Valneva SE
Analysts Presentation: Q1 2014

May 13th 2014

valneva

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Forward Looking Statements

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Valneva‘s Newsflow - Q1 2014 / beginning of Q2

April 2014

+ Valneva and Adimmune Corporation partner to commercialize Japanese encephalitis vaccine in Taiwan

March 2014

+ New research agreement and transfer of an existing commercial agreement to Emergent Biosolutions for the development of vaccines in the EB66® cell line.
+ Aeras initiates phase II clinical trial of a tuberculosis vaccine candidate using Valneva’s IC31® adjuvant
+ Approval and launch in South America of a second veterinary vaccine produced in the EB66® cell line
+ Continuation decision of the Phase II/III clinical trial for the Pseudomonas aeruginosa vaccine candidate
+ First ever marketing authorization for a human vaccine produced in the EB66® cell line

February 2014

+ Fourth antibody discovery program launched by Sanofi Pasteur

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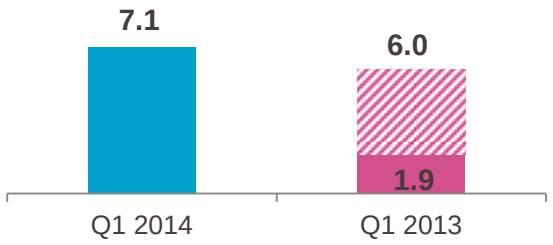
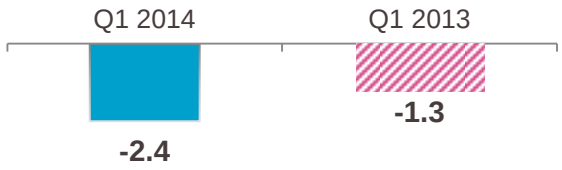
Key figures Q1 2014
IFRS unaudited, EUR million

Q1 2013
Q1 2013 pro forma*

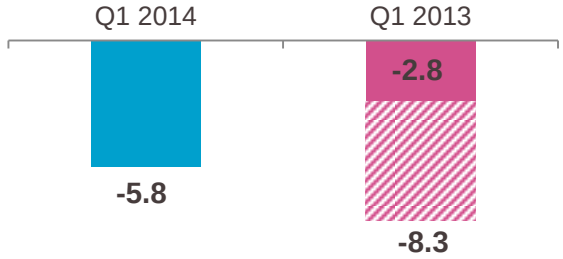
Revenues & grants



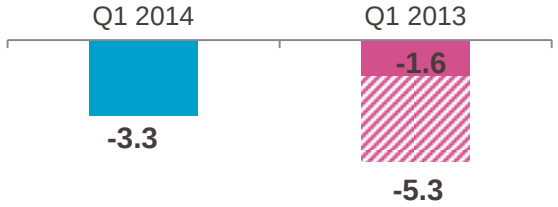
Cost of goods and services



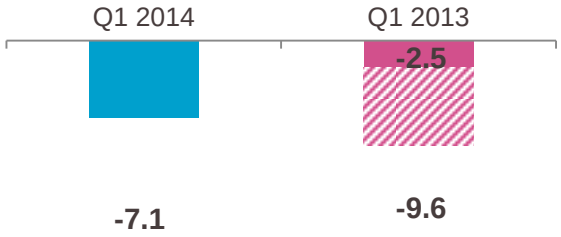
R&D expenses



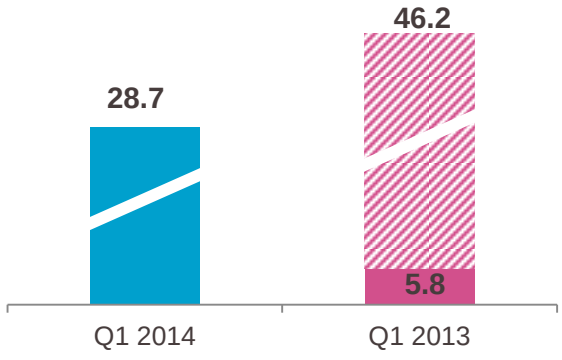
EBITDA



Net loss



Cash



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

Q1 2014 Profit & Loss
IFRS unaudited, EUR in thousands

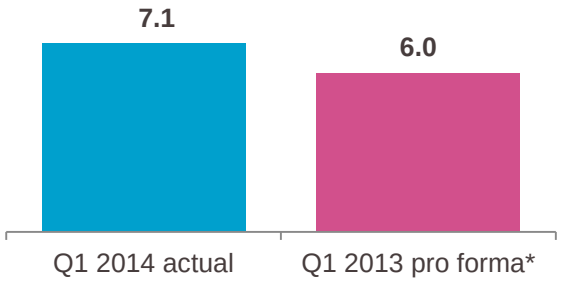
	IFRS actual		Pro forma* actual
	Q1 2014	Q1 2013	Q1 2013
Product sales	3,822	-	2,088
Revenues from collaborations, licensing & grants	3,273	1,877	3,955
Revenues and Grants	**7,095**	**1,877**	**6,043**
Cost of goods and services	(2,358)	-	(1,329)
R&D expenses	(5,776)	(2,824)	(8,329)
S,G&A expenses	(3,179)	(996)	(3,833)
Other income and expenses, net	(74)	(70)	665
Amortization of intangible assets	(2,156)	(412)	(1,075)
OPERATING LOSS	**(6,449)**	**(2,424)**	**(7,859)**
Finance & tax expenses, net	(663)	(125)	(1,745)
LOSS FOR THE PERIOD	**(7,112)**	**(2,549)**	**(9,604)**
EBITDA	**(3,293)**	**(1,575)**	**(5,255)**

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

Full year 2014 & outlook

Significant EBITDA improvement and reduction of net loss expected in 2014

Revenues & grants

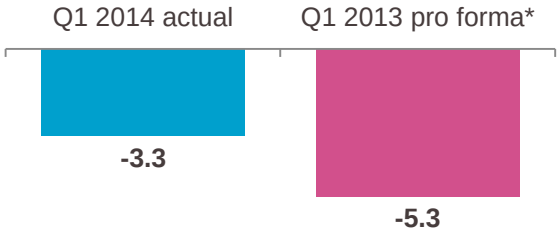


+ Significant revenue base from JEV product sales, licensing, collaborations and grants

EUR 40-45m revenues expected for FY 2014

(JEV sales growth offset by change in revenue recognition)

EBITDA

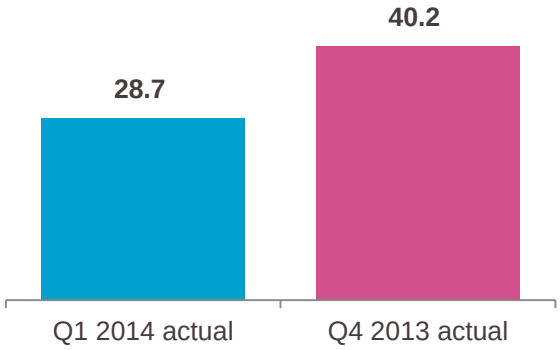


+ Focused spending in research and development, merger synergies effective in 2014

Significant improvement in operational results in 2014

(driven by merger synergies and savings in sales expenses)

Cash position



+ Cash outflow driven by R&D pipeline investments and changes in working capital

Significant reduction of operating cash outflow expected for FY 2014

(strong cash position remains management focus)

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

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IXIARO®/ JESPECT®

A marketed, unique product licensed in 35+ countries[7]

Japanese Encephalitis (JE): Most Common Viral Encephalitis in Asia[1]

+ JE is caused by a Flavivirus (like Dengue, Yellow Fever, Tick-borne Encephalitis)[2]
+ JE is the leading cause of viral neurological disease & disability in Asia[3]
+ JE results in 68,000 estimated symptomatic cases in Asia each year[4]
+ Between 1 in 25 and 1 in 1,000 infections lead to clinical disease[5]
+ Currently there is no effective treatment for JE[1]
+ JE is fatal in 20-30% of symptomatic cases and leaves half of the survivors with neurological sequelae[1]

The Product

+ Vero-cell derived, inactivated
+ No gelatin, no stabilizers
+ Alum-adjuvanted
+ Liquid formulation
+ 2 injections (day 0 and 28)
+ For travellers, including adults and children aged 2 months and above*
+ For military personnel (exclusive contract with US Department of Defense)[8]

Global Marketing and Distribution Agreements

US, EU, Asia[6]	NOVARTIS
Australia, New Zealand	CSL
India, Indian subcontinent[6] (local manufacturing based on Valneva's technology)	BE Biological E. Limited
Taiwan NEW	Adimmune Corporation

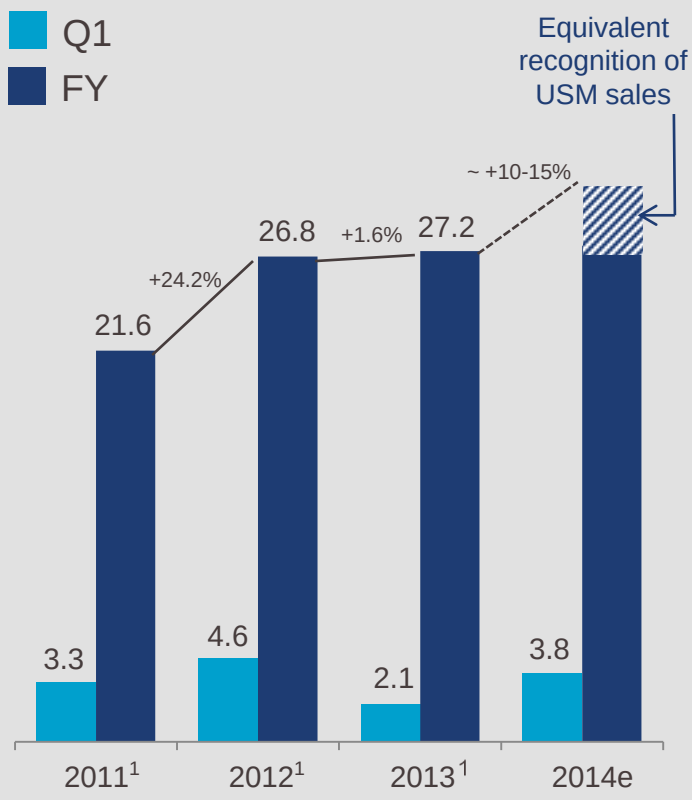
1 CDC. MMWR 2010;59:1-27; 2 CDC. MMWR 2010;59:1-27 Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; 3 Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; 4 WHO. Bull World Health Organ 2011; 89:766–774E.; 5 van den Hurk AF et al. Annu Rev Entomol 2009;54:17-35; 6 M&D rights, not yet approved or launched; 6 trade name JEEV®; 7 EU (28 countries), Norway, Lichtenstein, Iceland, Switzerland, Israel, Hong Kong, Singapore, Macau, USA, Canada, Australia, New Zealand; 8 PR Intercell 2009-05-08.

* **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.**

IXIARO®/ JESPECT®

Towards continued growth of in-market sales and increased profitability

Product sales revenues in EUR m



Q1 2014 sales analysis

+ Due to the seasonality of travel vaccines, the first quarter typically represents the lowest net sales period
+ Solid double-digit year-on year in-market sales growth across key markets
+ Strong delivery sales to distribution partners following reduction of inventory levels in Q1 2013

Business potential

+ Military business driven by troop deployment to Asia and adoption of JE vaccination policy
+ Improved traveller penetration rates led by education and improved product features
+ Valneva has a gross margin target of ~50% on net sales revenues
+ Long term in-market business potential of ~EUR 150-200m[2]

1 Intercell pro forma product sales incl. sales before merger
2 Travel vaccine market to 2017, GBI Research published on 14 May 2013 / total JEV market potential / all markets

Valneva and Adimmune partner to commercialize Japanese Encephalitis vaccine in Taiwan

Important step forward in Valneva's JE vaccine expansion strategy

Market Overview	+ JEV included in Taiwanese NIP – annual demand ~600kds/yr + Adimmune legacy sole source supplier (20+ yrs) of JE-MB + Taiwanese ACIP recently recommended introduction of JE-VC
Deal Principles	+ Adimmune entitled to register and commercialize Valneva's JE vaccine under a local trade name + Companies intend to develop, manufacture and commercialize JE vaccine from bulk product delivered by Valneva + First revenues from Adimmune expected in H2 2016

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EB66® in influenza

Replacement of egg-based manufacturing – exclusively licensed to GSK

Pandemic influenza

Japan:

NEW

+ **H5N1 Pandemic vaccine approved (Kaketsuken *)**
+ Facility in Kumamoto with 80 million doses pandemic capacity
+ Kaketsuken may supply pandemic vaccines for stockpiling, under national directive

US:**

+ Construction of manufacturing facility in Bryan-College, Texas (USD 91m)

NEW

+ **US Department of Health and Human Services (HHS) announced that the site could supply under Emergency Use Authorization (EUA) in case of pandemic from 2017 onwards.*****

Kaketsuken's EB66® influenza vaccine manufacturing facility, Japan

GSK-Texas A&M, EB66® influenza vaccine manufacturing center, USA

Seasonal influenza

+ First EB66® based seasonal flu vaccine approval expected in 2018-2019
+ Leveraging on pandemic development path and manufacturing capabilities

Near term: **3%–6% royalty on potential revenues resulting from pandemic stockpiling or outbreak**

Medium term: **expected additional milestones and royalties from development of seasonal influenza vaccine**

*: GSK's co-development partner in Japan under the EB66® license agreement
**: funded by Department of Health and Human Services (HHS)
***: see Internet Link (http://www.fiercevaccines.com/story/report-emergency-flu-vaccine-manufacturing-site-will-be-online-2017/2014-04-10)

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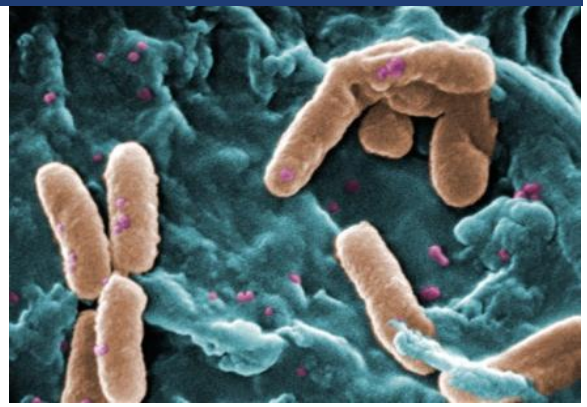
Pseudomonas aeruginosa
Targeting an unmet medical need

IC43 vaccine candidate (Phase II/III)

+ Represents ~20% of all nosocomial infections[1,3]
+ Target population: 700,000 to one million intensive care unit patients on mechanical ventilation in the U.S. and Europe annually[2]
+ Pseudomonas aeruginosa colonization of ventilated patients is associated with increased mortality rate[4]
+ All-cause mortality rate of 20% to 40% (at day 28) in this target population[2]



Our product candidate

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

Current development

+ Study targeting approx. 800 patients
+ Reduction in mortality as primary endpoint
+ Interim analysis after approx. 400 patients completed
+ Current trial co-financed by Novartis
+ Potential development milestones of up to EUR 120m and royalty payments[5]

Sources: 1 Pseudomonas Infection, Selina SP Chen, Russell W Steele, MD – Chapter on Epidemiology http://emedicine.medscape.com/article/970904-overview#a0199;
2 Valneva internal information; 3 Vincent JP et al, JAMA, 1995; p639-644; 4 Robert Koch Institut: Gesundheitsbericht des Bundes Heft 8
5 Under SAA with Novartis: Intercell Annual report 2012, p. 39,45

Pseudomonas aeruginosa

Current Phase II/III interim analysis indicates further confirmation of previous findings

Previous Key Findings

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

Current Interim Findings**

Phase II/III interim (394 patients)[3]:

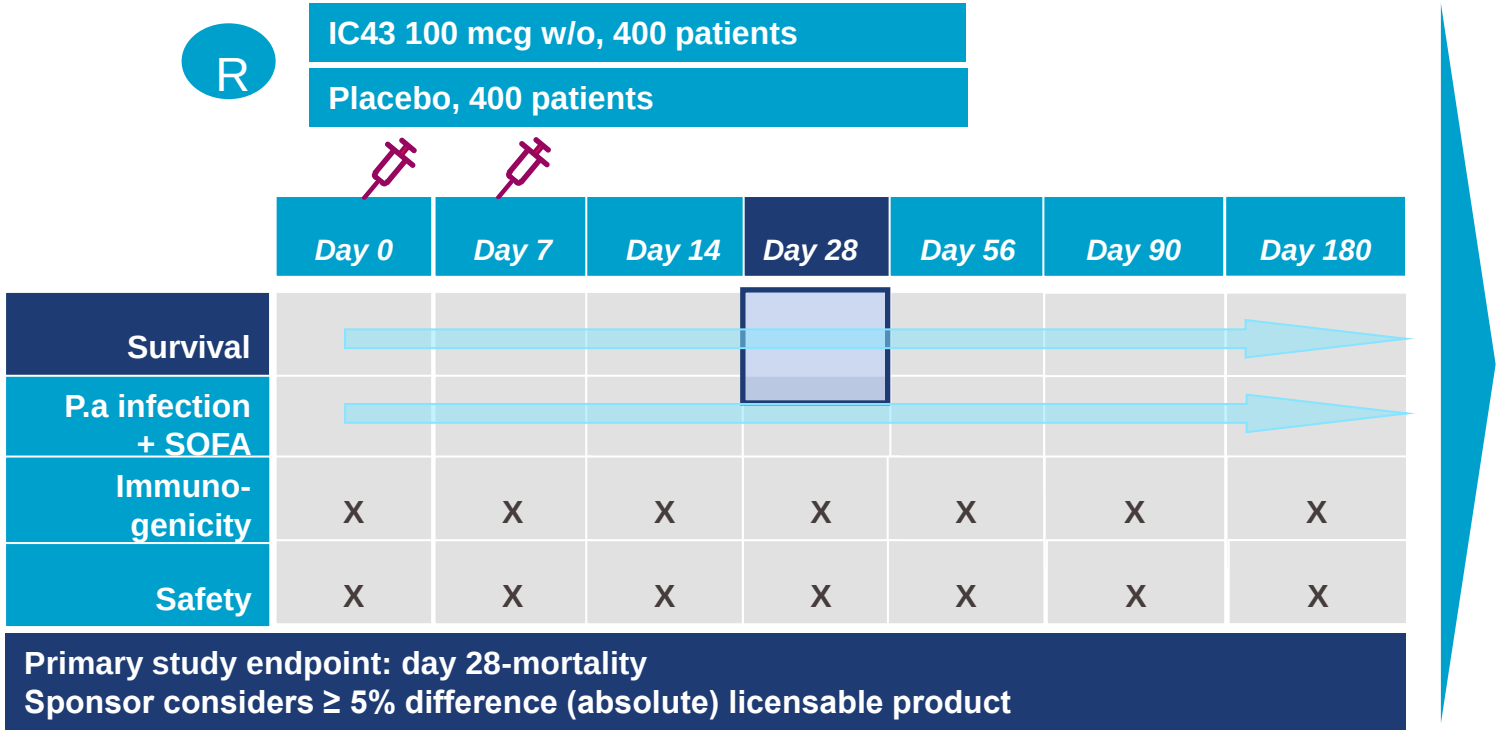
+ Clinically meaningful difference in mortality rates Vaccine-Placebo
+ No safety concerns regarding safety profile
+ Difference in mortality not as pronounced and planned based on Ph II (therefore formally futile)
+ Trends on mortality progression (efficacy) confirmed

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

Pseudomonas aeruginosa
IC43-202 – A Confirmatory Efficacy Study

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



+ Potential consideration to extend sample size if necessary and justified

+ Recruitment of patients for clinical trial is expected to resume Q2 2014
+ Preliminary results are expected at the end of 2015 / early 2016
+ Trial conduct and end-point unchanged

*Based on EMA scientific advice obtained in October 2011

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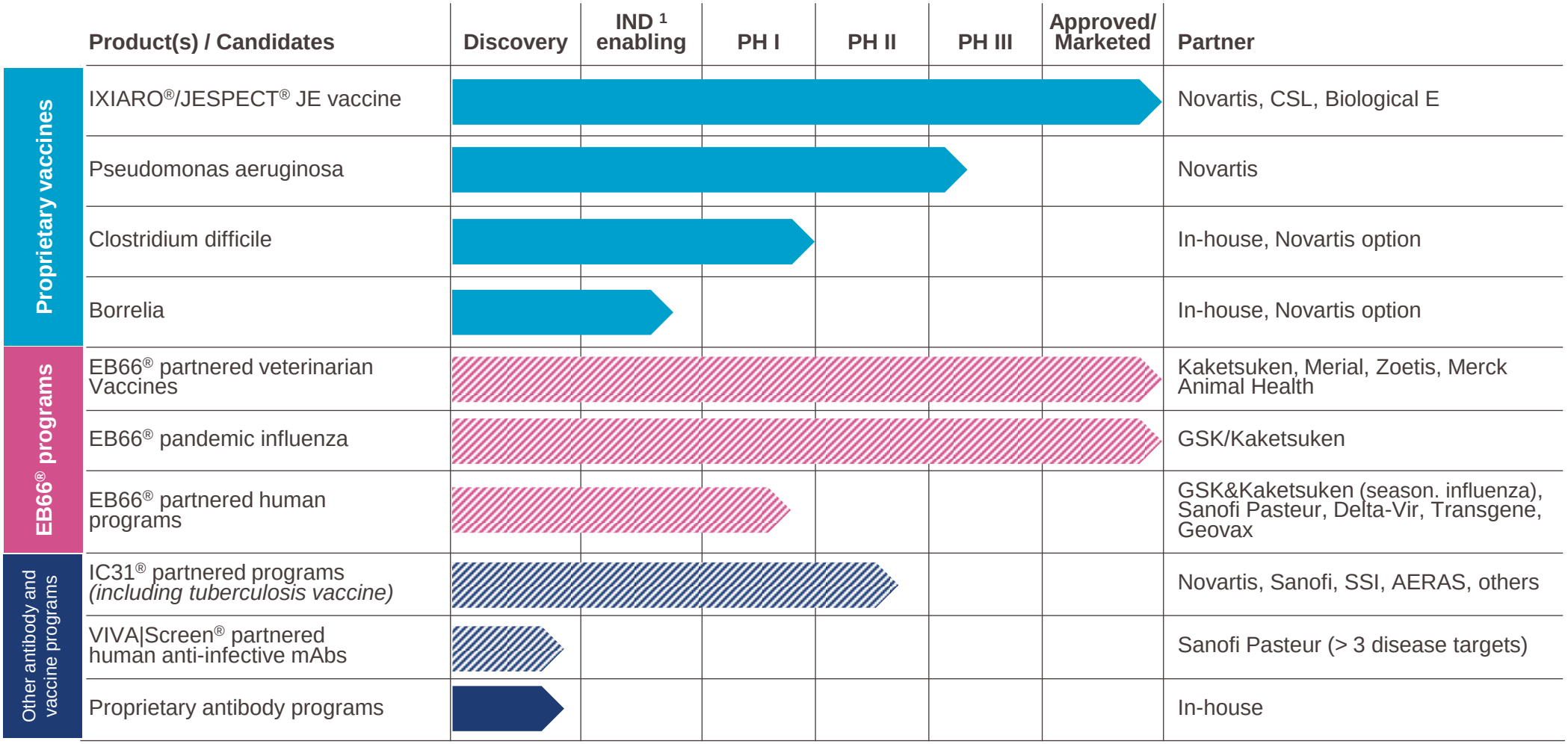
Valneva's pipeline of commercialized and R&D assets

From discovery through to market – in-house and with partners



[1] Investigational New Drug

solid color: in-house program

shaded color: program managed by partner(s)

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“Novartis and GSK trade assets as pharma industry reshapes”[1]

NOVARTIS

gsk GlaxoSmithKline

+ Major contemplated transaction, including the divestment of Novartis’ vaccines business (excluding flu) to GSK, expected to close in the first half of 2015.

+ Valneva expects to benefit from two existing strategic partners joining forces.

  › Valneva‘s key assets partnered with Novartis are potentially highly complementary to GSK; e.g. Pseudomonas and C. difficile vaccines are not programs GSK already has in its clinical development portfolio.

  › We do not expect an impact on Flu/EB66® cell-culture partnership with GSK since the Novartis flu business (including their cell-culture based flu vaccine) is not part of the contemplated transaction.

[1] Reuters April 22nd 2014

Valneva's Q1 2014 key milestones and FY 2014 outlook

Significant potential value inflection points

✓ *Completed*

Q1 2014

+ Phase II/III study continuation Pseudomonas aeruginosa ✓
+ Market approval and launch of EB66® pandemic influenza vaccine in Japan ✓
+ Fourth antibody program with Sanofi Pasteur using the VIVA|Screen® platform ✓
+ Approval of a second veterinary product produced in the EB66® cell line (FARVET) ✓
+ New EB66® license agreement: Emergent Biosolutions) ✓
+ New IC31® Tuberculosis data (Aeras) ✓

Q2 and H2 2014

+ New agreement to commercialize JEV vaccine in Taiwan (Adimmune Corporation) ✓
+ Approval of another veterinary product produced in the EB66® cell line
+ Phase II trial start for C. difficile* vaccine candidate
+ Further IC31® / Tuberculosis data
+ New EB66® licenses agreements
+ Sanofi potential opt-in milestone for first VIVA|Screen® antibody program
+ Phase I trial start for Borrelia vaccine candidate

* Subject to regulatory acceptance and agreement with development partner

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Thank you
Danke
Merci

valneva