Valneva SE presents its Q1 2015 financial results

Analyst Presentation
May 12, 2015

valneva

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Forward Looking Statements

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1. Introduction – Key Events – *Thomas Lingelbach*

2. Financial report Q1 2015 and outlook – *Reinhard Kandera*

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6. Outlook – *Thomas Lingelbach*

7. Q&A

Valneva's Newsflow

March 2015

+ First approval for a human vaccine produced in EB66® – Japan (protoype vaccine)
+ Exclusive license agreement with Jianshun Biosciences to commercialize EB66® in China
+ Two new deals on EB66® vaccine cell line platform

February 2015

+ Valneva acquiring DUKORAL® to strengthen Valneva's travelers vaccine franchise and to become a leading pure-play vaccines biotech company
+ Valneva announces the successful completion of its EUR 45 million capital increase

January 2015

+ Exclusive worldwide license to Immune Targeting Systems for development of Hepatitis B vaccines in combination with the IC31® adjuvant
+ Spin-off of antibody business: Valneva and BliNK Therapeutics created BliNK Biomedical

Integration of acquired vaccine DUKORAL® and Nordic vaccine distribution progressing well

In February 2015, the Company completed the acquisition of Crucell Sweden AB, including the Nordics vaccine distribution business and all assets, licenses and privileges related to DUKORAL®, a vaccine against Cholera and Travelers' Diarrhea caused by ETEC.

+ Integration of Valneva Sweden AB is progressing well

+ Valneva is leading manufacturing, supply and sales activities while it continues to integrate transitional services, processes and systems from the seller

+ The Nordics vaccine distribution business is now operated by Valneva under the traditional brand of "SBL Vaccines", and the Company is progressing initiatives to further grow this business segment

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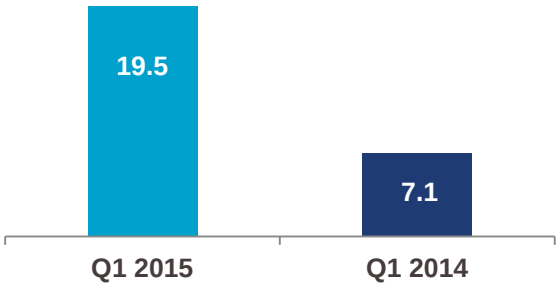
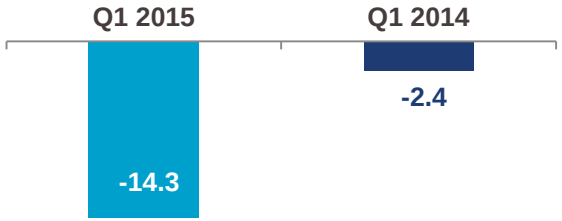
Q1 2015 Financial Results

Compared to Q1 2014 (IFRS, EUR million, unaudited)

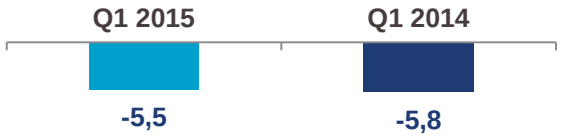
Revenues & Grants



COGS



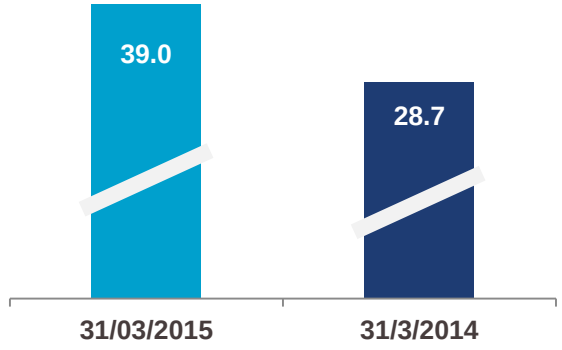
R&D Expenses



EBITDA

Net loss

Cash position



Q1 2015 Profit & Loss
(EUR in thousands, unaudited)

	Three months ended March 31, 2015	2014
Product sales	15,137	3,822
Revenues from collaborations and licensing, grants	4,364	3,273
Revenues and grants	**19,501**	**7,095**
Cost of goods and services	(14,258)	(2,358)
R&D expenses	(5,504)	(5,776)
S,G&A expenses	(4,028)	(3,179)
Other income and expenses, net	152	(74)
Amortization and impairment	(1,824)	(2,156)
OPERATING LOSS	**(5,962)**	**(6,449)**
Finance, investment and income tax expenses / income	943	(664)
Loss from discontinued operations	-	-
LOSS FOR THE PERIOD	**(5,019)**	**(7,112)**
EBITDA*	**(3,063)**	**(3,293)**

* calculated as operating loss deducting amortization, depreciation & impairment

Q1 2015 Financial Analysis
Compared to Q1 2014 figures

Revenues
+ Aggregate revenues & grants increased by EUR 12.4m to EUR 19.5m driven by increase in product sales:
  - IXIARO®/JESPECT®: EUR 9.7m – compared to EUR 3.8m in Q1 2014
  - DUKORAL® : EUR 4.5m – new
  - Nordics trade: EUR 0.9m – new
+ IXIARO®/JESPECT® sales increase due to timing of deliveries to distribution partners, favourable foreign exchange effects and growth of product sales in the market

Cost of goods and services
+ EUR 6.7m IXIARO®/JESPECT® COGS leading to a 31.2% gross margin
+ EUR 6.8m COGS for DUKORAL® and Nordics trade driven by acquisition accounting effects (acquired inventory which was valued at its fair market value)

Research and development expenses
+ Decrease from EUR 5.8m to EUR 5.5m, includes effects from spin-off of the antibody business

Sales, general and administrative expenses
+ Increase in cost driven by selling expenses that were added by acquisition of distribution infrastructure in Nordic countries

Q1 2015 Financial Analysis
Compared to Q1 2014 figures

Amortization and impairment of intangible assets
+ EUR 1.8m non-cash amortization charges resulting primarily from intangible assets previously recognized in the course of Valneva's merger history

Financial income and expenses
+ Positive currency effects from USD denominated financial assets, partially offset by negative currency effects from USD loan
+ New line item "Result from investments in affiliates" resulting from BLINK antibody spin-off
  - contributed non-cash share in loss of EUR 0.1m

Net loss
+ Significant improvement from EUR 7.1m to EUR 5.0m

EBITDA
+ Reduction of EBITDA loss by 7.0% to EUR 3.1m shows progress towards strategic goal of operational break-even despite negative non-cash COGS effect from acquisition accounting

Cash position
+ EUR 39.0m cash position further strengthened by early 2015 capital increase

* for detailed explanation of pro forma assumptions and reconciliation to IFRS results see notes to Valneva's consolidated financial statements available on the Company's webpage www.valneva.com

2015 Financial Outlook

Revenues

+ Growth to EUR 75-85m driven by recent DUKORAL®/Nordic Trade acquisition and organic revenue growth (revenue includes DUKORAL® product sales by the seller's group entities under transitional service agreement)
+ IXIARO®/JESPECT® net sales revenues to reach approximately EUR 30m

Net loss / EBITDA

+ 2015 to be marked by integration of DUKORAL®/Nordic Trade
+ 2015 results may be significantly impacted by non-cash effects from acquisition accounting
+ Valneva expects to continue to strive towards break-even following the transitional period of 2015 and the integration of the recently acquired business

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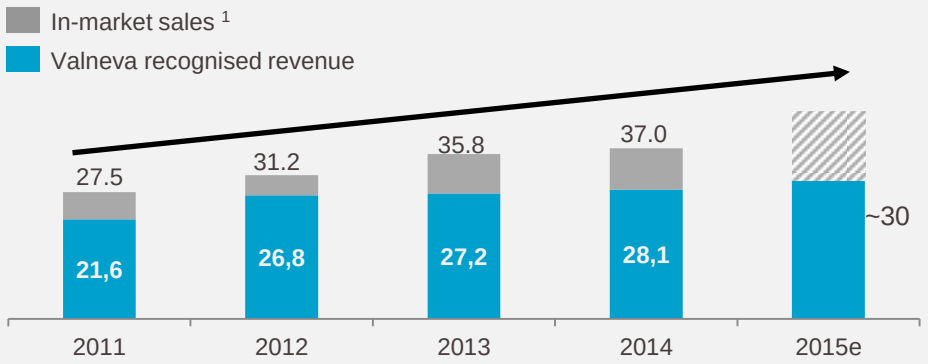
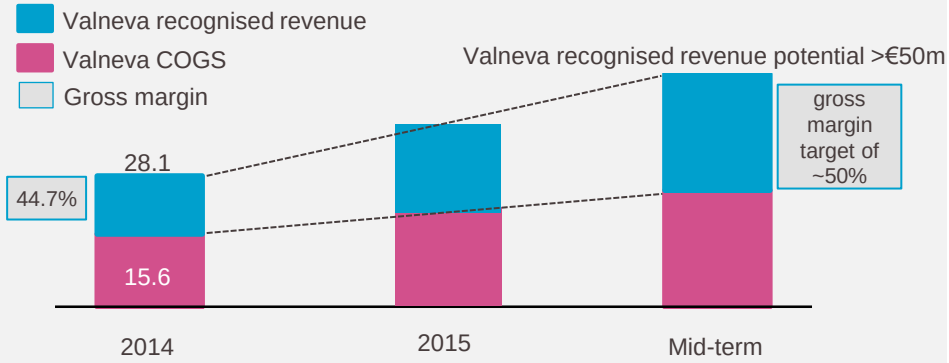
Commercial product: Japanese Encephalitis Vaccine 1/2

Successful commercialization with renowned partners including GSK

Annual sales growth development* (EUR m)



Mid-term outlook (EUR m)



Marketing and distribution partnerships

GlaxoSmithKline Biologicals

+ IXIARO®
  - › US
  - › Europe
  - › Asia[2]

CSL

+ JESPECT®
  - › Australia
  - › New Zealand

Revenue from transfer prices

Asian endemic partnerships

Biological E. Limited

+ JEEV®
  - › India, Indian subcontinent
  - › Produced locally based on Valneva's technology

Royalties

Adimmune Corporation

+ Local trade name (tbd)
  - › Taiwan
  - › Produced locally based on Valneva's bulk supply

Revenue from transfer prices

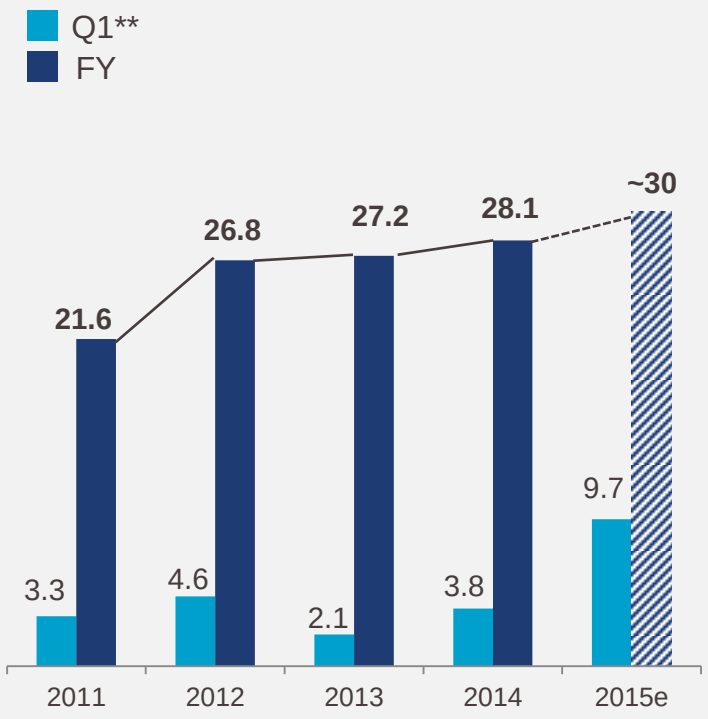
* 2010-2012 Intercell product sales before merger, 2013 pro forma sales

1 Sales reports from partners and Valneva direct in-market sales; **2** M&D rights, product available in selected territories only

Commercial product: Japanese Encephalitis Vaccine 2/2

IXIARO®/JESPECT® update

Product sales revenues in EUR m*



Q1 2015 update**

IXIARO®/JESPECT® Q1 2015 product sales EUR 9.7m vs. EUR 3.8m in Q1 2014

+ Positively impacted by the timing of deliveries and exchange rates
+ Showing continued growth of product sales in the market

Positive recommendation from CHMP for European approval of alternative, rapid IXIARO® vaccination schedule for adults

2015 Outlook confirmed

Continued double-digit in-market sales growth expected

+ driven by promotional efforts: further collaboration with the U.S. Military to support enhanced vaccination recommendations and policies

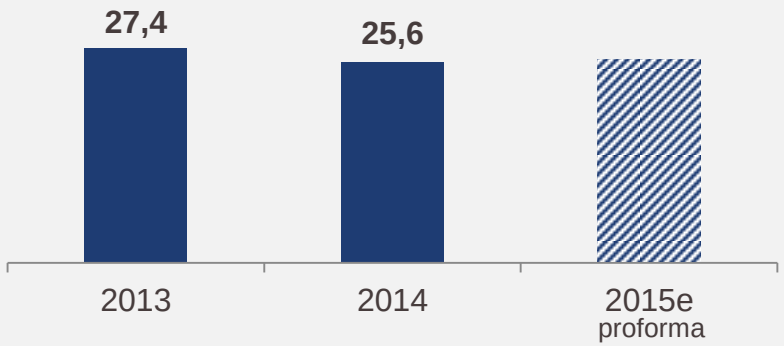
2015 guidance for IXIARO®/JESPECT® revenues of ~ EUR 30m

* Intercell pro forma basis, ** unaudited

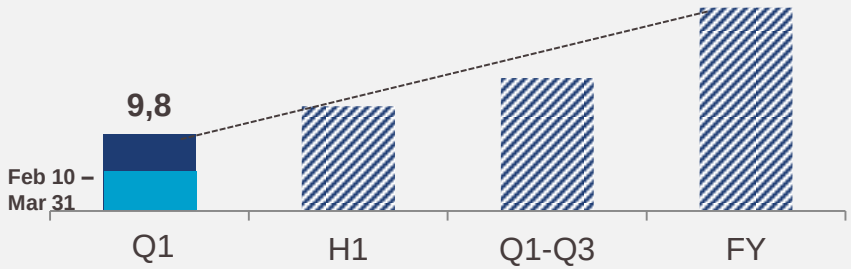
Commercial product: Cholera/ (ETEC)* Vaccine
DUKORAL® analysis of sales and growth potential

DUKORAL® sales[1] in EURm

Development of annual sales



Forecast product sales 2015 (proforma)



Q1 update

+ Transfer process of regulatory licenses initiated/ongoing
+ Own sales and marketing force in key markets like Canada with the objective to directly control commercialization
+ Signing of marketing & distribution agreements with partners

Growth initiatives

+ Sales performance correlates to level of marketing and promotion
  - › Strengthen and motivate key marketing team
  - › Increased focus on marketing activities
  - › Extended Key Opinion Leader management
+ Direct to consumers (DTC) awareness campaigns
  - › Advertising & Promotion spend in key markets
  - › Targeted direct sales efforts
+ Develop different marketing channels

1 Johnson & Johnson proforma management reporting, unaudited figures

Commercial platform – Nordics Trade

Existing trade business offers opportunity for further growth

SBL vaccines

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

Key strengths

+ Legacy domestic player in the 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

Overview current products/customers

Product sales*

Feb 10 – Mar 31 2015:
EUR 5.4 m

Q1 2015 pro-forma:
EUR 11.3 m

GlaxoSmithKline Biologicals, valneva, Crucell, Vivotif®, ENCEPUR®, MENVEO, Rabipur®, DUKORAL®, IXIARO®

Strategy

+ Leverage infrastructure for our products in one of Europe's key travel markets
+ Build dedicated business in the business and leverage Valneva's BD to attract new customers

* incl. DUKORAL® worldwide

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EB66® cell line platform

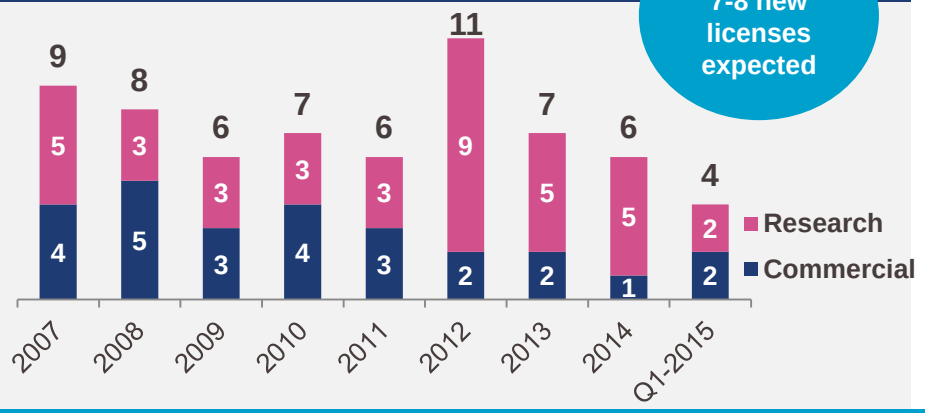
A breakthrough technology in vaccine production

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 30m 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

EB66® licenses



EB66®'s regulatory approvals & commercialization status

Licence agreements in human vaccines

Prototype Influenza vaccine approved in Japan

H5N1 Pandemic vaccine approved in Japan

+ Completion of facility in Kumamoto with 80 million doses pandemic capacity & expected stockpiling in 2015

Construction of manufacturing facility in Texas (USD 91m) & supply of 50 million doses within 4 months of receiving a flu virus strain from 2017 onwards

License agreements in veterinary vaccines

Three vaccines approved

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

Additional approvals expected in the coming months

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

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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]
+ 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)

+ Phase II showed statistically significant reduction in mortality (day 28)[6]
+ Current study targeting 800 patients co-financed by GSK[7]
  - › Reduction in mortality as primary endpoint
  - › We consider ≥5% absolute difference licensable product
+ Interim analysis after 400 patients[8]
  - › 700 of 800 patients already enrolled
  - › Trial extension under evaluation
+ Results expected end 2015 / early 2016

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 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** 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: Clostridium Difficile vaccine

Targeting healthcare-associated diarrhea, with market potential at 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 U.S. & 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 disease, 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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Event calendar and anticipated news flow 2015

Continued progress reported and multiple near-term events ahead

Commercialized products

+ Dukoral® & Nordics trade to broaden revenue base and add commercialization platform
+ Further growth of Japanese Encephalitis vaccine net sales revenues to ~EUR 30m
+ Overall Group revenues to reach between EUR 75-85m

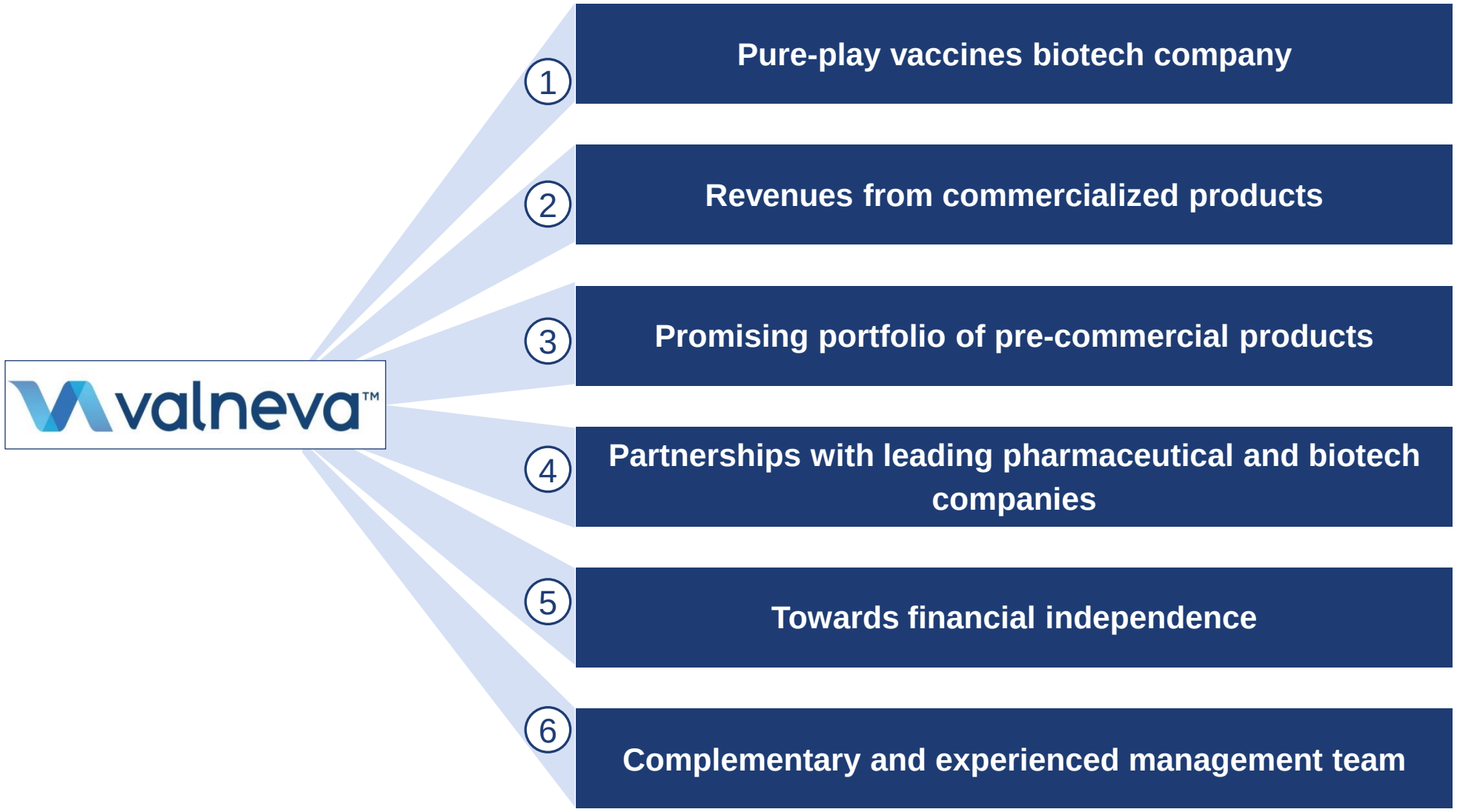
Technologies & Services

+ 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
+ Phase II/III clinical study results from Pseudomonas Aeruginosa vaccine candidate end of 2015 or early 2016

Company highlights



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Thank you
Merci
Danke

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