Valneva presents its Q3 2015 financial results

Analyst Presentation
November 10, 2015

valneva

Forward-looking statements

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Agenda

1. **Introduction – Thomas Lingelbach**
2. Financial report Q3 2015 – Reinhard Kandera
3. Commercialized Products & EB66® – Franck Grimaud
4. R&D programs – Thomas Lingelbach
5. Outlook – Thomas Lingelbach
6. Q&A

Major progress in further building Valneva as a fully integrated vaccine company

Integration of DUKORAL® franchise and Nordics trade business progressing well

Progress in taking direct control over marketing and distribution of IXIARO® to increase margin and profitability

+ Transfer of commercial activities for IXIARO® either to Valneva´ s own teams or new country partners early next year
+ On track to deliver substantial IXIARO® product sales growth up to 50m with a gross-margin above 50% for 2016

New sales & marketing set-ups for IXIARO® and DUKORAL® established or close to execution for key countries

Financial performance in line with strategic plan to progress towards break-even

Significant near term clinical data points on two most advanced R&D programs ahead

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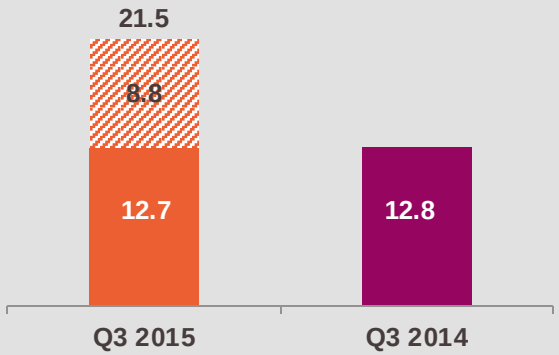
Q3 2015 financial results

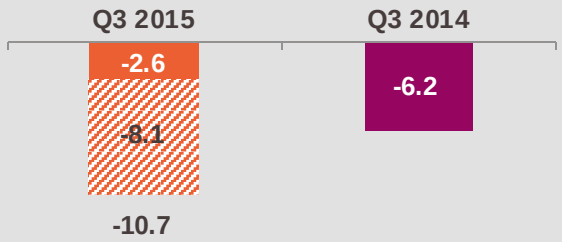
Compared to Q3 2014 (IFRS, EUR million, unaudited)

attributable to acquired Crucell Sweden AB and DUKORAL business

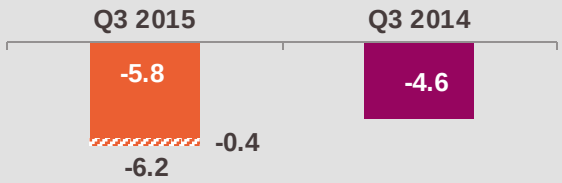
Revenues & Grants



COGS

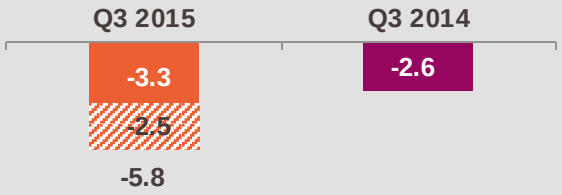


R&D Expenses

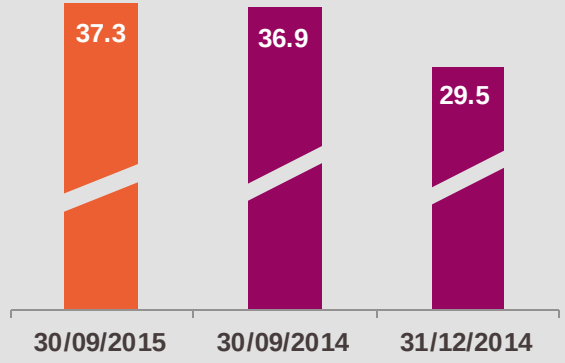


EBITDA*

Net loss



Cash position



* Calculated by adding Q3 2015 amortization, depreciation and impairment of EUR 3.2m to the Q3 2015 operating loss of EUR -2.7m

Q3/Q3 YTD 2015 Profit & Loss

EUR in thousands, unaudited

	3 months ended September 30		9 months ended September 30	
	2015	2014	2015	2014
Product sales	16,672	9,518	44,169	19,282
Revenues from collaborations and licensing, grants	4,796	3,326	16,513	10,034
Cost of goods and services	(10,658)	(6,225)	(37,711)	(10,150)
R&D expenses	(6,241)	(4,630)	(18,730)	(15,220)
SG&A expenses	(5,482)	(2,858)	(16,169)	(10,225)
Other income and expenses, net	163	(104)	309	(241)
Amortization and impairment	(1,905)	(2,024)	(5,689)	(7,446)
OPERATING LOSS	**(2,654)**	**(2,997)**	**(17,308)**	**(13,966)**
Finance, investment and income tax expenses / income	(3,196)	428	(2,529)	(786)
LOSS FOR THE PERIOD	**(5,850)**	**(2,568)**	**(19,838)**	**(14,752)**
EBITDA*	**501**	**(15)**	**(8,012)**	**(3,610)**

*Calculated by adding Q3 2015 amortization, depreciation and impairment of EUR 3.2m to the Q3 2015 operating loss of EUR -2.7m

Q3 YTD 2015 financial analysis

Compared to Q3 YTD 2014 figures, unaudited

9M Aggregate revenues & grants more than doubled to EUR 60.7m from EUR 29.3m

› EUR 24.2m from newly acquired Crucell Sweden/DUKORAL® business

Product sales & gross margins

› IXIARO®/JESPECT®:	EUR 24.7m (+28.3%)	44.0% gross margin
› DUKORAL® :	EUR 12.3m (new)	negative gross margin
› Nordics trade:	EUR 7.1m (new)	28.6% gross margin

COGS of newly acquired products negatively impacted by idle capacity costs and acquisition accounting effects*

Collaboration & licensing revenues increased to EUR 13.2m from EUR 6.1m

› +53.7% revenue growth in 9M excluding acquisition (EUR 3.8 from acquired business)

Research and development expenses

+ Increase to EUR 18.7m from EUR 15.2m driven by clinical study costs for late stage pipeline projects

* product inventory recorded at fair market value at acquisition date and not at historical manufacturing cost

Q3 YTD 2015 financial analysis

Compared to Q3 YTD 2014 figures, unaudited

Sales, general and administrative expenses

+ Increase by EUR 5.9m to EUR 16.2m; includes EUR 6.4m SG&A costs from acquired business, primarily for marketing & sales infrastructure

Loss and EBITDA driven by acquisition effects

- **› YoY improvement in 9M period when excluding acquired business**
- **› Positive EBITDA in Q3**

+ 9M Net Loss: EUR 19.8m (+34.5% or EUR 5.1m yoy); includes net loss of acquired business of EUR 5.6m

+ 9M EBITDA: EUR -8.0m (compared to EUR 3.6m in 9M 2014); includes EUR -5.6m from acquired business

Strong Cash position

+ EUR 37.3m, strengthened by the capital increase in early 2015;

FY 2015 financial outlook confirmed: Revenues above EUR 75m, negative EBITDA and increased net loss expected due to acquisition effects and IXIARO® transition

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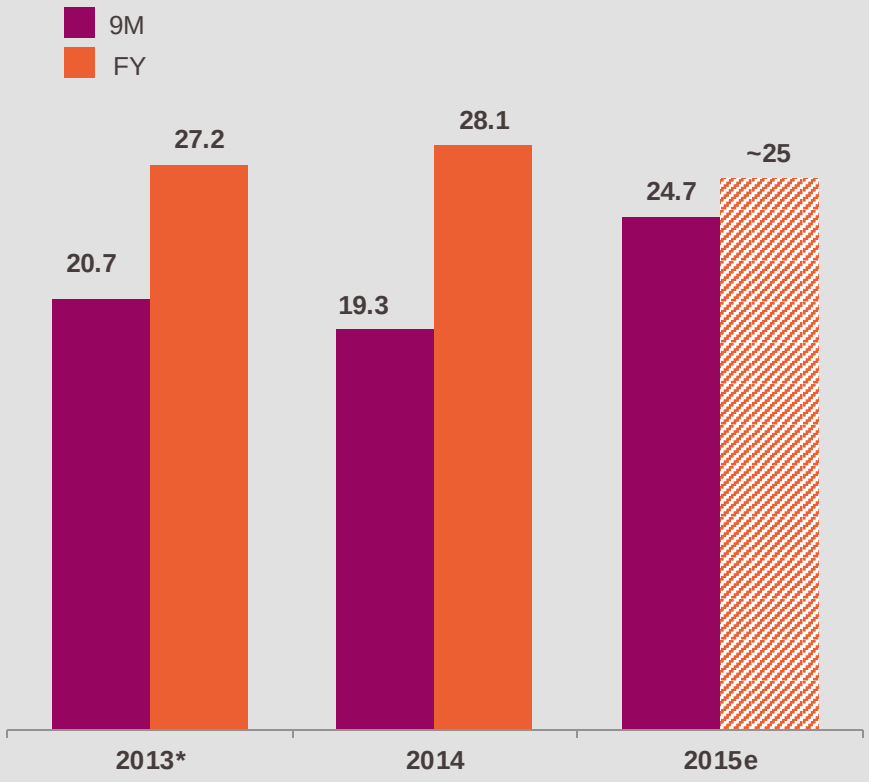
Commercial product: Japanese encephalitis vaccine

Strong growth of IXIARO®/JESPECT® in-market sales

Product sales revenues (EUR m)



Q3/9M 2015 sales analysis

+ Q3 revenues +1.7% to EUR 9.7m vs. EUR 9.5 m in Q3 2014

+ 9M revenues +28.3% to EUR 24.7m vs. EUR 19.3m (9M 2014)
  - › Strong growth of in-market sales, driven by increasing vaccination rates in the key private travelers markets in Europe and the U.S., strong demand by the U.S. military

FY 2015 Outlook

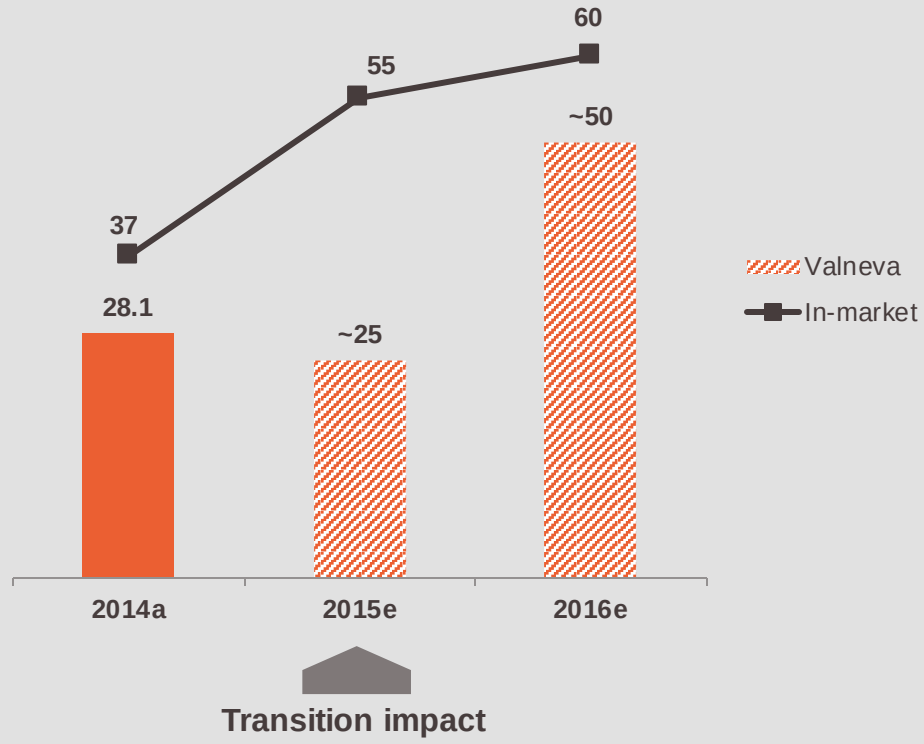
+ FY 2015 sales expected to be less than 2014 (EUR 28.1m), Q4 sales negatively affected by M&D transition to Valneva
  - › Deliveries for most markets have stopped, GSK selling remaining inventory
  - › In-market sales expected to be consistent with previous estimates

* For detailed explanation of pro forma assumptions and reconciliation to IFRS results see the Company's website www.valneva.com

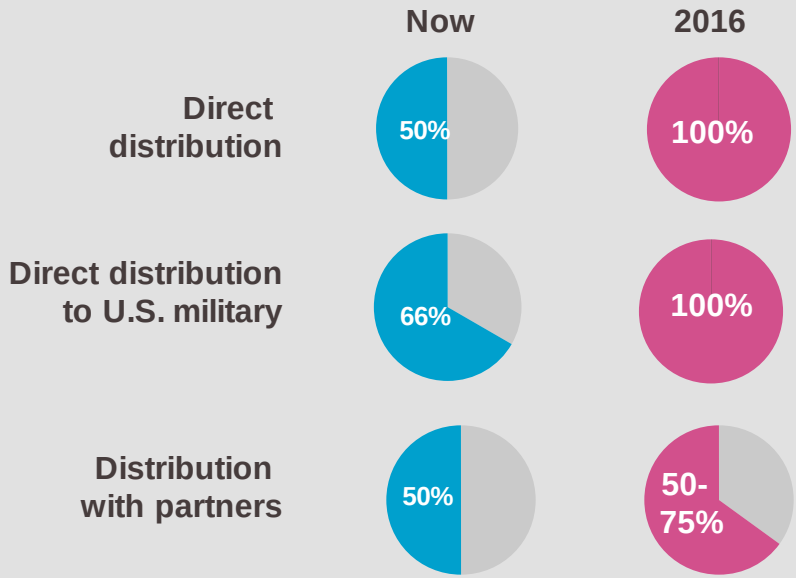
Commercial product: Japanese encephalitis vaccine

Strong growth of IXIARO®/JESPECT® in-market sales

Product sales revenues (EUR m)



Revenue recognition of in-market sales



Valneva expects to significantly improve sales margin and profitability of its JE vaccine in 2016 and onwards.

* For detailed explanation of pro forma assumptions and reconciliation to IFRS results see the Company's website www.valneva.com

New sales & marketing infrastructures for IXIARO® and DUKORAL® for key countries

Covering 90% of the Company's expected 2016 product sales

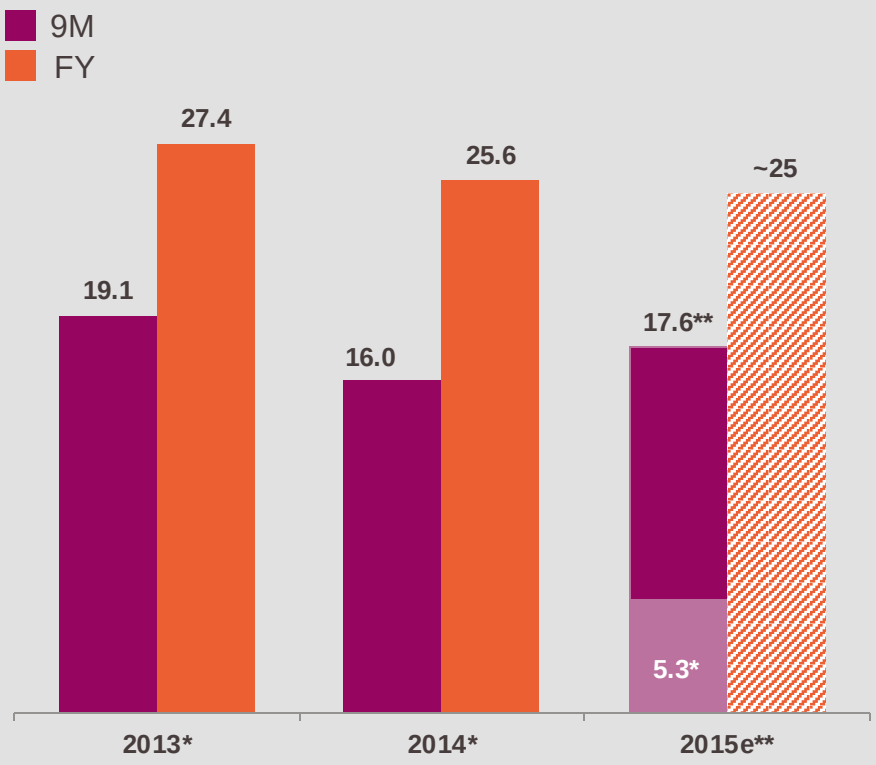
	IXIARO®	DUKORAL®
U.S. private	VaxServe	-
U.S. Military	Valneva*	-
Canada	Valneva Canada	Valneva Canada
Europe		
Germany, Austria	Partner, close to contract finalization	Partner, close to contract finalization
UK	Valneva UK	Valneva UK
Scandinavian countries	Valneva Sweden	Valneva Sweden
Rest of Europe	Partners, close to contract finalization	PaxVax, other agreements close to contract finalization
Australia, New Zealand	bioCSL	bioCSL
Taiwan	Adimmune Corporation**	-
Israel, Singapore, Hongkong	Partner, close to contract finalization	Partner, close to contract finalization

* Through its subsidiary Intercell USA, **product based on Valneva's technology

Commercial product: Cholera/ (ETEC) vaccine

DUKORAL® analysis of sales and growth potential

DUKORAL® sales (in EUR m, pro forma**)



Q3/9M 2015 sales analysis

+ Q3 revenues slightly decreased to EUR 4.2m from EUR 4.5 m in Q3 2014
+ 9M pro forma revenues were EUR 17.6m** vs. EUR 16.0m (9M 2014)
+ Strong sales in key markets (Canada and other select markets in Europe), positive impact from favorable exchange rates

Outlook

+ Own sales force in Canada to directly control commercialization
+ M&D network: combination of Valneva's own sales and marketing teams and country-specific agreements:
  - › U.S. company PaxVax to commercialize DUKORAL® in Italy, Spain and Portugal
+ Promotional efforts and geographical expansion
+ Investment to build for future growth

* Johnson & Johnson pro forma management reporting, unaudited figures, ** including sales achieved by the previous owner between Jan 1 and Feb 9, 2015

Nordics trade and update on integration of the acquired business

Nordics trade business

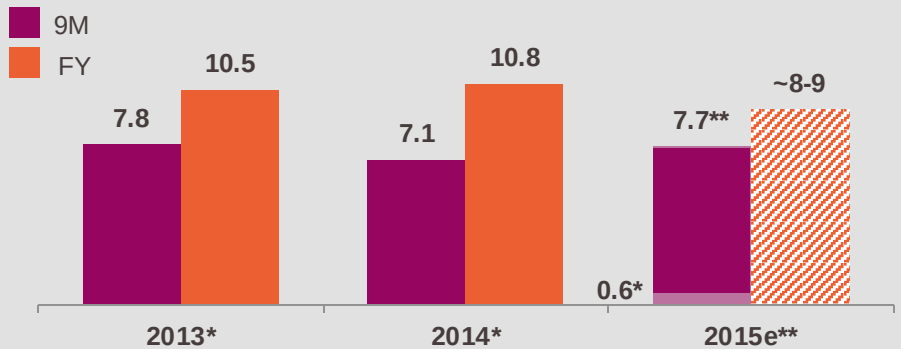
+ Q3 2015 revenues amounted to EUR 2.7m vs. EUR 2.0m pro forma in Q3 2014
+ 9M 2015 revenues of EUR 7.7m** vs. EUR 7.1m in 9M 2014
+ Leverage S&M infrastructure for 3rd party products in one of Europe's key travel markets (i.e. PaxVax's typhoid vaccine VIVOTIF®)

Update on Integration

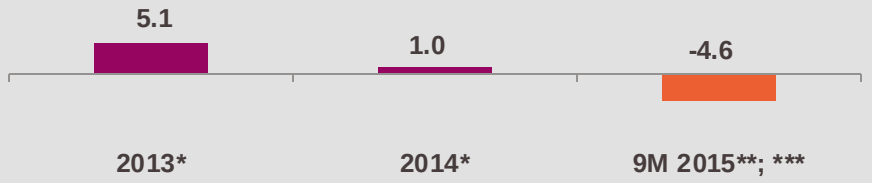
+ Integration of acquired business into Valneva progressing
+ Restructuring of the cost base of manufacturing site in Sweden ongoing

The Company expects the acquired business to become profitable following the transitional 2015 period.

Sales of 3rd party products (in EUR m, pro forma**)



Profit/Loss in EUR m, pro forma



* Johnson & Johnson pro forma management reporting, unaudited figures, ** including period from the previous owner between Jan 1 and Feb 9, 2015; *** including accounting effects from acquisition

EB66® cell line platform for efficient vaccine production

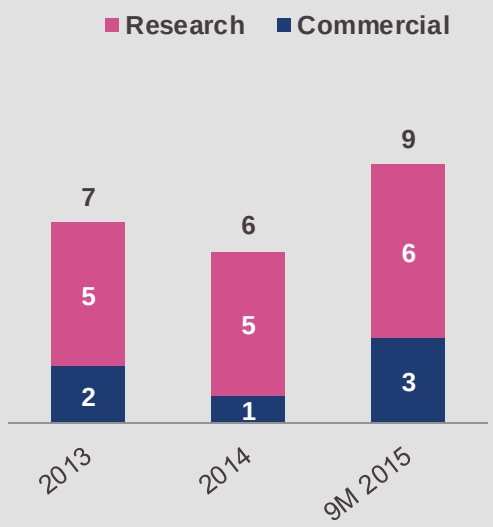
Two new EB66® licenses recently signed

Revenue generating platform

+ Fully characterized cell-line (avian embryonic stem cell derived) for efficient large scale manufacturing of human and veterinary vaccines
+ Over 35 agreements with the world's largest pharmaceutical companies
+ 7 new licenses signed on average per year
+ EUR 34m in upfront, milestones & research fees received YTD
+ Exclusive license to Jianshun Biosciences to commercialize EB66® in China (granted in March 2015)

JSB 健顺生物 IOSCIENCES

9 new licenses already signed this year



Two license agreements recently signed

Commercial agreement with one of the top 5 animal health companies worldwide

+ License to enter into field trials with vaccine derived from EB66® cells against an undisclosed disease target

Clinical development agreement with Jenner Institute

+ A partnership formed between the University of Oxford and the Pirbright Institute to develop innovative vaccines against major global infectious diseases
+ License to use EB66® to manufacture vaccines through phase II study

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Pre-commercial product: Pseudomonas aeruginosa vaccine

Targeting hospital-acquired pneumonia, with a market potential of USD 1bn

Pseudomonas aeruginosa

+ Causes ~20% of all nosocomial (hospital-acquired) infections [1,2]
  - › Presence of Pseudomonas aeruginosa in ventilated patients associated with increased mortality rate[3]
+ Resistance to antimicrobial agents is increasingly common[4]
+ Target population: patients in intensive care units on mechanical ventilation
  - › Up to 1,000,000 in the U.S. and Europe per year[5]
  - › All-cause mortality rate of 20% to 40% in this target population[6]

Commercial position

+ Hospital-acquired pneumonia is a major healthcare burden with additional costs estimated ~USD10,000 per case[6]
  - › No commercial vaccine available
  - › Medical need expected to result in fast adoption by specialist and insurers, even in case of modest efficacy
  - › Valneva has most advanced late-stage vaccine candidate of the industry
+ Total market estimate of USD 1bn for U.S. and Europe in target population

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** Robert Koch Institut: Gesundheitsbericht des Bundes Heft 8; **4** Rosenthal VD et al. International Nosocomial Infection Control Consortium (INICC) report, data summary for 2003-2008, issued June 2009. **5** McConville, M.D., John P. Kress, M.D. Weaning Patients from the Ventilator, N Engl J Med 2012; 367:2233-2239; **6** Vincent et al, JAMA 1995; 274:639-644;

Pre-commercial product: Pseudomonas aeruginosa vaccine

Valneva's vaccine candidate VLA43 is being tested in a clinical phase II/III study

Valneva's vaccine candidate

+ Recombinant OprF/I fusion produced in E.coli
+ No preservatives
+ Liquid formulation
+ 2 injections (days 0 and 7)

Advantages

+ Only clinical vaccine program
+ Resistance not expected
+ OprF/I are highly conserved proteins => broad strain coverage possible

Current development status

+ 800 patients enrolled (co-financed by GSK[1])
+ Reduction in mortality as primary endpoint
+ Interim analysis after 400 patients[2] confirmed clinically meaningful effect but less pronounced
+ Valneva considers ≥5% absolute difference licensable product
+ Valneva conducted additional post-hoc analysis and amended trial protocol
  - › Addition of a secondary endpoint for subgroup of patients

Competition

+ No vaccine on the market
+ Antibiotic treatment on the market
+ Vaccines in pre-clinical development: Astrogenetix, GlycoVaxyn, Vaxdyn
+ Many active antibody programs in pre-clinical stages

Data release expected in Q2 2016

+ Valneva will release data from the ongoing phase II/III efficacy trial, including day 180 follow-up time-points

1 GSK opt-in rights under pre-defined terms: GSK will have rights to opt in, under SAA with GSK: Intercell Annual report 2012, p. 39,45; 2 Valneva PR 2013-10-30 and 2014-03-24. Fully blinded, analysis conducted by Data Monitoring Committee;

Pre-commercial product: Clostridium difficile vaccine

Vaccine targeting healthcare-associated diarrhea, an increasing threat to elderly

Clostridium difficile

+ Single most common pathogen of acute healthcare-associated infections in the U.S.[1]
  - › Estimated 450,000 cases of Clostridium difficile annually[2]
  - › Approximately 29,000 died within 30 days after diagnosis[2]
+ Estimated 172,000 cases in EU member states per year[3]
+ Current antibiotic treatments have significant limitations with recurrence in ~20% of cases[4]
+ Wide range of severity, complicated cases may require emergency surgical intervention associa up to 80% mortality[4]

Commercial position

+ Infections associated with significant economic burden due to prolongation of hospitalization, est. USD 4.8 billion for U.S. acute care facilities alone[5]
+ About one-third of cases are community-acquired, indicating need for prevention beyond the hospital setting[2]
+ No commercial vaccine available
+ One amongst three clinical stage programs in the industry
  - › Potential competitive advantage on more cost efficient production
+ Target groups: elective admissions and long-term care facility residents
+ Total market estimate of >USD 1 bn/year target groups[6]

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** Dubberke ER, Clinical Infectious Diseases 55, no. suppl 2 (2012): S88-S92; **6** VacZine Analytics Clostridium difficile prophylactic vaccines Market View, January 2014;

Pre-commercial product: Clostridium difficile vaccine

Current development status VLA84 (Phase II)

Valneva's vaccine candidate

+ Vaccine targeting primary prevention through active immunization of risk groups, potentially extending towards more universal prophylaxis in the elderly population
+ Recombinant fusion protein of relevant parts of toxins A and B
+ Liquid formulation (w/ and w/o Alum)
+ 3 injections on days 0, 7 and 28

Advantages

+ Production at low cost of goods possible
+ Excellent stability profile
+ Fully characterized recombinant protein

Current development status

+ Phase I in healthy adults and elderly successfully completed[1]
+ Vaccine highly immunogenic and generally safe[2]
+ Phase II to confirm final vaccine candidate in older adults and elderly (≥ 50 years of age) ongoing[3]
+ Study conducted in U.S. & Germany

Competition

Vaccine candidates

+ Sanofi: clinical phase III study ongoing[5]
+ Pfizer: clinical phase II study ongoing[6]

Merck's monoclonal antibody

+ Targeting recurring Clostridium difficile only

First phase II results expected to be disclosed within next weeks

+ GSK will have rights to opt in[4]

1: NCT01296386; **2** Valneva CSR IC84-101; **3** NCT02316470; **4** If Phase II successful under pre-defined terms, under SAA with GSK: Intercell Annual report 2012, p. 39,45; **5** NCT01887912; **6** NCT02561195

Pre-commercial product: Lyme borreliosis vaccine

Targeting Lyme borreliosis, with market potential of above EUR 500m

Lyme borreliosis

+ Transmitted by Ixodes ticks[1], causing Lyme borreliosis
+ Most common vector borne illness in the Northern Hemisphere
  - › Estimated ~300,000 cases per year in U.S.[3] and ~85,000 cases per year in Europe[2]
+ Delayed or inadequate treatment can lead to very serious symptoms, involving the joints, heart, and central nervous system, and can be disabling.
+ A vaccine needs to protect against the major species causing the disease
  - › Targeting the outer surface protein A (OspA) of Borrelia (several serotypes present)

Commercial position

+ No commercial vaccine available
+ Market potential of >EUR 500m for Europe and U.S.[5]
  - › Priority in Europe markets where high awareness on tick transmitted diseases exists
  - › In key high-incidence territories penetration rates of up to 10% can be expected, given likely reimbursement status

Current development status VLA15 (Pre-clinical)

+ Pre-clinical testing completed
+ IND submission initiated
+ Clinical entry planned for 2016
+ GSK opt-in rights[4]

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** If Phase II successful under pre-defined terms, under SAA with GSK: Intercell Annual report 2012, p. 39,45; **5** Estimate of Valneva, concentrated in private markets

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Outlook: R&D pipeline 2015/2016

Our in-house vaccine development programs are moving towards next value inflection points

Pseudomonas aeruginosa
+ Final phase II/III data release in Q2 2016

Clostridium difficile
+ First phase II clinical results in Q4 2015

Lyme borreliosis
+ Phase I clinical study to be initiated in H2 2016

Additional pre-clinical R&D programs are progressing
+ Valneva is conducting pre-clinical vaccine research for new vaccine candidates
+ Lead projects in the area of travel vaccines, other vaccine indications in areas of high, unmet medical need.

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Thank you.

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