Valneva presents its Q1 2016 financial results

Analyst Presentation
May 11, 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 Q1 2016 – Reinhard Kandera

3. Commercialized products & EB66® – Franck Grimaud

4. R&D programs – Thomas Lingelbach

5. 2016 outlook – Thomas Lingelbach

6. Q&A

Valneva's newsflow

March 2016

+ Valneva presented at the 16th World Vaccine Congress in Washington D.C.
+ Valneva announced FY 2015 results, confirmed positive trend towards strong revenue growth and EBITDA break-even, and presented its 2020 strategy
+ Valneva signed $42 million IXIARO® supply contract with US Government

February 2016

+ New R&D collaboration with GlaxoSmithKline for the EB66® cell line
+ Valneva evaluating development of Zika vaccine as virus spreads through the Americas

January 2016

+ Successful establishment of new global marketing and distribution network
+ Approval of Japanese encephalitis vaccine in Taiwan through commercial partner Adimmune

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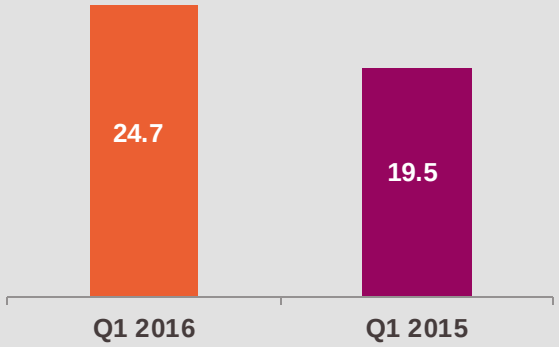
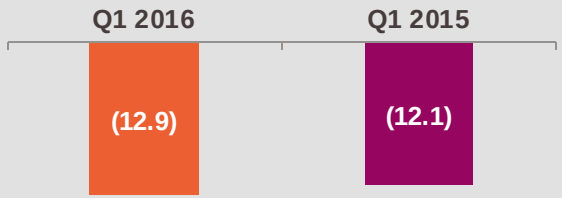
Q1 2016 financial results

Compared to Q1 2015 (IFRS, € million)

Revenues & Grants

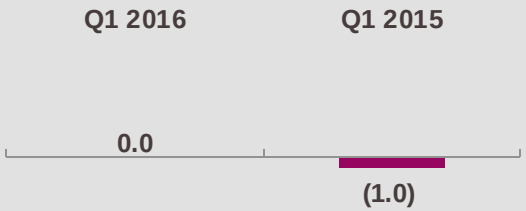


COGS

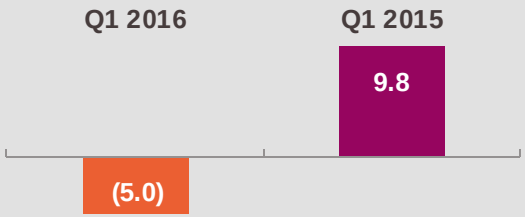


R&D Expenses

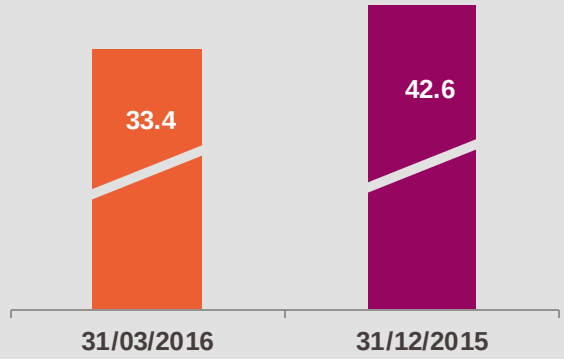
EBITDA*



Net profit/loss



Cash position



*Calculated by adding Q1 2016 amortization, depreciation and impairment of €2.7m (Q1 2015: €2.8m) to the Q1 2016 operating loss of €2.7m (Q1 2015: €3.7m)

Q1 2016 profit & loss (unaudited)

€ in thousand

	3 months ended March 31	
	2016	2015
Revenues and grants	**24,687**	**19,501**
Cost of goods and services	(12,921)	(12,110)
R&D expenses	(5,798)	(5,504)
Distribution and marketing expenses	(3,295)	(1,218)
General and administrative expenses	(3,765)	(2,768)
Amortization and impairment	(1,720)	(1,793)
Other income / (expense)	91	152
OPERATING LOSS	**(2,721)**	**(3,741)**
Finance results and tax (including one-offs*)	(2,317)	13,533
LOSS FOR THE PERIOD	**(5,037)**	**9,792**
EBITDA**	**14**	**(961)**

* Gain from bargain purchase included in Q1 2015 (€13.2m)
** Calculated by adding amortization, depreciation and impairment to operating loss

Business segment overview

Two profitable segments funding R&D pipeline

	Revenues	Operating profit/loss (before amortization*)
Commercial products	**€20.5m**	**€4.8m**
	45% gross margin	23% operating margin
Technologies & services	**€2.7m**	**€0.6m**
	41% gross margin	23% operating margin
Proprietary R&D	**€1.4m**	**(€2.6m)**
		€4.1m R&D expenses
Overhead		**(€3.8m)**
		15% of operating expenses
Subtotal		**(€1.0m)**
Amortization *		**(€1.7m)**
Total Operating Loss		**(€2.7m)**

*of merger/acquisition related intangible assets – non cash

Financial analysis Q1 2016

Product sales	35.1% increase to €20.4m Driven by strong IXIARO®/JESPECT® sales (up 50.2% compared to Q1 2015)
Total revenues & grants	€24.7m (up 26.6% compared to Q1 2015) - on track to meet €90-100m revenue goal for FY 2016
COGS	€12.9m total COGS yielding 47.7% gross margin, including 44.8% gross margin on product sales
R&D expenses	Driven by R&D pipeline expansion while spending on late stage programs is decreasing
Distribution & marketing expenses	Increase to €3.3m (vs. €1.2m in Q1 2015) driven by establishment of own sales & marketing organization
G&A expenses	36.0% increase to €3.8m due to full inclusion of acquired Swedish business and broadened geographical presence

Financial analysis Q1 2016 (continued)

Amortization of intangible assets	€1.7m non-cash amortization charges on acquired intangible assets
Financial income and expenses	Last year's Q1 2015 includes €13.2m retrospective gain related to Crucell Sweden and DUKORAL® acquisition
EBITDA	(Slightly) positive EBITDA confirms trend towards operational break-even
Net Loss	€5.0 million net loss compares to €9.8m net profit in Q1 2015 (driven by acquisition one-off effect); Operating loss improved in line with EBITDA improvement
Cash	€33.4 million net cash at quarter-end; Q1 cash-out flow driven by working capital effects

2016 financial outlook confirmed

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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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

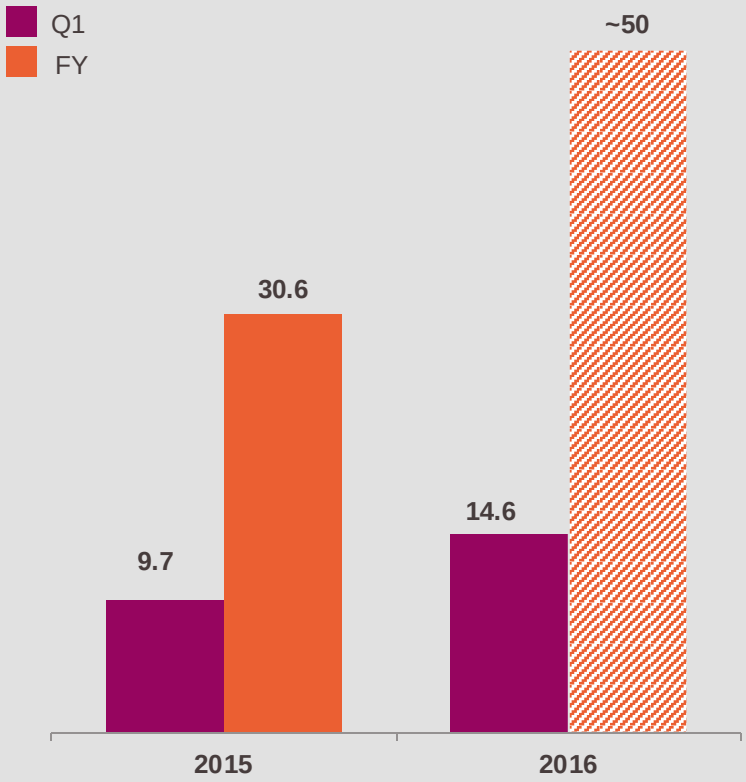
Geographical expansion

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®: significant growth in Q1 2016

Product sales revenues in € million



Q1 2016 sales analysis

IXIARO®/JESPECT® product sales increased to €14.6m

+ Compared to €9.7m (Q1 2015)

Growth mainly driven by strong sales to the US military

+ 95% revenue growth vs. Q1 2015 driven by direct capturing of full revenues following GSK termination

Travel market sales growing despite negative effect from transition towards new sales & marketing structure

+ 12% revenue growth vs. Q1 2015
+ Transition in most countries started with April 1, Q1 revenues mainly include true-ups for EU/ROW

Outlook

Product sales are expected to grow to ~€50m in 2016

+ Based on observed demand pattern in the travelers' markets and supplies to the US military

Valneva will supply IXIARO® doses to US military for a total value of $42m over a two-year period

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

Increased communication with KOL

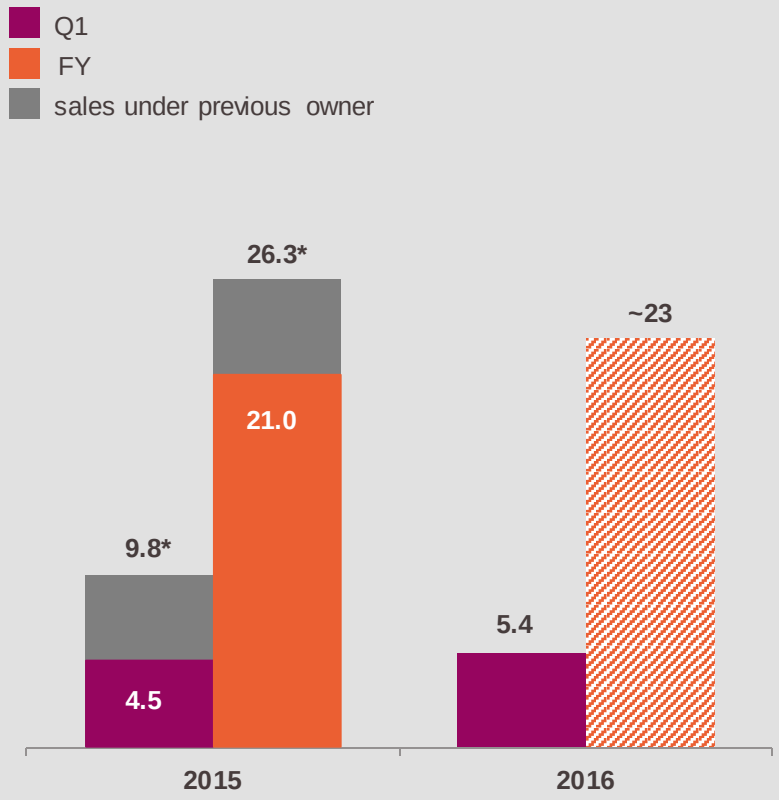
Explore further product life cycle possibilities

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

DUKORAL® update

Product sales revenues in € million



Q1 2016 sales analysis

DUKORAL® product sales reached €5.4m

+ Compared to €4.5m (Q1 2015)
+ Compared to €9.8m pro-forma revenues[2] (Q1 2015)

Lower sales due to updated product monograph in Canada

+ Valneva temporarily ceased promotional efforts

Outlook

Q1 sales in line to meet Company expectations of ~€23m product sales in 2016

Growing DUKORAL® 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 sales incl. €5.3m under previous owner;

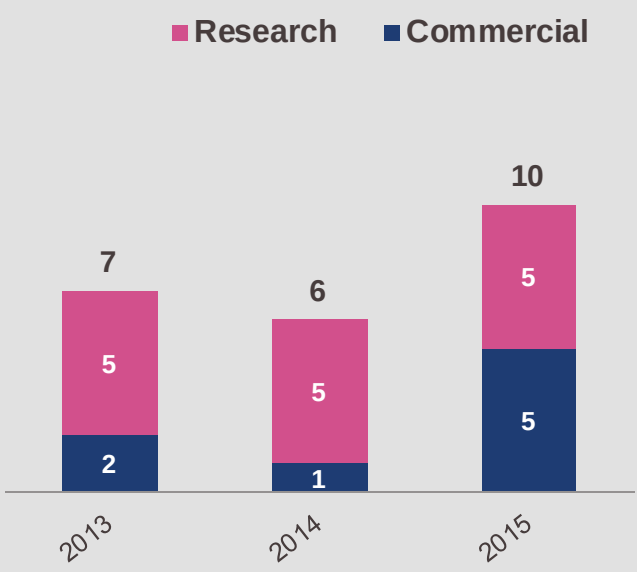
EB66® platform for efficient large scale vaccine production

Potential additional milestones of up to €80m

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 development of EB66® based influenza vaccines

+ The scope of this agreement was recently reduced and is now focused on the development and validation of EB66® analytical assays
+ GSK is developing its influenza vaccines in the US in partnership with Texas A&M University System

First Japanese stockpiling for EB66® based Pandemic influenza vaccine expected

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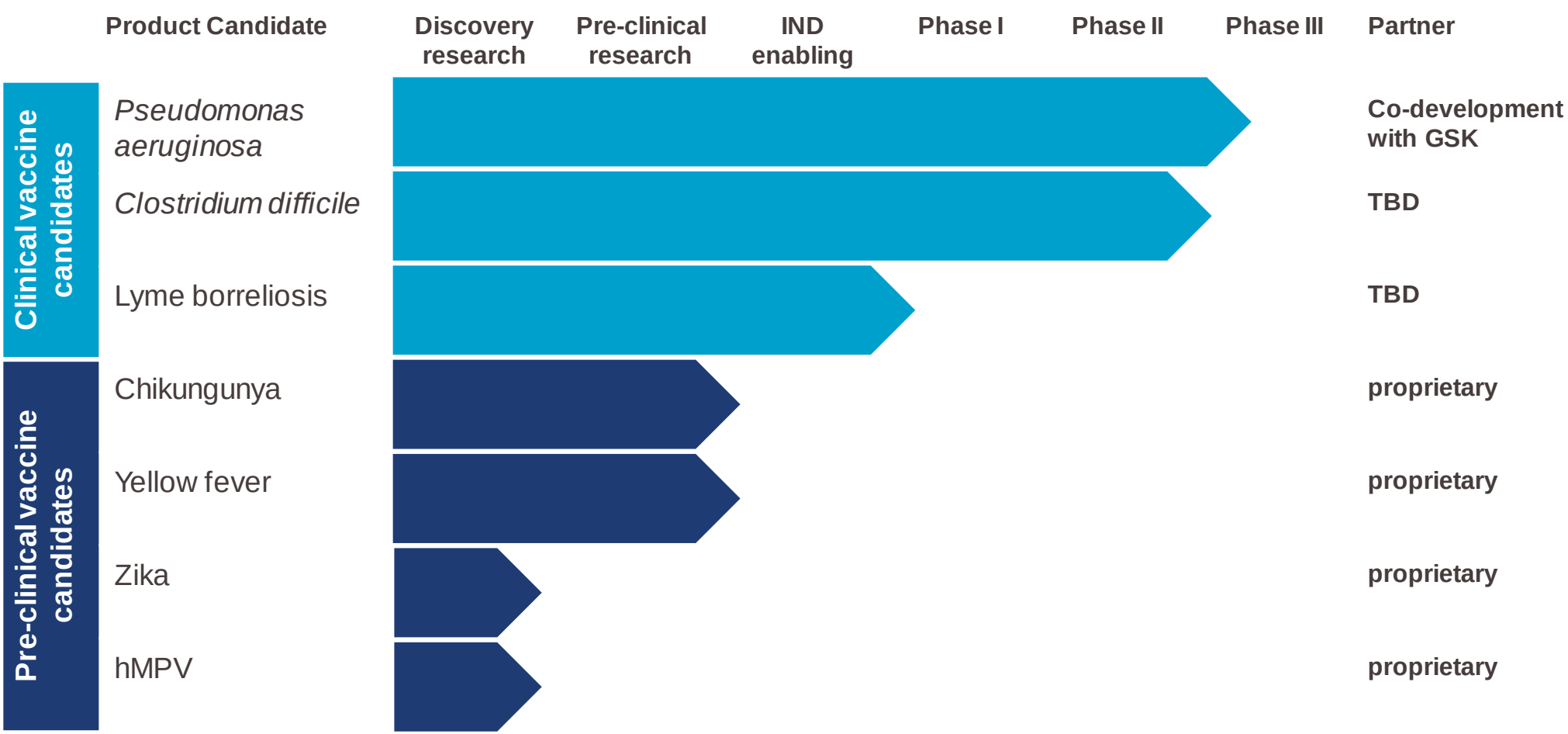
Valneva's pipeline of vaccine candidates

New research candidates for future clinical development



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 is currently conducting full analysis of the ongoing efficacy trial, including day 180 follow-up time-points, expecting data still in Q2 2016**
- **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

- **Final study close-out expected mid 2016**
- **GSK waived option rights for strategic reasons ahead of final data analysis**
- **Discussions with potential partners initiated**

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;

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

+ **Discussions with potential partners initiated and the Company reaffirms its expectation to enter into a partnering agreement for this program by the end of this year**

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 + Expected gross margin on product sales of approximately 50% in 2016
Technologies & Services	+ Additional EB66® and IC31® licensing agreements + First Japanese stockpiling for EB66® based Pandemic influenza vaccine
Vaccine candidates	+ *Pseudomonas aeruginosa* Phase II/III results 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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