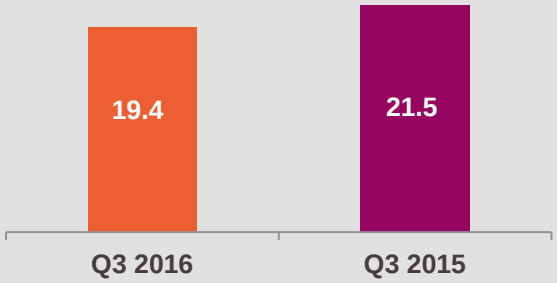
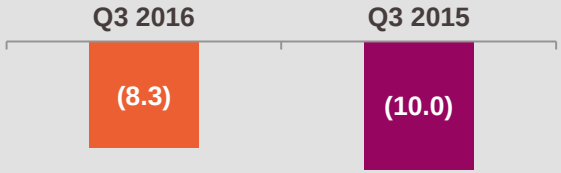
Q3 2016 financial results

Compared to Q3 2015 (IFRS, € million, unaudited*)

Revenues & Grants

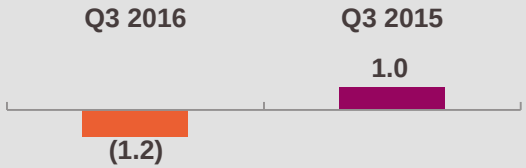


COGS

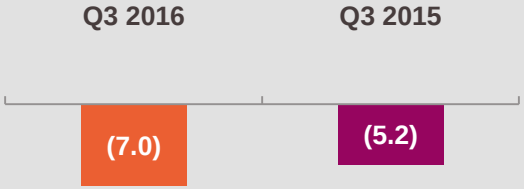


R&D Expenses

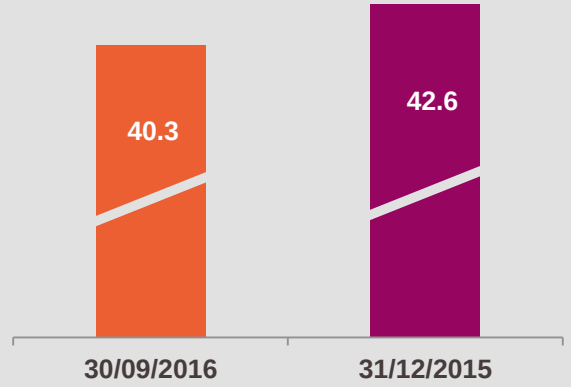
EBITDA*



Net profit/loss



Cash position



*Calculated by excluding Q3 2016 amortization, depreciation and impairment of €2.8m (Q3 2015: €2.8m) from the Q3 2016 operating loss of €4.0m (Q3 2015: €1.8m)

Q3/9M 2016 profit & loss (unaudited)

€ in thousand

	3 months ended Sep 30,		9 months ended Sep 30,	
	2016	2015	2016	2015
Revenues and grants	**19,354**	**21,468**	**70,741**	**60,682**
Cost of goods and services	(8,291)	(9,988)	(29,981)	(33,646)
R&D expenses	(6,262)	(6,241)	(18,719)	(18,730)
Distribution and marketing expenses	(3,929)	(2,293)	(11,285)	(5,784)
General and administrative expenses	(3,080)	(3,122)	(10,403)	(10,205)
Other income / (expense)	(20)	163	23	309
Amortization and impairment	(1,795)	(1,818)	(39,453)	(5,456)
Gain on bargain purchase	-	-	-	13,183
OPERATING LOSS	**(4,023)**	**(1,831)**	**(39,077)**	**352**
Finance results and tax	(2,984)	(3,333)	(7,389)	(4,570)
LOSS FOR THE PERIOD	**(7,007)**	**(5,164)**	**(46,467)**	**(4,218)**
EBITDA*	**(1,209)**	**1,039**	**3,463**	**(4,307)**

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

Business segment overview 9M 2016

Two profitable segments funding R&D pipeline and overhead

	Revenues	Operating profit/loss (before amortization*)
Commercial products	**€56.8m**	**€17.2m**
	55% gross margin	30% operating margin
Technologies & services	**€8.6m**	**€2.6m**
	46% gross margin	30% operating margin
Proprietary R&D	**€5.4m**	**(€8.8m)**
		€14.1m R&D expenses
Overhead		**(€10.7m)**
		15% of operating expenses
Subtotal		**€0.4m**
Amortization & Impairment*		**(€39.5m)**
Total Operating Loss		**(€39.1m)**

*of merger/acquisition related intangible assets – non cash

Financial analysis 9M 2016

Performance ahead of initial expectations

Product sales	28.3% increase to €56.6m - driven by strong IXIARO®/JESPECT® sales (up 61.3% compared to 9M 2015)
Total revenues & grants	€70.7m (up 16.5% compared to 9M 2015) - on track towards higher end of FY 2016 revenue goal
COGS	€30.0m total COGS yielding 57.6% gross margin, including 55.4% gross margin on commercial products
R&D expenses	€18.7m - flat yoy; driven by R&D pipeline expansion while spending on late stage programs is decreasing
Distribution & marketing expenses	Increase to €11.3m (vs. €5.8m in 9M 2015) driven by establishment of own sales & marketing organization
G&A expenses	1.9% increase to €10.4m – but “pro forma” decrease given the full inclusion of acquired Swedish business

Financial analysis H1 2016 (continued)

Amortization of intangible assets	€39.5m non-cash amortization charges on acquired intangible assets (includes one-time impairment charges of €34.1m related to the *Pseudomonas aeruginosa* project from Q2)
Financial income and expenses	Negative effects from EUR/GBP exchange rates following “Brexit” included; However, operating results are benefitting from weak GBP
EBITDA*	9M 2016 EBITDA of €3.5m confirms trend towards operational break-even, now already expected for FY2016
Net Loss	€46.5 million net loss (includes one-time impairment charges of €34.1m related to the *Pseudomonas aeruginosa* project)
Cash	€ 40.3m net cash at quarter-end; positive net cash flow and positive operating cash flow in Q3;

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

2016 financial outlook

Financial guidance increased on the back of strong 9M performance

Revenues	€95 – 100m total revenues (up to 20% growth vs. 2015)
Commercial products	€75 – 80m product sales (up to 30% growth vs. 2015) Higher than 50% gross margin on product sales (vs. 32% in 2015)
R&D investments	€25m R&D expenses (at 2015 level)
EBITDA	EBITDA break-even now expected for FY 2016, already €1 – 5m EBITDA profit (vs. €8.5m EBITDA loss in 2015)

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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 personnel 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

Growth drivers

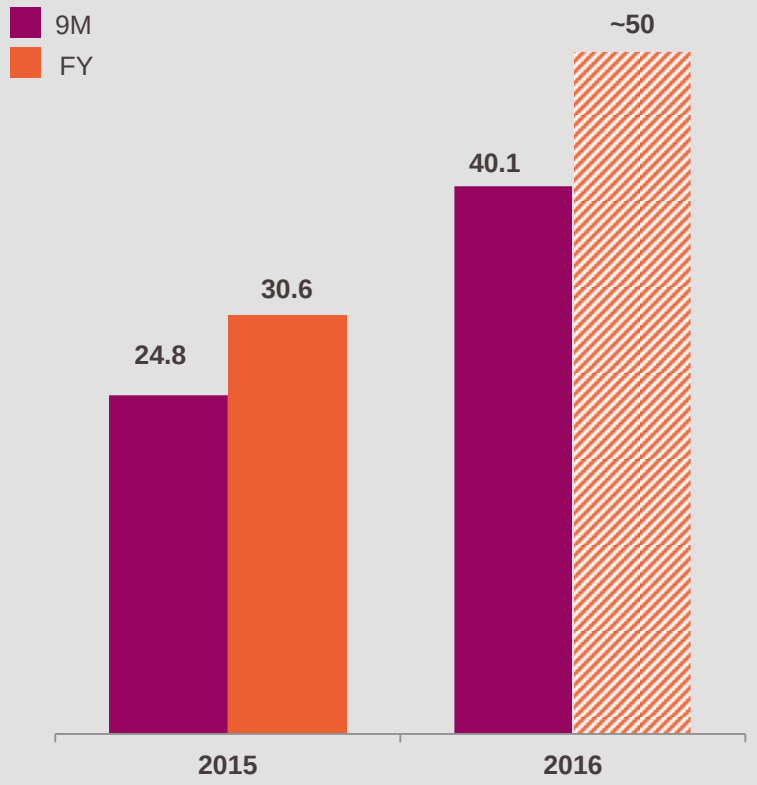
+ **Increased product adoption by travelers through reinforced product awareness and improved usage with rapid-immunization-schedule**
+ **Improved recommendations**
+ **Geographical expansion**

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

Leading commercial product: Japanese encephalitis vaccine

IXIARO®/JESPECT®: additional revenue margins under the new sales and distribution network

Revenues in € million



IXIARO®/JESPECT® Q3/9M 2016 revenue analysis

9M 2016 revenues grew 61.2% to €40.1m: € 39.9m product sales and €0.2m royalties
(vs. €24.8m in 9M 2015)

+ Improved product margin through Valneva's new distribution network
+ Policy adoption by USM and full revenue recognition
+ Increased penetration in key traveler markets

Q3 2016 revenues reached €9.8m (vs. €9.7m in Q3 2015)

+ Q3 sales lower due to usual quarterly sales fluctuations driven by order patterns of major clients such as USM

Outlook

Valneva confirms its FY 2016 guidance of ~€50m product sales

+ Based on expected sales and confirmed orders in the travelers' markets and planned supplies to the US military

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

Established vaccine in the field of 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

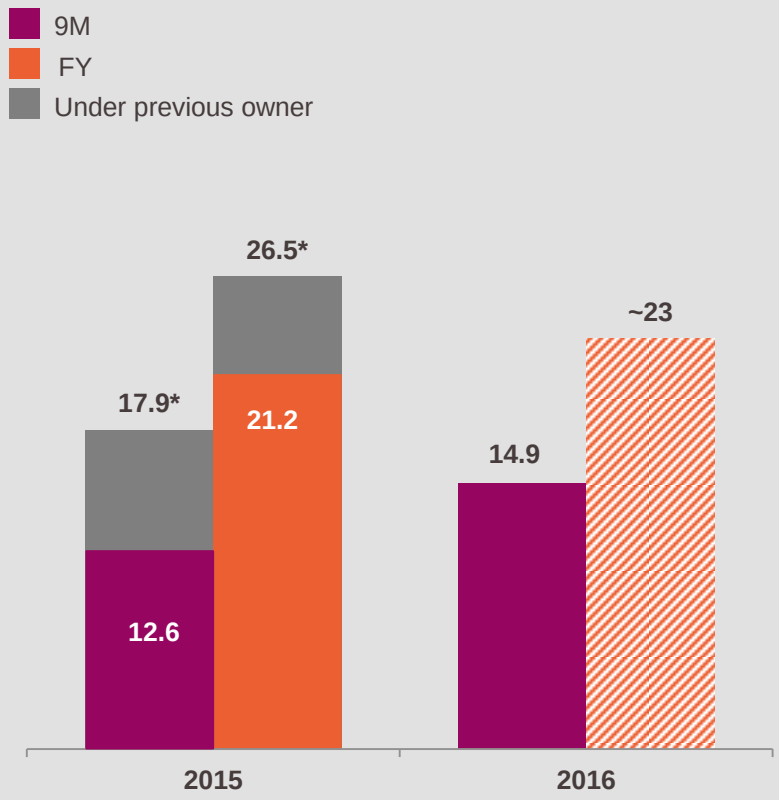
Growth opportunities

+ **HCP and lay public disease awareness campaigns**
+ **Label harmonization across all key countries**
+ **Product life cycle management**
+ **Territory expansion**

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.

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

Revenues in € million



DUKORAL® Q3/9M 2016 revenue analysis

9M 2016 revenues reached €14.9m
(vs. €12.6m of Valneva sales in 9M 2015)

\+ Increase sales due to sustained promotional efforts by Valneva and its distribution partners

Q3 2016 revenues rose to €5.1

\+ Strong education and partnership focus with key customers resulting in increased travel penetration

Outlook

Product sales in line to meet Company expectations of ~€23m in 2016

Valneva expects to grow DUKORAL® sales by way of promotional efforts, geographic expansion, and potential further product 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);
***** pro-forma revenues incl. €5.3m under previous owner;

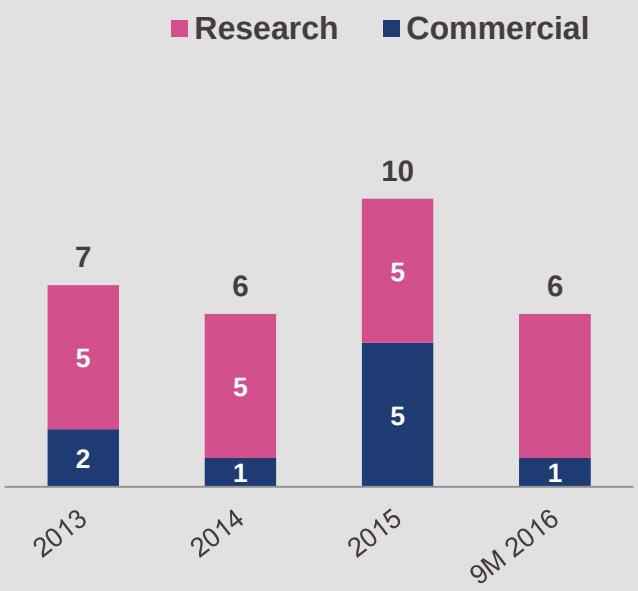
EB66® platform for efficient large scale vaccine production

The technology is 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**
+ **~ 7 new licenses per year**
+ **€34m** in upfront, milestones & research fees **received to date**
+ **Exclusive license to**:
  - › **GSK** for EB66®-based pandemic and seasonal influenza vaccines
  - › **Jianshun Biosciences** to commercialize EB66® in China

6 new agreements signed in 2016



Recent highlights

GE Healthcare and Valneva collaboration delivers optimized cell culture medium for vaccine production

+ Collaboration jointly developed a new medium optimized for productivity of virus expression in EB66® cells
+ Robust production process will increase reliability and end-product quality

New research agreement with German animal health firm IDT Biologika GmbH

+ to use the EB66® cell line to research new veterinary vaccines

New Pharmacopia guidelines open the use of EB66 for live attenuated vaccines

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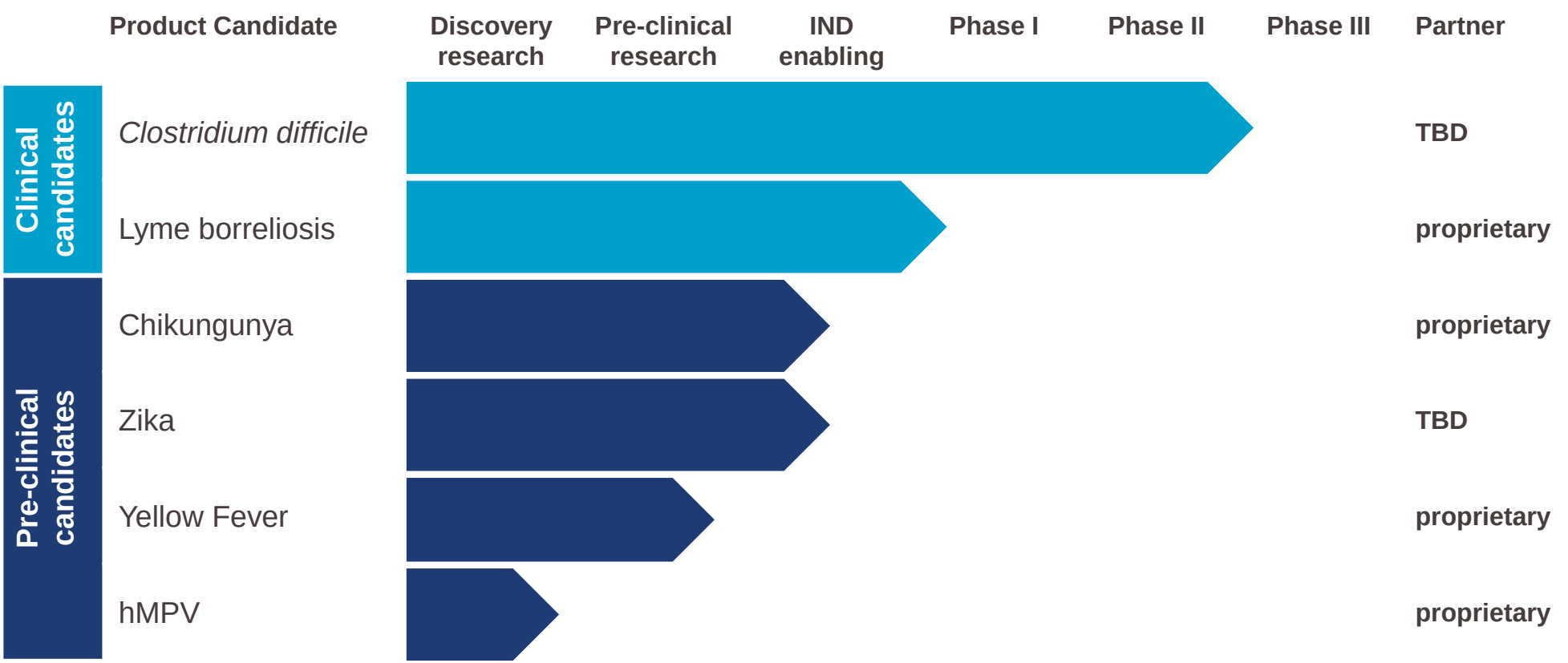
Valneva's pipeline of vaccine candidates

New pre-clinical candidates for future clinical development



Pre-commercial product: Clostridium difficile vaccine

Vaccine targeting healthcare-associated diarrhea, an increasing threat to 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 >USD 1 bn/year target groups[5]**

Current development status VLA84

+ **Final positive Phase II results 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

+ **Comparable immunological profile to the only more advanced vaccine program targeting primary prevention of CDI (according to published Phase II data[6])**
+ **Supported by the competitive data comparison, Valneva continues to seek a partner and 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 2014; **6** G. de Bruyn et al. Vaccine 34 (2016) 2170-2178

Pre-commercial product: *Clostridium difficile* vaccine

Next steps

Phase II study close-out

+ **Final Phase II results of Valneva's Clostridium difficile vaccine candidate confirmed positive initial Phase II data that were released at the end of 2015.**

VLA 84 – ready for Phase III

+ **The study design was agreed with regulators in Europe and the US with the aim of supporting a subsequent progression into Phase III.**

Licensing agreement

+ **Valneva continues to seek a partner and is in discussions with several potential partners. The Company has revised its expected timelines for entering into a partnering deal to 2017.**

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 (Pre-clinical)

+ **Pre-clinical testing completed**
  - › Data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans
+ **IND submission initiated**

Phase I to commence at the end of 2016

+ **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**
+ **Valneva organizes a Lyme KOL event in NY on Dec 12, 2016 co-presented by Prof Stanley A. Plotkin**

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** Estimate of Valneva, concentrated in private markets

Pre-clinical candidate: Zika virus vaccine

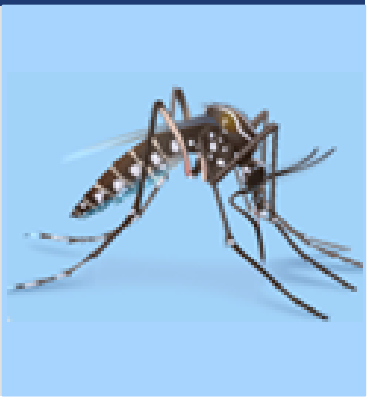
Targeting a Public Health Emergency of International Concern

Zika virus disease

- Transmitted mostly by Aedes species mosquito, same species also transmits Dengue, Yellow Fever etc.
- Zika infection is associated with microencephaly, severe brain defects and Gullian-Barre syndrome (GBS)
- Economic impact of Zika estimated $3.5 billion in 2016[1]
- No vaccine available

Valneva's vaccine candidate

- Vero cell based, highly purified, inactivated, whole-virus ("PIV"), alum adjuvanted
- Biological, chemical & physical profile similar to IXIARO®
- Two injections expected to generate full protection in humans



Current development status VLA1601 (Pre-clinical)

- **Pre-clinical proof of concept achieved**
  - Animal data generated in validated mouse-model used as correlate of protection (PRNT)
  - Vaccine elicts high titered antibodies that also cross neutralize various Zika virus strains
- **Preliminary discussions held with European Medicines Agency**

Phase I could commence early 2017

- Valneva intends to leverage IXIARO® production facility - Clinical trial material manufacturing possible in short term
- Competitive advantage on regulatory pathway and full industrialization foreseen given full application of JEV technology
- Partnering evaluations initiated

1 http://pubdocs.worldbank.org/en/410321455758564708/The-short-term-economic-costs-of-Zika-in-LCR-final-doc-autores-feb-18.pdf

Event calendar and anticipated news flow 2016

Commercialized products	+ FY 2016 product sales guidance narrowed to the upper end of the expected range to reach €75 to €80m (up to 30% growth) + Successful establishment of own global marketing & distribution network leading to IXIARO®/JESPECT® sales exceeding €50m in 2016 + Expected gross margin on product sales of above 50% in 2016
Technologies & Services	+ Signing of additional EB66® and IC31® licensing agreements
Vaccine candidates	+ Phase III partnering discussions for the *Clostridium difficile* vaccine candidate – entering into a partnering deal expected in 2017 + Lyme borreliosis Phase I clinical trial to commence by the end 2016 + Decision on a second clinical candidate to progress into Phase I clinical trial in 2017

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Thank you.

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