Valneva presents its FY 2016 financial results

Analyst Presentation
March 23, 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. 2016 review – Thomas Lingelbach

2. Financial report Q4 & FY 2016 – Reinhard Kandera

3. Commercialized Products & EB66® – Franck Grimaud

4. R&D programs – Thomas Lingelbach

5. 2017 outlook and 2020 strategy – Thomas Lingelbach

6. Q&A

Valneva's business year 2016
Excellent operational performance

Significant sales growth following establishment of new commercial network
+ IXIARO® /JESPECT® revenues increased by 73.1% to €53.2 million in 2016 (vs €30.7 million in 2015)
+ Taking over marketing and distribution responsibilities in several geographic territories

DUKORAL® - strong sales performance
+ DUKORAL® revenues grew to €24.7 million in 2016 (vs €21.2 million in 2015)
+ Continuous investment by way of promotional efforts and geographic expansion

Strong financial performance
+ Total revenues of €97.9 million in 2016 (vs €83.3 million in 2015)
+ EBITDA growth to €2.8 million in 2016 (vs €8.5 million loss in 2015)

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.

Valneva's business year 2016

Our vaccines R&D efforts are of strategic importance in order to generate long-term returns

Clinical vaccine candidates

+ Successful completion of Phase II study announced in 2016; Phase III-ready ***Clostridium difficile*** vaccine candidate partnering agreement sought in 2017
+ Phase I clinical trial for **Lyme disease** vaccine candidate initiated; Company will advance Phase I trial in 2017 and expects to accelerate program's progression towards Phase II

Technology business segment further developed into positive cash generator offering a basis for internal programs and partnerships

+ 10 new license agreements on the EB66® vaccine production cell line in 2016, partners continue to develop and license EB66® based programs

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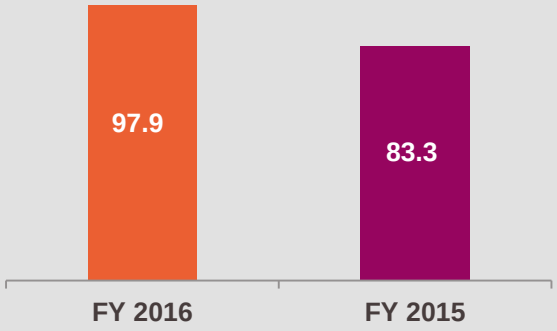
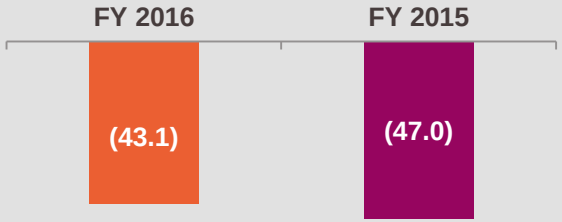
Full Year 2016 financial results

Compared to FY 2015 (IFRS, € million, audited)

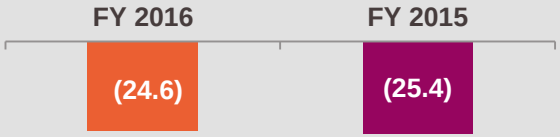
Revenues & Grants



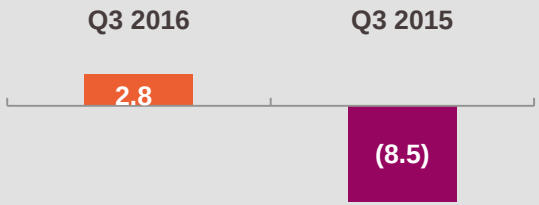
COGS



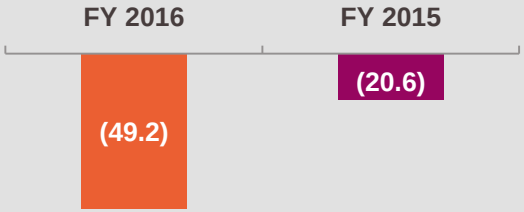
R&D Expenses



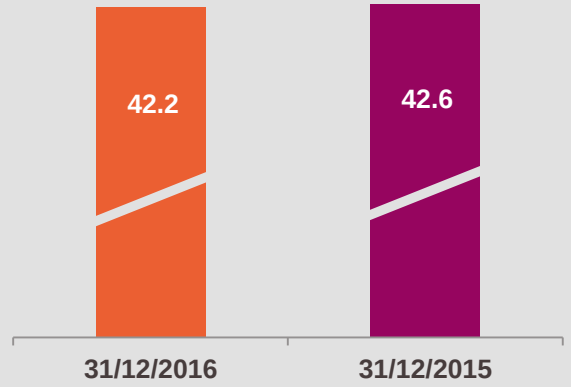
EBITDA*



Net profit/loss



Cash position



*Calculated by excluding FY 2016 amortization, depreciation, impairment and bargain purchase gain of €45.4m (FY 2015: -€1.7m) from the FY 2016 operating loss of €42.6m (FY 2015: €6.8m)

Full Year 2016 Profit & Loss (audited)

€ in thousand

	3 months ended Dec 31,		12 months ended Dec 31,	
	2016	2015	2016	2015
Revenues and grants	**27,151**	**22,652**	**97,892**	**83,335**
Cost of goods and services	(13,094)	(13,315)	(43,076)	(46,961)
R&D expenses	(5,871)	(6,636)	(24,589)	(25,367)
Distribution and marketing expenses	(5,354)	(3,337)	(16,639)	(9,121)
General and administrative expenses	(4,008)	(4,188)	(14,412)	(14,394)
Other income / (expense)	(521)	(461)	(498)	(152)
Amortization and impairment	(1,793)	(1,818)	(41,246)	(7,273)
Bargain purchase gain	-	-	-	13,183
OPERATING LOSS	**(3,491)**	**(7,103)**	**(42,568)**	**(6,751)**
Finance, investment results and tax	773	(9,296)	(6,616)	(13,866)
LOSS FOR THE PERIOD	**(2,717)**	**(16,398)**	**(49,184)**	**(20,617)**
EBITDA*	**(653)**	**(4,185)**	**2,810**	**(8,492)**

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

Business segment overview Full Year 2016

Two profitable segments funding R&D pipeline and overhead

	Revenues	Operating profit/loss (before amortization & impairment*)
Commercial products	**€80.8m**	**€23.4m**
	54% gross margin	29% operating margin
Technologies & services	**€10.1m**	**€2.1m**
	39% gross margin	21% operating margin
Proprietary R&D	**€7.0m**	**(€11.9m)**
		€18.8m R&D expenses
Overhead		**(€14.9m)**
		15% of operating expenses
Subtotal		**(€1.3m)**
Amortization & Impairment*		**(€41.2m)**
Total Operating Loss		**(€42.6m)**

*of merger/acquisition related intangible assets – non cash

Financial analysis Full Year 2016

Performance ahead of initial expectations

Product sales	30.7% increase to €80.4m - driven by strong IXIARO®/JESPECT® sales (up 73.1% compared to FY 2015)
Total revenues & grants	€97.9m (up 17.5% compared to FY 2015)
COGS	€43.1m total COGS yielding 56.0% gross margin, including 54.3% gross margin on commercial products
R&D expenses	€24.6m – slightly decreasing from €25.4 in FY 2015; driven by R&D pipeline expansion while spending on late stage programs is decreasing
Distribution & marketing expenses	Increased to €16.6m (vs. €9.1m in FY 2015) driven by establishment of own sales & marketing organization
G&A expenses	Flat at €14.4m – despite full inclusion of acquired Swedish business and new distribution subsidiaries

Financial analysis Full Year 2016
First year of positive EBITDA in 2016

Amortization of intangible assets	€41.2m non-cash amortization & impairment charges on acquired intangible assets (includes €34.1m Pseudomonas write off);€59.0m intangible assets remaining, 82% relating to IXIARO®
EBITDA*	Positive EBITDA of €2.8m in 2016 (vs an EBITDA loss of €8.5m in 2015); operational break-even achieved
Net Loss	€49.2 million net loss includes one-time impairment charges of €34.1m related to the Pseudomonas project
Cash	€42.2m net cash at year-end including €7.5m net proceeds from capital increase; positive operating cash flow in FY 2016
Debt	Total borrowings of €82.5m at year end: €28.4m long-term finance lease €43.9m loan from Pharmakon (including accrued interest) due for repayment in 2017/18 €10.2m other debt, mainly related to R&D tax credits and government grants Additional €25.0m loan facility available from EIB

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

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)	€24.6	€21 – 23m	–
EBITDA	€2.8	€5 – 10m	80 – 250% growth vs. 2016

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Valneva's new global marketing & distribution network established

With commercial teams in the US, Canada, the UK, Austria and the Nordics, Valneva is well positioned to directly serve the key markets for its own and third-party products.

+ More than 68% of 2016 product sales are expected to be generated by Valneva's own teams

+ Significant sales margin improvement of commercial vaccine expected in 2017

+ Valneva is actively searching for additional products to distribute either through acquisition or marketing & distribution agreements to leverage further its commercial infrastructure

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]

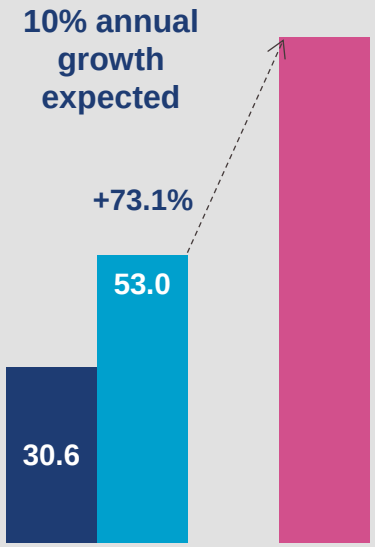
1 Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years of age.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

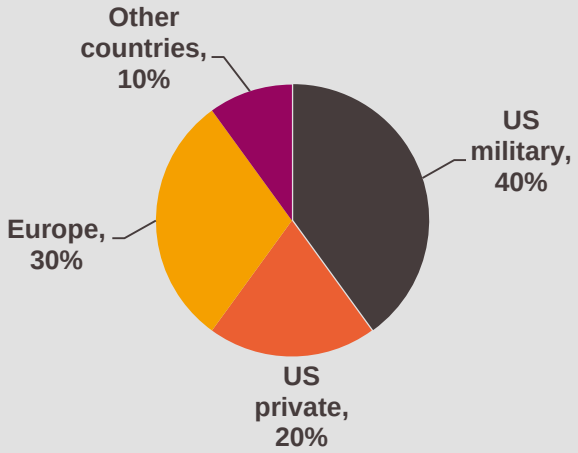
Product financials

2015 FY 2016[1] 2020

Valneva product sales in € million

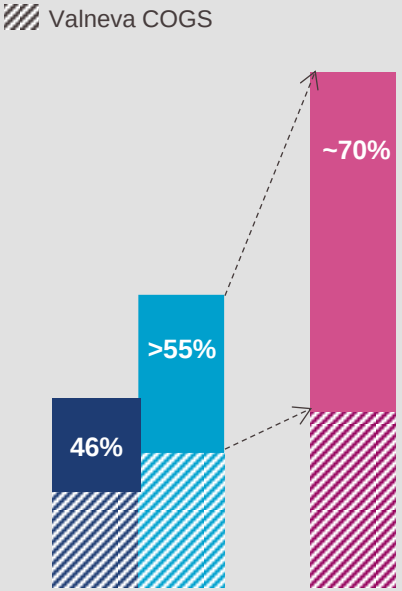


Geographic split



Split of 2016 product sales

Gross margin



10% mid-term annual sales growth expected

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

Growth expected in 2017

+ More than 80% 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 unaudited

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

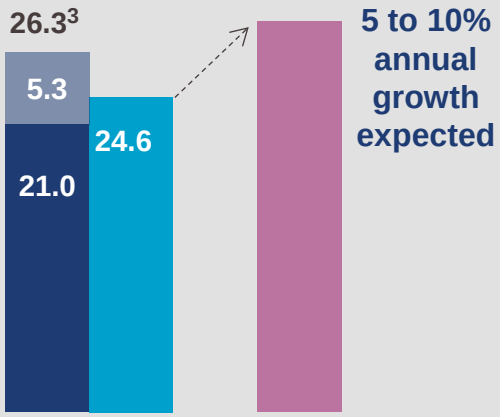
+ **363 million travelers** to Asia/South America/Africa in 2015[2]
+ Ongoing travel to risk regions, improved awareness and updating travel recommendations
  - › **Significant growth potential in key markets** (penetration rate <1%)[3]
+ Canada, Sweden, Australia account for ~75% of sales

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;

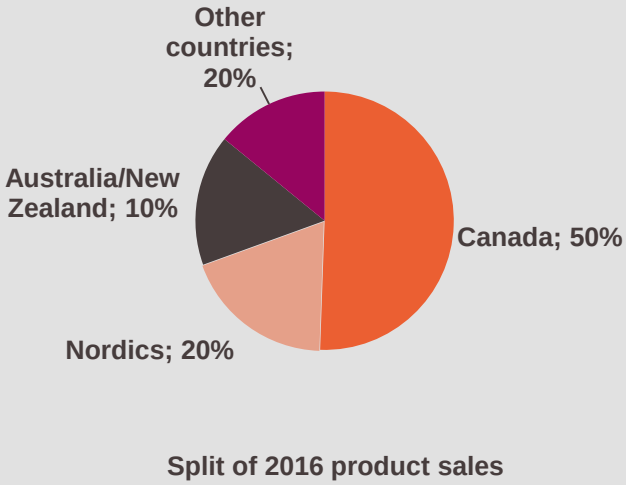
Commercial product: Cholera/ (ETEC[1]) vaccine
Product financials

2015 2016[2] 2020

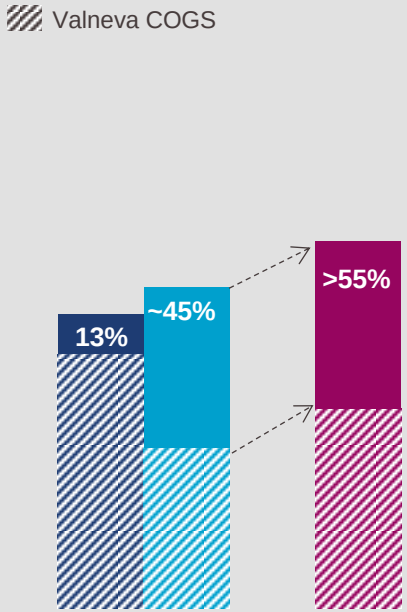
Product Sales in € million



Canada remains the most important market



Gross margin



5-10% sales growth expected in 2017

+ Significant growth opportunities outside Canada and through geographic expansion

Key revenue drivers 2017

+ Increased travel to endemic regions
+ Awareness campaigns for HCPs & lay public

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

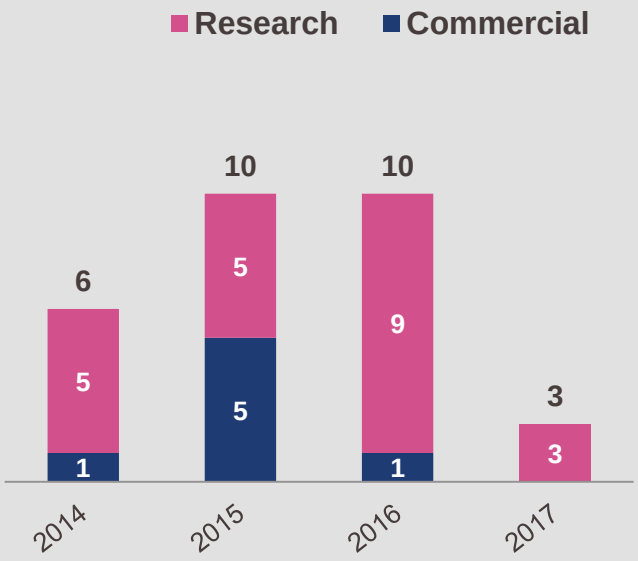
EB66® platform for efficient large scale vaccine production

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** to commercializes EB66® in China

10 new agreements signed in 2016



2016 highlights

+ **First royalties for an EB66® based human vaccine received in Japan**
+ **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® may open new markets for the technology**

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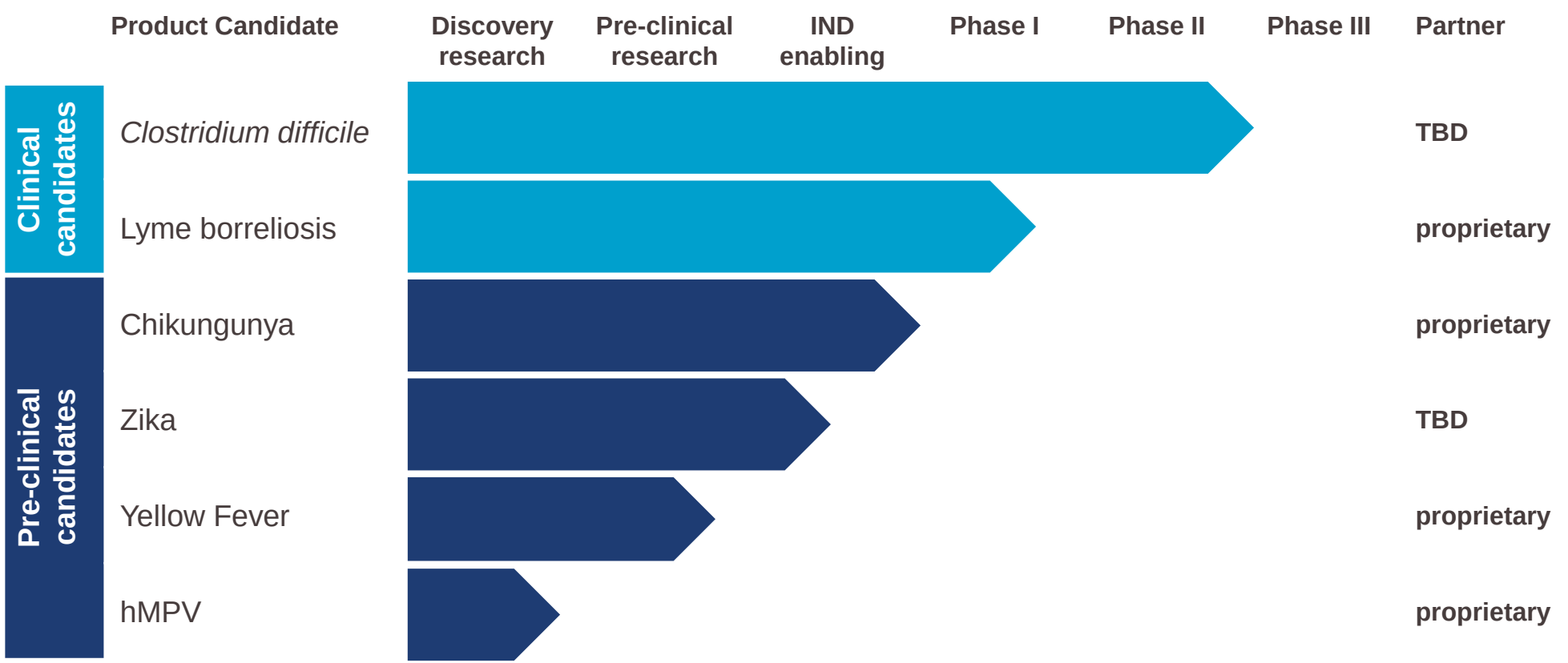
Valneva's pipeline of vaccine candidates

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**
- **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: study design was agreed with regulators in Europe and the US**
- **Comparable immunological profile to the only other late stage vaccine 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

Pre-commercial product: Lyme disease vaccine

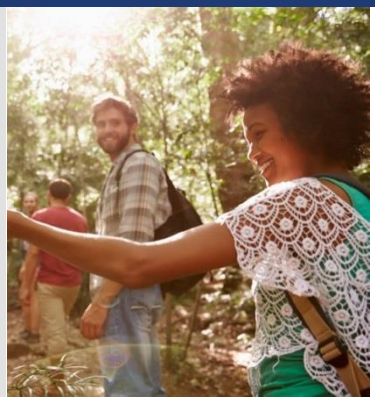
Market potential of approximately €700m - €800m[5]

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**



Current development status VLA15 (Phase I)

- **IND clearance in US and CTA approval in EU received**
  Clinical testing for VLA15 started
- **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]

Phase I clinical trial initiated

- **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; **5** Company estimate supported by independent market studies

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Valneva – expected newsflow and outlook

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 + 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 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) sought to be partnered + Other R&D partnering deals possible + Active discussions on broadening of commercial portfolio in travel vaccines

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 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

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Thank you.

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