Valneva SE presents its Q2/H1 2015 financial results

Analyst Presentation
August 31, 2015

valneva

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Forward Looking Statements

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The Company is providing the information in these materials as of this date, and we 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 – Key Events – *Thomas Lingelbach*

2. Financial report Q2/H1 2015 and outlook – *Reinhard Kandera*

3. Commercialized Products & EB66® – *Franck Grimaud*

4. R&D programs – *Thomas Lingelbach*

5. Outlook – *Thomas Lingelbach*

6. Q&A

Valneva's newsflow

July 2015

+ New EB66® agreements with Fatro and Kaketsuken, 7 deals signed since beginning of year
+ Valneva and PaxVax enter into marketing and distribution agreement

June 2015

+ Valneva takes direct control over M&D of IXIARO® to increase margin and profitability

May 2015

+ European approval of an alternative rapid IXIARO® vaccination schedule for adults

March 2015

+ Second approval for a human vaccine produced in EB66® – Japan (prototype vaccine)
+ Exclusive license agreement with Jianshun Biosciences to commercialize EB66® in China
+ New EB66® deals with Merial and two undisclosed veterinary vaccine manufacturers

February 2015

+ Valneva acquired DUKORAL® and a vaccine distribution infrastructure in the Nordics
+ Valneva announces the successful completion of its EUR 45 m capital increase

January 2015

+ Exclusive worldwide license to ITS (now Vaxin) for development of Hepatitis B vaccines in combination with the IC31® adjuvant
+ Spin-off of antibody business: Valneva and BliNK Therapeutics created BliNK Biomedical

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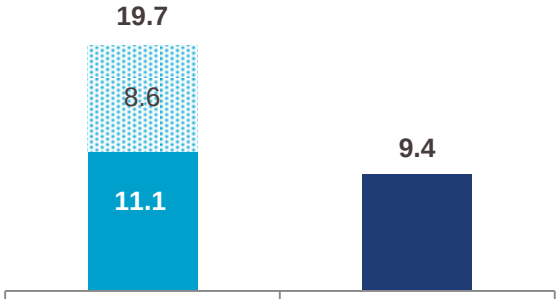
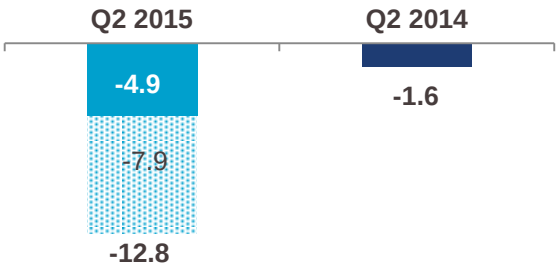
Q2 2015 Financial Results
Compared to Q2 2014 (IFRS, EUR million, unaudited*)

attributable to acquired Crucell Sweden AB and DUKORAL business

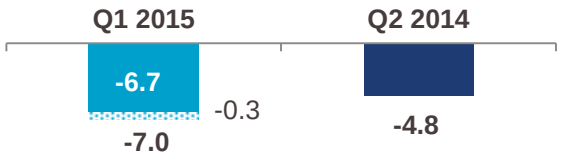
Revenues & Grants



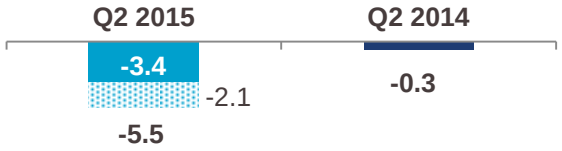
COGS



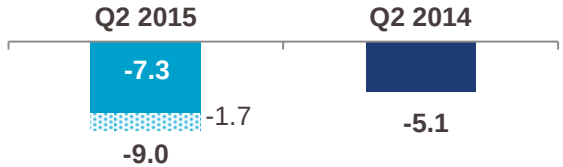
R&D Expenses



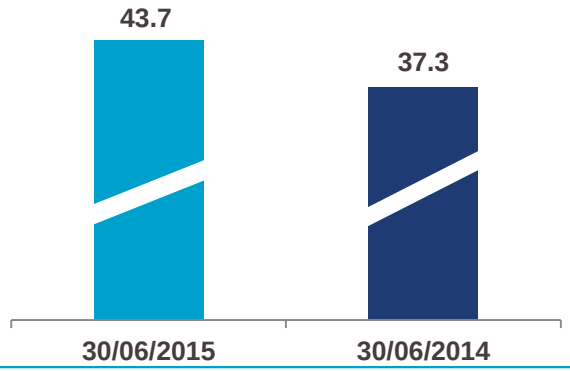
EBITDA**



Net loss



Cash position



* however auditors performed a limited review **calculated as operating loss deducting amortization, depreciation & impairment

Q2/H1 2015 Profit & Loss*
(EUR in thousands)

	3 months ended June 30,		6 months ended June 30,	
	2015	*2014*	*2015*	*2014*
Product sales	12,360	5,941	27,497	9,764
Revenues from collaborations and licensing, grants	7,353	3,434	11,717	6,707
Revenues and grants	19,713	9,376	**39,214**	**16,471**
Cost of goods and services	(12,795)	(1,566)	(27,053)	(3,925)
R&D expenses	(6,985)	(4,814)	(12,489)	(10,590)
S,G&A expenses	(6,660)	(4,188)	(10,688)	(7,368)
Other income and expenses, net	(6)	(63)	146	(136)
Amortization and impairment	(1,960)	(3,266)	(3,784)	(5,421)
OPERATING LOSS	**(8,693)**	**(4,521)**	**(14,654)**	**(10,969)**
Finance, investment and income tax expenses / income	(277)	(551)	666	(1,214)
LOSS FOR THE PERIOD	**(8,970)**	**(5,071)**	**(13,988)**	**(12,184)**
EBITDA**	**(5,450)**	**(302)**	**(8,513)**	**(3,595)**

*unaudited; ** calculated as operating loss deducting amortization, depreciation & impairment

H1 2015 Financial Analysis
Compared to H1 2014 figures

Revenues

+ Increase of aggregate revenues & grants by EUR 22.7 to EUR 39.2m; includes EUR 14.9 from newly acquired Crucell Sweden/Dukoral business

+ Product sales include:	IXIARO®/JESPECT®:	EUR 15.1m (+54.0%)
	DUKORAL® :	EUR 8.1m (new)
	Nordics trade:	EUR 4.3m (new)

+ Collaboration, licensing & service income increased by EUR 5.1m to EUR 9.7m including EUR 2.5 from acquired business; EUR 2.6m growth (+57.6%) excluding acquisition effect

Cost of goods and services

+ EUR 11.2m IXIARO®/JESPECT® COGS => 25.6% gross margin
+ EUR 10.0m COGS for DUKORAL®, impacted by idle capacity costs during manufacturing transition period and by non-cash accounting effects (product inventory recorded at fair market value and not at manufacturing cost)
+ EUR 3.4m COGS for Nordics trade => 20.9% gross margin (also impacted by accounting effects)
+ EUR 2.4m cost of services

H1 2015 Financial Analysis

Compared to H1 2014 figures

Research and development expenses

+ Increase to EUR 12.5m from EUR 10.6m driven by clinical study costs for late stage pipeline projects

Sales, general and administrative expenses

+ Increase by EUR 3.3m to EUR 10.7m; includes EUR 4.2m SG&A costs from acquired business, primarily for marketing & sales infrastructure

Amortization and impairment of intangible assets

+ EUR 3.8m non-cash amortization charges;
  no impairments in H1 2015 (compared to EUR 1.3m in H1 2014)

Net loss

+ H1 net loss: EUR 14.0m (+14.8% or EUR 1.8m yoy);
  includes net loss of acquired business of EUR 3.1m

EBITDA

+ H1 EBITDA: EUR -8.5m (- EUR 4.9m yoy);
  includes EUR -4.1m from acquired business

Cash position

+ EUR 43.7m, strengthened by the capital increase in early 2015;
  compared to EUR 37.3m at June 30, 2014

Financial Outlook

2015 marked by integration of Crucell Sweden/DUKORAL® and temporary IXIARO® transition impact

FY 2015 revenues and grants:
expected at lower end of communicated EUR 75 to EUR 85 m range

+ Growth driven by acquired Crucell Sweden and Dukoral® business
+ Negative short-term transition impact from taking direct control of IXIARO®'s marketing and distribution
+ Significant improvement in revenues and profitability of the JE vaccine expected from 2016 onwards

FY 2015 net loss: No improvement in net loss in this transitional year but setting the base for moving towards break-even

+ Integration of DUKORAL® and Nordics trade, cost improvements and decreasing impact of acquisition accounting effects
+ Build-up of marketing and distribution of the Company's key value generator IXIARO® to improve product margin and profitability

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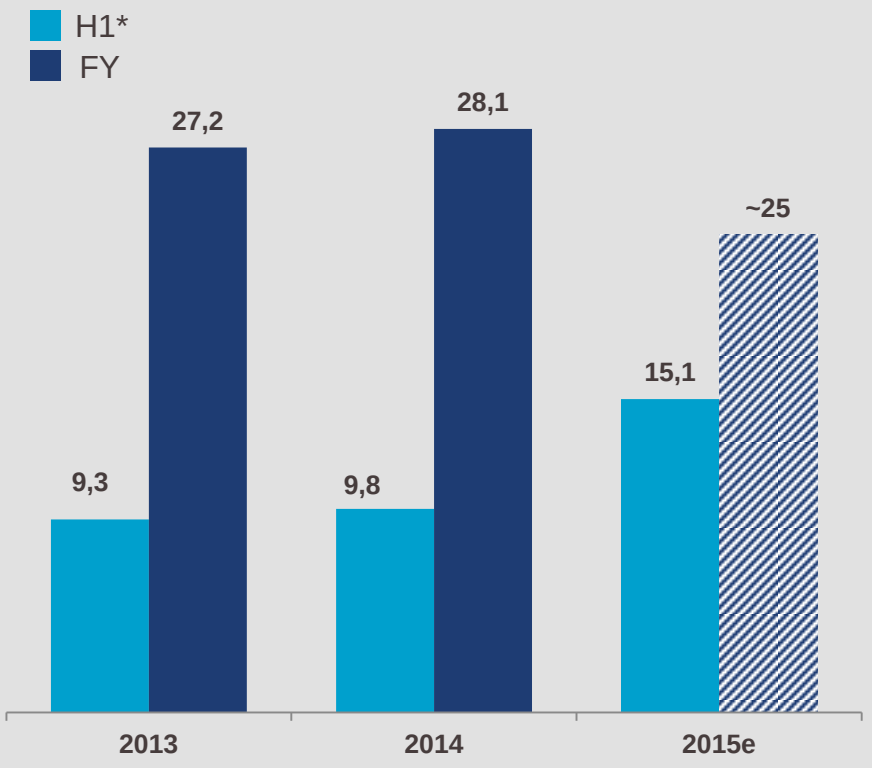
Commercial product: Japanese encephalitis vaccine 1/2
IXIARO®/JESPECT® update

Product sales revenues (in EUR m)



Q2/H1 2015 update

JE vaccine product sales revenues increased by 54% to EUR 15.1m in H1 2015 vs. EUR 9.8m in H1 2014

+ Benefiting from continued growth of in-market sales

Q2 2015 product sales EUR 5.3m vs. EUR 5.9m in Q2 2014

+ Slightly impacted by timing effects of deliveries to main distributor

European approval of an alternative rapid IXIARO® vaccination schedule for adults

2015 Outlook

Sales will be negatively affected by M&D transition from GSK to Valneva: now expected to be EUR 25m compared to previous guidance of EUR 30m

+ In-market sales are expected to be consistent with previous estimates, lower revenues result primarily from GSK‘s right to sell its remaining inventories

Valneva to fully make up for this short-term adverse financial impact already in 2016

Commercial product: Japanese encephalitis vaccine 2/2

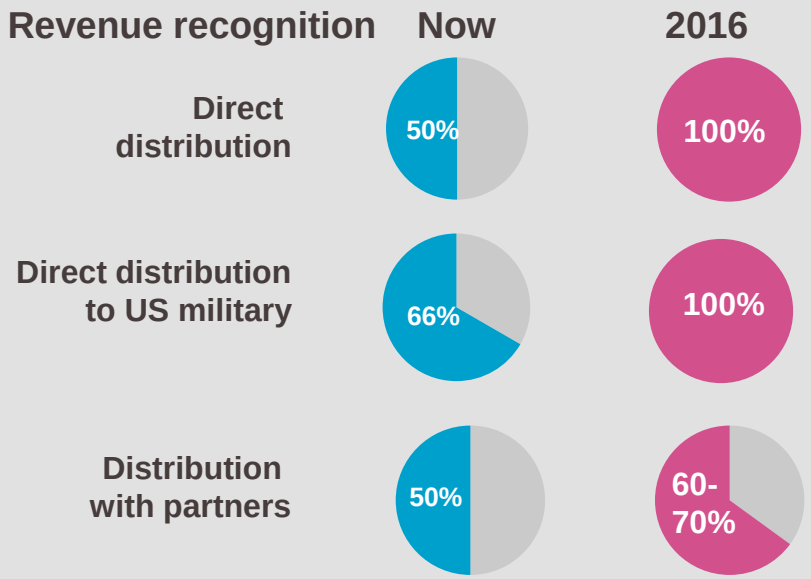
Valneva takes direct control over marketing and distribution of IXIARO® to increase margin and profitability

Valneva has terminated the IXIARO®-related marketing and distribution agreement with GSK

+ Valneva to manage the commercialization and future growth of IXIARO®
+ Through own sales & marketing teams (Canada, European Nordic countries) and with established local partners, direct distribution to US military
+ Opportunity to leverage synergies with recently acquired vaccine DUKORAL® and distribution infrastructure in the Nordics
+ Strategic Alliance Agreement for R&D portfolio remains; EB66® license agreements not impacted

This step supports Valneva's strategy to become a leading, independent and fully integrated vaccines biotech company.

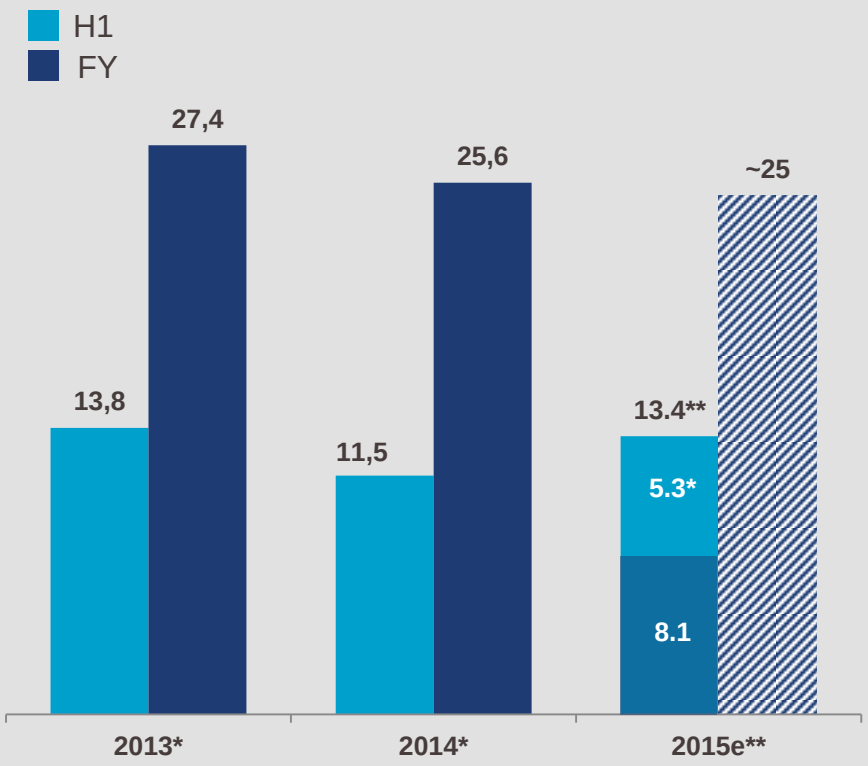
Significant improvement of sales margin and profitability of IXIARO® expected from 2016



Following the completion of the transition, annual IXIARO® net sales revenues are expected to increase to more than EUR 50 million.

Commercial product: Cholera/ (ETEC) vaccine
DUKORAL® analysis of sales and growth potential

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



Q2/H1 Update

H1 2015 DUKORAL® pro forma product sales revenues amounted to EUR 13.4m compared to 11.5m pro forma in H1 2014**

+ Strong sales in key markets (Canada and other select markets in Europe), positive impact from favorable exchange rates
+ Completion of gradual take-over of transitional services before year-end expected

Growth initiatives

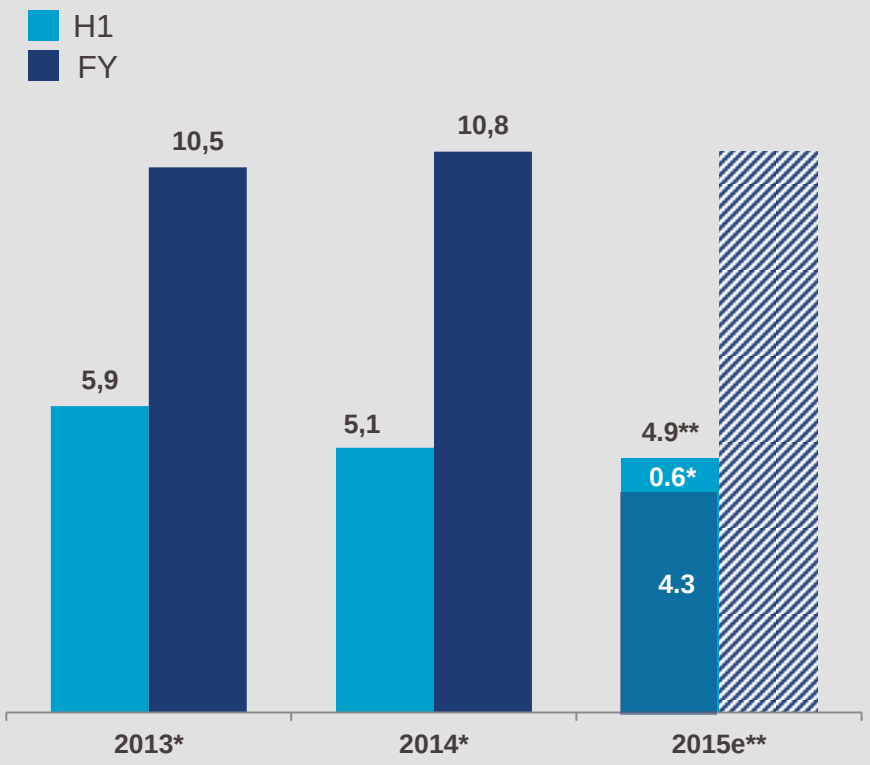
+ Own sales and marketing force in Canada with the objective to directly control commercialization
+ Marketing and distribution network is being set up for other territories: combination of Valneva's own sales and marketing teams and country-specific agreements:
  - › US company PaxVax will commercialize DUKORAL® in Italy, Spain and Portugal
+ Promotional efforts and geographical expansion

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

Commercial platform – Nordics Trade

Leveraging presence in the European Nordic countries with complementary products

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



SBL Vaccin Distribution

+ Business established historically to distribute the company's own vaccines
+ Marketing, sales & distribution services are offered to third-parties
+ Joint operations with Solna manufacturing site

Key Strengths

+ Domestic player in Nordics vaccine space
+ Established contacts with all distributors and channels
+ High share of voice amongst customers
+ Established contacts with all Nordic key opinion leaders in the travel segment

Strategy

+ Leverage infrastructure for our products in one of Europe's key travel markets
+ Valneva will commercialize VIVOTIF® in Canada, Sweden, Norway, Denmark and Finland

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

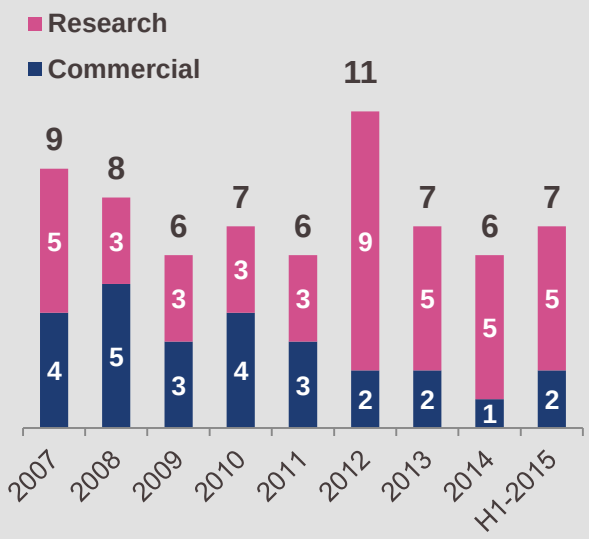
EB66® cell line platform
A breakthrough technology in vaccine production

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 biggest 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

Yearly target of 7 new licenses per year reached



EB66®'s regulatory approvals & commercialization status

Approved human vaccines

+ Prototype influenza vaccine, Japan – Kaketsuken
+ H5N1 pandemic vaccine, Japan – Kaketsuken

Approved veterinary vaccines:

+ Duck Parvovirus (MDPV), Europe – Merial
+ Inclusion body hepatitis (IBH), Latin America – Farvet
+ Egg drop Syndrome, Japan – Kaketsuken

Potential additional milestones of up to EUR 80m and royalty payments from existing licenses

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Pre-commercial product: Pseudomonas aeruginosa vaccine 1/3

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]
+ Target population: patients in the intensive care unit on mechanical ventilation
  - › Up to 1,000,000 in the U.S. and Europe per year[4]
  - › All-cause mortality rate of 20% to 40% in this target population[5]

Current development status VLA43 (phase II/III)

+ 800 patients enrolled in current ph II/III study (co-financed by GSK[7])
  - › Reduction in mortality as primary endpoint
  - › Interim analysis after 400 patients[8] confirmed clinically meaningful effect but less pronounced
  - › We consider ≥5% absolute difference licensable product
+ Valneva conducted additional post-hoc analysis and supportive research
  - › Current trial protocol will be amended to include additional endpoints
  - › Data release expected Q2/2016 – awaiting data including Day 180 follow-up

Commercial position

+ Hospital-acquired pneumonia is a major healthcare burden with additional costs estimated ~USD10,000 per case[9]
  - › 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 US 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** McConville, M.D., John P. Kress, M.D. Weaning Patients from the Ventilator, N Engl J Med 2012; 367:2233-2239; **5** Vincent et al, JAMA 1995; 274:639-644; **6** Valneva CSR IC43-201; **7** GSK opt-in rights under pre-defined terms, under SAA with GSK: Intercell Annual report 2012, p. 39,45; **8** Valneva PR 2013-10-30 and 2014-03-24. Fully blinded, analysis conducted by Data Monitoring Committee; **9** P.W. Stone, Economic burden of healthcare-associated infections: an American perspective. Expert Rev Pharmacoecon Outcomes Res. Oct 2009; 9(5): 417–422.

Pre-commercial product: Pseudomonas aeruginosa vaccine 2/3

Overview of study findings, phase II post-hoc analysis and update of phase II/III study

Pre-clinical[1]

Protective in a murine lethal Pseudomonas aeruginosa challenge model

Phase I (163 subjects)[2]

Immunogenic in healthy volunteers, Safe and well tolerated

Phase II (400 patients)[2]

+ Immunogenic in ICU patients, no safety concerns
+ Significant reduction of all-cause mortality vs. placebo*
+ Significant prognostic value of OprF/I titer on survival
+ Reduced mortality rates in patients with infection

Interim findings** from phase II/III interim (394 patients)[3]

+ Clinically meaningful difference in mortality rates vaccine-placebo
+ No safety concerns regarding safety profile
+ Difference in mortality not as pronounced and planned based on phase II (therefore formally futile)
+ Trends on mortality progression (efficacy) confirmed

Additional findings from phase II post-hoc analysis

+ Interesting findings in sub-patient populations with certain co-morbidities

Additional research on the contemplated mode-of-action conducted

Potential extension of the current phase II/III evaluated

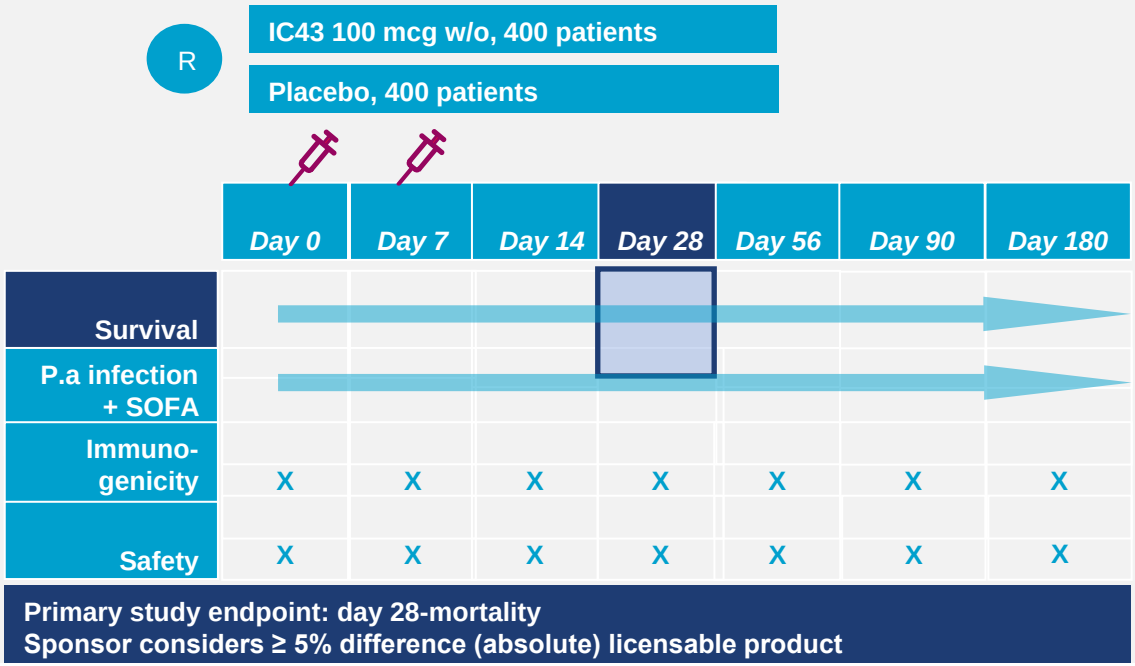
+ Valneva and GSK decided not to extent the study further
+ Study protocol will be amended for additional clinical endpoints
+ Valneva will await full analysis from phase II/III efficacy trial, incl. day 180 follow-up time-points before releasing data in Q2 2016
+ Current study keeps pivotal character should the primary endpoint be met, and hence be in support of product licensure

1 Investigator's Brochure 8.0, section "non-clinical pharmacology studies", pp 26-28, 2 Intercell PR 2010.10.25, 3 Valneva PR 2013.10.30.
*: Statistically significant reduction of mortality for group vaccinated with 100mcg w/o Alum (formulation chosen for ongoing phase II/III trial)
** Fully blinded / Analysis conducted by Data Monitoring Committee

Pre-commercial product: Pseudomonas aeruginosa vaccine 3/3

VLA43-202 – a confirmatory efficacy study with pivotal character

+ Phase II/III, double-blind, randomized, multi-center, placebo-controlled pivotal efficacy study*
+ Participating countries: Austria, Belgium, Hungary, Germany, Spain, Czech Republic



Possible positive outcomes of phase II/III study:

If primary endpoint is met, study outcome supports product licensure.

Primary endpoint not met, but study confirms a clinically meaningful vaccines effect, phase III study required for product licensure.

Primary endpoint not met, but study confirms vaccines effect in different target setting, phase III study with different endpoints required.

*Based on EMA scientific advice obtained in October 2011

Pre-commercial product: Clostridium difficile vaccine

Targeting healthcare-associated diarrhea, with market potential of USD 1bn

Clostridium difficile

+ Single most common pathogen of acute healthcare-associated diarrhea in the US[1]
  - › Estimated 470,000 cases of Clostridium Difficile globally in 2013[2]
  - › 75% of cases reported in US, incidence rising[3]
  - › Linked to 14,000 deaths per year in US[1]
  - › Estimated 172,000 cases in EU member states per year[4]
+ Target groups: elective admissions and long-term care facility residents

Current development status VLA84 (phase II)

+ Phase I in healthy adults and elderly successfully completed
  - › Vaccine highly immunogenic and generally safe[5]
+ Phase II for final vaccine candidate in elderly (≥ 50 years of age)
  - › Study conducted in US & Germany
  - › Data expected by end 2015
  - › GSK opt-in rights[6]

Commercial position

+ Infections associated with significant economic burden due to prolongation of hospitalization[7]
+ One amongst three clinical stage programs in the industry
  - › Expected to enter market as number two
  - › Potential competitive advantage on more cost efficient production
+ Total market estimate of > USD 1 bn/year target groups

Source picture: www.123rf.com; **1** CDC MMWR (2012) Vol.61; **2** VacZine Analytics Clostridium difficile prophylactic vaccines Market View, January 2014; **3** 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; **4** Clostridium difficile infection in Europe. A CDI Europe Report.; **5** Valneva CSR IC43-201; **6** if Phase II successful under pre-defined terms, under SAA with GSK: Intercell Annual report 2012, p. 39,45; **7** Dubberke ER, Clinical Infectious Diseases 55, no. suppl 2 (2012): S88-S92;

Pre-commercial product: Lyme borreliosis vaccine

Targeting Lyme borreliose, with market potential above EUR 500m

Lyme borreliosis

+ Is transmitted by Ixodes ticks[1], causing Lyme borreliosis
+ Lyme disease is the most common vector borne illness in the Northern Hemisphere
  - › Estimated ~85,000 cases per year in Europe[2]
  - › Estimated ~300,000 cases per year in US[3]
+ A vaccine needs to protect against the major species causing the disease
  - › Targeting the outer surface protein A (OspA) of Borrelia (several serotypes present)

Current development status VLA15 (Pre-clinical)

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

Commercial position

+ One of only two multi-serotype targeting vaccine approaches in the industry
+ Market potential of >EUR 500m for Europe and US[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

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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Anticipated news flow/progress till year end 2015/2016

Commercialized products

+ Deliver on financial performance targets
+ IXIARO® transition including new commercial partners/infrastructure
+ Integration Valneva Sweden/DUKORAL®

Technologies & Services

+ Additional EB66® and IC31® licensing agreements expected
+ Clinical entry (Phase I/II) for EB66® based seasonal influenza vaccine anticipated
+ First Japanese stockpiling for EB66 ® based pandemic influenza vaccine expected

R&D programs

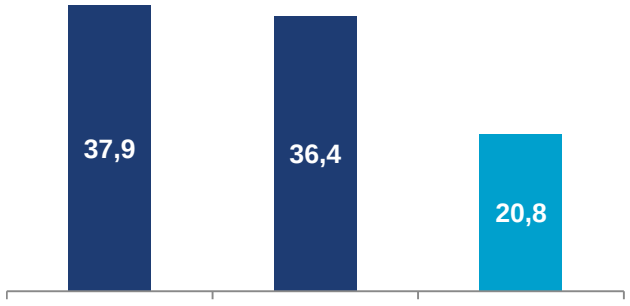
+ Phase II clinical study results from Clostridium difficile vaccine candidate
+ Pseudomonas aeruginosa vaccine candidate: amended study protocol of phase II/III for additional clinical endpoints: data release in Q2 2016
+ Phase I clinical study for Lyme borreliosis vaccine candidate to be initiated in 2016

Update on transition and integration of the acquired DUKORAL® and Crucell Sweden AB business

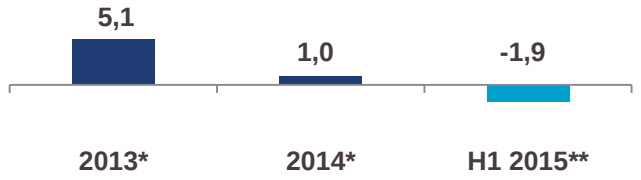
+ Acquired business showed negative gross margin and moderate net loss in H1 2015
+ Integration into Valneva is progressing and restructuring of the cost base of manufacturing site in Sweden ongoing
+ Cost of goods were negatively impacted by idle capacity costs during manufacturing transition and by acquisition accounting effects (acquired product inventory at fair market value)

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

Revenues in EUR m, pro forma



Profit/Loss in EUR m, pro forma



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2. Financial report Q2/H1 2015 and outlook – *Reinhard Kandera*
3. Commercialized Products & EB66® – *Franck Grimaud*
4. R&D programs – *Thomas Lingelbach*
5. Outlook – *Thomas Lingelbach*
6. **Q&A**

Thank you
Merci
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Tack

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