Valneva presents its FY 2015 financial results

Analyst Presentation
March 21, 2016

valneva

Forward-looking statements

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Agenda

1. 2015 review and 2020 vision – Thomas Lingelbach

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5. 2016 outlook – Thomas Lingelbach

6. Q&A

Valneva's business year 2015

Excellent operational performance and major strategic steps, focusing on growing revenues and profitability

Valneva acquired and successfully integrated DUKORAL®

+ Expansion of commercial vaccine portfolio with a Cholera /(ETEC[1]) vaccine as a second product
+ Addition of a commercial organization in the Nordics

Valneva established its own global commercial infrastructure

+ Termination of IXIARO®-related marketing & distribution agreement with GSK to take direct control over IXIARO® distribution
+ Opening of two new commercial offices in Canada and the UK, expansion of US team to focus on IXIARO® distribution to the US Military
+ Country-specific marketing & distribution agreements with leading local distributors

Solid financial performance despite integration of Swedish activities and IXIARO® transition

+ Total revenues of €83.3 million in 2015 (€42.4 million in 2014)
+ EBITDA loss of €8.5 million in 2015 (€7.4 million in 2014)

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 2015

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

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 2015, partners continue to develop and license EB66® based programs

Late stage clinical vaccine candidates progressed to next value inflection points

+ Positive Phase II results for Clostridium difficile vaccine candidate
+ Completion of ~ 800 patients enrolment for the Phase II/III trial of the Company's most advanced vaccine candidate Pseudomonas aeruginosa

2020 Strategy – A journey to success

Becoming the leading independent pure-play vaccine company

Products

Growing revenues from existing and future products to €250m

R&D

Investing at least 20% of revenues in R&D programs delivering patient benefit and market capitalization

Financials

Achieving financial self-sustainability and positive cumulative cash-generation

Growth

Generating organic growth complemented by opportunistic M&A strategies

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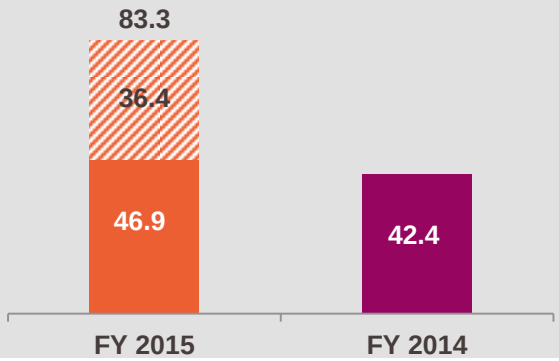
Full year 2015 financial results

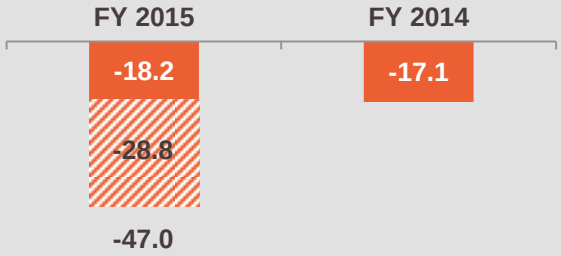
Compared to FY 2014 (IFRS, € million)

attributable to acquired Crucell Sweden AB and DUKORAL® business

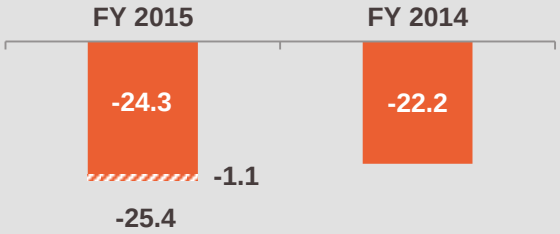
Revenues & Grants



COGS



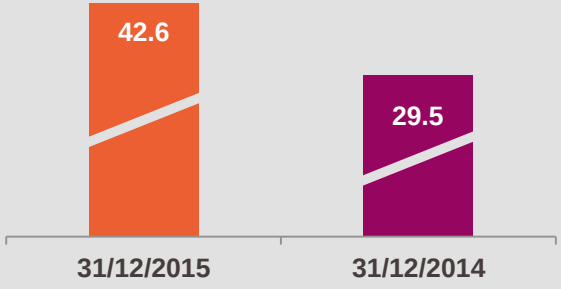
R&D Expenses



EBITDA*

Net loss

Cash position



* Calculated by adding 2015 amortization, depreciation and impairment of €11.4m to the 2015 operating loss of € -19.9m

Two profitable business segments
Investments in R&D pipeline

	Revenues	Operating Profit/Loss (before amortization*)
Commercial products	**€62.1m** 32% gross margin	**€8.5m** 14% operating margin
Technologies & services	**€12.6m** 60% gross margin	**€4.6m** 36% operating margin
Vaccine candidates	**€8.7m**	**(€11.2m)** €19.8m R&D expenses
Overhead		**(€14.5m)**
Total		**(€12.6m)** **(€19.9m)** after amortization*

*of merger/acquisition related intangible assets – non cash

Q4 (unaudited) / Full Year 2015 Profit & Loss

€ in thousand

	3 months ended December 31		12 months ended December 31	
	2015	2014	2015	2014
Revenues and grants	**22,652**	**13,113**	**83,334**	**42,429**
Cost of goods and services	(13,315)	(6,994)	(46,961)	(17,144)
R&D expenses	(6,636)	(7,022)	(25,367)	(22,242)
S,G&A and other expenses	(7,986)	(4,071)	(23,667)	(14,537)
Amortization and impairment	(1,818)	(4,877)	(7,273)	(12,323)
OPERATING LOSS	**(7,103)**	**(9,851)**	**(19,934)**	**(23,817)**
Finance result (including one-offs*)	(9,296)	(1,669)	(683)	(2,455)
LOSS FOR THE PERIOD	**(16,398)**	**(11,520)**	**(20,617)**	**(26,272)**
EBITDA**	**(4,185)**	**(3,754)**	**(8,492)**	**(7,364)**

* Gain from bargain purchase and impairment of BLiNK investment

** Calculated by adding Q4 / Full Year 2015 amortization, depreciation and impairment to the Q4 / Full Year 2015 operating loss

A 22% net loss improvement to €20.6m

Significant one-off effects included in finance expenses

Amortization of intangible assets	(€7.3m) impact on 2015 bottom line result; as a reminder: Company records significant non-cash amortization charges on acquired intangible assets;
Financial income / expenses	(€6.7m) finance expenses mainly due to interest payments; €15m loan repaid in Q1 2016; €2.1m finance income mainly from currency gains
Impairment of BLiNK asset	(€9.0m) impairment charge in Q4 2015 on shareholding in BLiNK Biomedical SAS (spin-off of Valneva's antibody technology, now focused on early product development)
Gain on bargain purchase from Crucell acquisition	€13.2m gain related to Q1 acquisition of Crucell Sweden & DUKORAL®; Purchase price reduction of €25m agreed with the seller in Dec. 2015; PPA retrospectively* adjusted, resulting in „negative goodwill"

*effect in Q1 2015

2016 financial outlook

Strong revenue growth and positive trend towards EBITDA break-even

Revenues	€90 – 100m total revenues (up to 20% growth vs. 2015)
Commercial Products	€70 – 80m product sales (up to 30% growth vs. 2015) 50% gross margin on product sales (vs. 32% in 2015)
R&D investments	€25m R&D expenses (at 2015 level)
EBITDA	Close to operational break-even Less than €5m EBITDA loss (vs. €8.5m in 2015)

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Valneva's new global marketing & distribution network established

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

+ More than 60% of 2016 product sales are expected to be generated by Valneva's own teams

+ Significant improvement of sales margin and profitability of JE vaccine IXIARO® expected in 2016 and onwards

+ Country-specific marketing and distribution agreements with leading local distribution partners including VaxServe and GSK

+ Valneva is actively searching for products to in-license in order to leverage 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 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

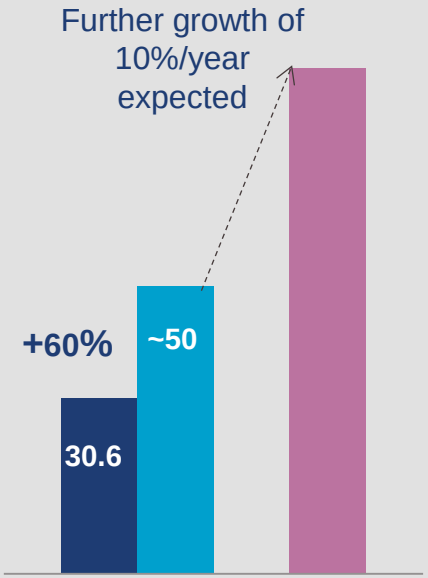
1 Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO® can be used in children from 3 years of age.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

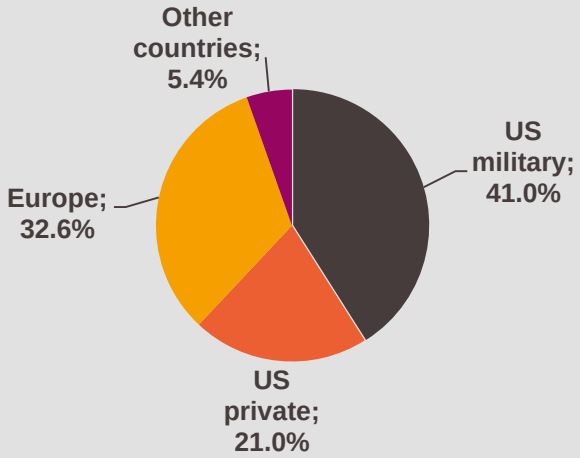
Product financials

2015 2016[1] 2020

Valneva sales in € million

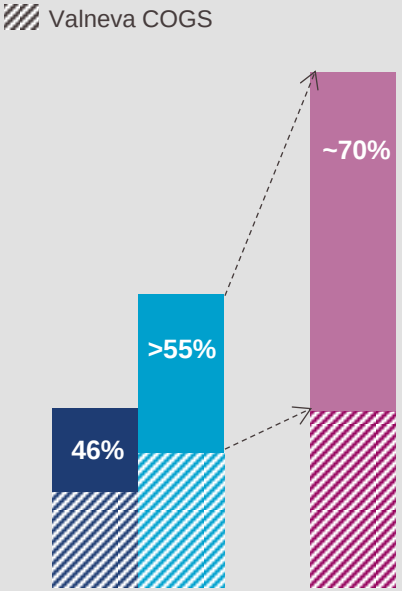


US military sales already secured



Expected split of 2016 product sales

Gross margin



10% year on year growth expected

+ Increased product adoption in the US (military/private)
+ Conservative assumption for Europe

2016: 60% yoy growth expected

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

Largely fixed manufacturing cost structure to translate into over-proportional margin growth

1 estimated;

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
+ PaxVax' cholera vaccine Orochol® filed in the US

Growth opportunities

New commercialization strategy

Support label harmonization across all key countries

Reinforced KOL management

Explore further product life cycle possibilities

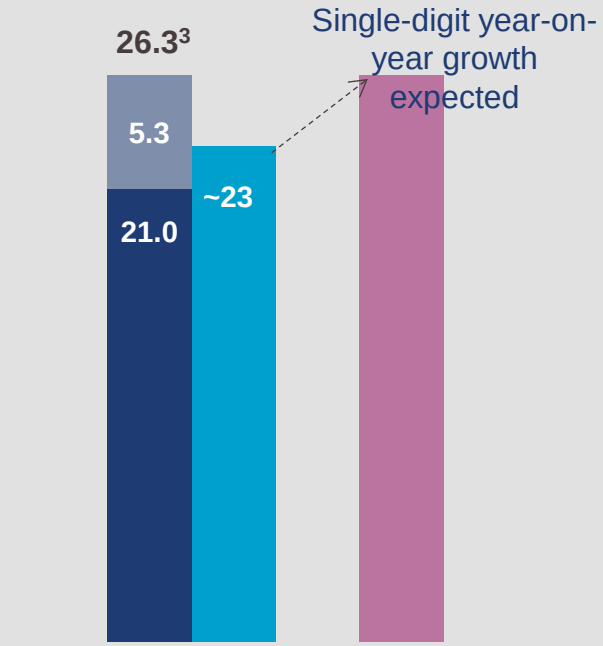
1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

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

Product financials

2015 2016[2] 2020[2]

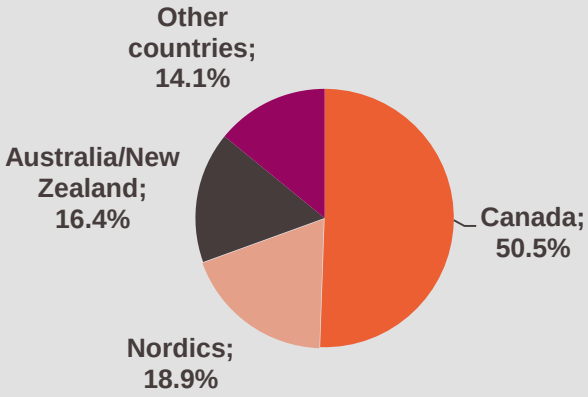
Sales in € million



€23m sales target 2016

+ Sales to be negatively impacted by label change in Canada

Canada still the most important market

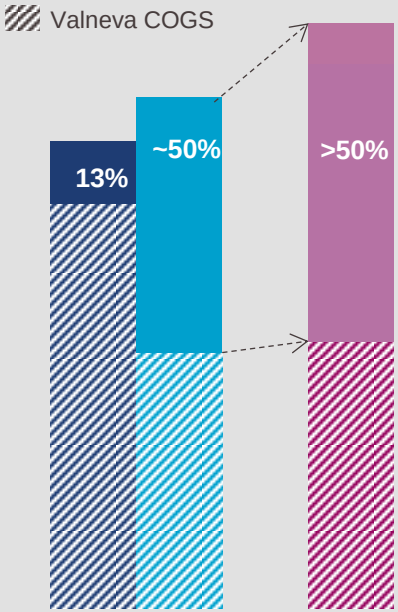


Expected split of 2016 product sales

5% growth outside Canada

+ Significant growth opportunities outside Canada and through geographic expansion

Gross margin



Future margin improvement

+ Adverse impacts through integration
+ Good efficiency improvements ahead

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

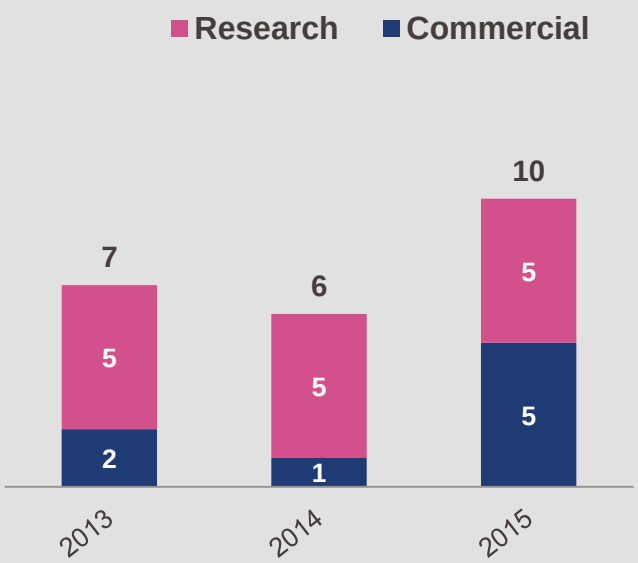
EB66® platform for efficient large scale vaccine production

10 new agreements signed in 2015

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

10 new agreements signed in 2015



Highlights

New R&D collaboration agreement with GSK for the development of EB66®-based influenza vaccines

+ Valneva supplies process development services for EB66®-based influenza vaccines, sponsored by the US Department of Health and Human Services

Approval of EB66® based prototype influenza vaccine in Japan

Agreement with global animal health company Merial

Valneva entered the Chinese market
Granting exclusive rights to commercialize EB66® cell line to partner JSB

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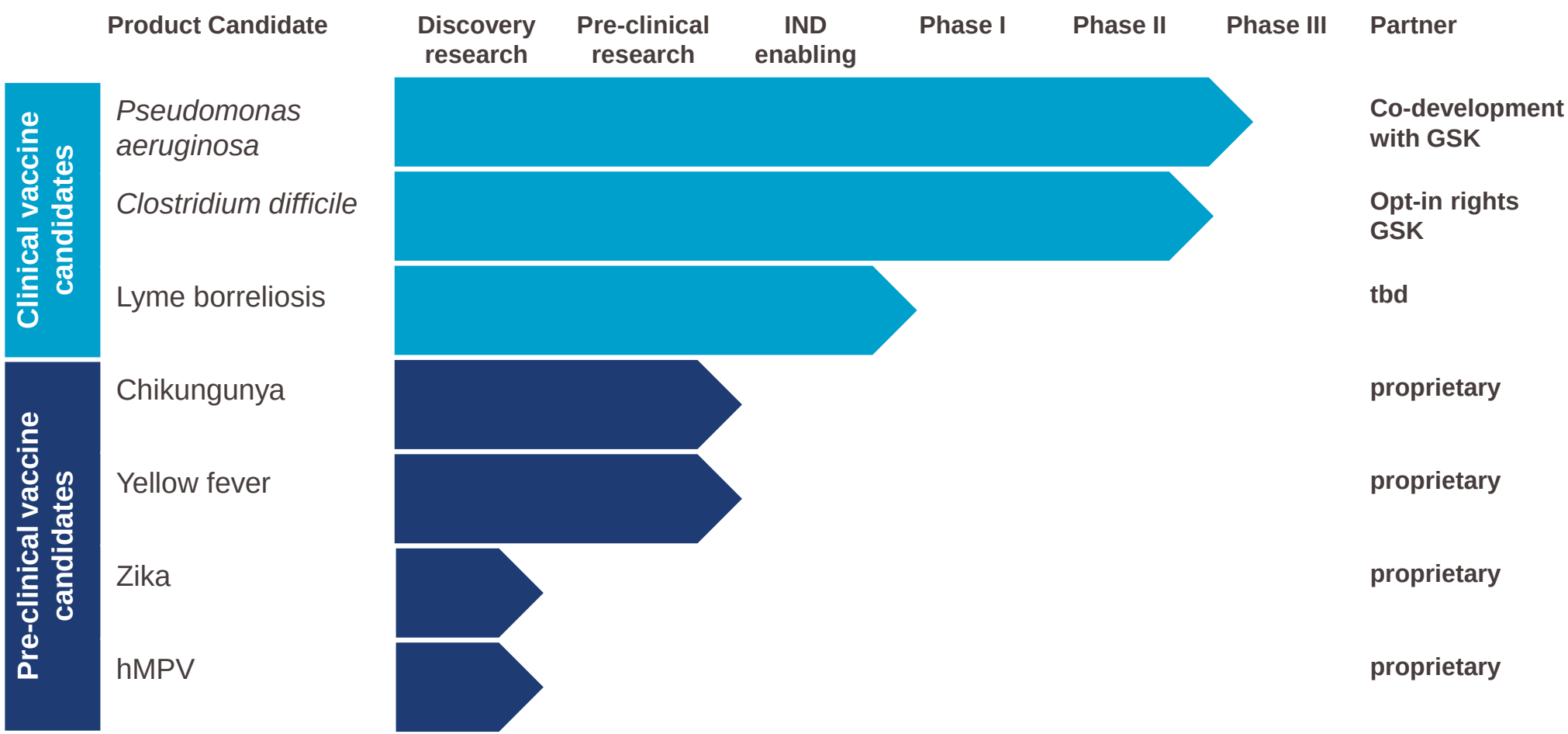
Valneva's pipeline of vaccine candidates



Pre-commercial product: Pseudomonas aeruginosa vaccine

Data release from Phase II/III trial expected in Q2 2016

Pseudomonas aeruginosa

- **Causes ~20% of all hospital-acquired infections** [1,2]
- **Target population: patients in intensive care units on mechanical ventilation**
  - **Up to 1 million in the US and Europe per year**[3]
  - **All-cause mortality rate of 20% to 40% in this target population**[4]

Valneva's vaccine candidate

Only program in clinical development

No vaccine on the market

Current development status VLA 43

- **Phase II/III enrolment completed** (800 patients) (co-financed by GSK)[5]
- **Reduction in mortality as primary endpoint**
- **Interim analysis after 400 patients** confirmed clinically meaningful effect but less pronounced
- **Addition of a secondary endpoint** for a subgroup of patients following Phase II post -hoc analysis

Phase II/III data release expected in Q2 2016

- **Valneva awaits full analysis of the ongoing efficacy trial, including day 180 follow-up time-points, before releasing data**
- **Valneva considers that ≥5% absolute difference in mortality should support the ongoing development of a licensable product**
- **GSK opt-in rights**

Picture from www.rtmagazine.com; **1** Pseudomonas Infection, Selina SP Chen, Russell W Steele, MD – Chapter on Epidemiology www.emedicine.medscape.com; 2 Vincent JP et al, JAMA, 1995; p639-644; **3** McConville, M.D., John P. Kress, M.D. Weaning Patients from the Ventilator, N Engl J Med 2012; 367:2233-2239; **4** Vincent et al, JAMA 1995; 274:639-644

Pre-commercial product: Pseudomonas aeruginosa vaccine

Potential routes to marketing approval

3 options for the product to reach the market

Phase II/III primary endpoint met (reduction of all-cause mortality on Day 28),

\+ **Trial in support of product licensure**

Study does not meet primary endpoint but confirms clinically meaningful effect

\+ **Confirmatory pivotal Phase III efficacy study required**

Different efficacy read-outs in subgroups of patients with certain co-morbidities

\+ **Valneva could launch a confirmatory Phase III trial on subgroup**

1 To be determined upon final data discussion and consultation with the authorities

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

- **Vaccine targeting primary prevention**
- **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

- **Positive Phase II results announced in Nov. 2015**
- **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 2016

- **Next steps to be announced after final study close-out (expected mid 2016) and consultations with regulators and partner**
- **Valneva aims for a licensing agreement in 2016**
  - **GSK opt-in rights[6]**
  - **Discussions with other potential partners ongoing**

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** If Phase II successful under pre-defined terms; SAA with GSK, Registration Doc. 2014, p 13, 55;

Pre-commercial product: *Clostridium difficile* vaccine

Next steps

Phase II study close-out

+ **Immune response and safety parameters monitored until Day 210, final study close-out expected mid 2016.**

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

+ **GSK has opt-in rights to the program following Phase II completion**
+ **Discussions with other potential partners initiated**

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 in 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**

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

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Event calendar and anticipated newsflow 2016

Commercialized products	+ Product sales in the expected range of €70 to €80m (up to 30% growth) + Successful implementation of own global marketing & distribution network with IXIARO®/JESPECT® sales of ~€50m + Growth of DUKORAL® outside Canada
Technologies & Services	+ Additional EB66® and IC31® licensing agreements expected + First Japanese stockpiling for EB66® based Pandemic influenza vaccine expected
Vaccine candidates	+ Pseudomonas aeruginosa Phase II/III results expected in Q2 2016 + Phase III partnering agreement for the Clostridium difficile vaccine candidate + Lyme borreliosis Phase I clinical trial to commence in 2016

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Thank you.

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