

Analysts Presentation H1 2013

August 28, 2013





Disclaimer

Forward Looking Statements

These materials contain certain forward-looking statements relating to the business of Valneva SE (the “Company”), including with respect to the progress, timing and completion of the Company’s research, development and clinical trials for product candidates, the Company’s ability to manufacture, market, commercialize and achieve market acceptance for product candidates, its ability to protect its intellectual property and operate its business without infringing on the intellectual property rights of others, the Company’s estimates for future performance and its estimates regarding anticipated operating losses, future revenues, capital requirements and its needs for additional financing. In addition, even if the Company’s actual results or development are consistent with the forward-looking statements contained in this presentation, those results or developments may not be indicative of the Company’s results or developments in the future. In some cases, you can identify forward-looking statements by words such as “could,” “should,” “may,” “expects,” “anticipates,” “believes,” “intends,” “estimates,” or similar words. These forward-looking statements are based largely on the Company’s current expectations 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 Company’s expectations 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, the impact of the global credit crisis, and the Company’s 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. 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.



Valneva:

Analysts Presentation H1 2013

1. Introductory note - *Thomas Lingelbach*

2. Financial Report H1 - *Reinhard Kandra*

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6. Outlook – *Franck Grimaud*

7. Q & A

Valneva SE company overview

Creating a European leader in vaccines and antibodies

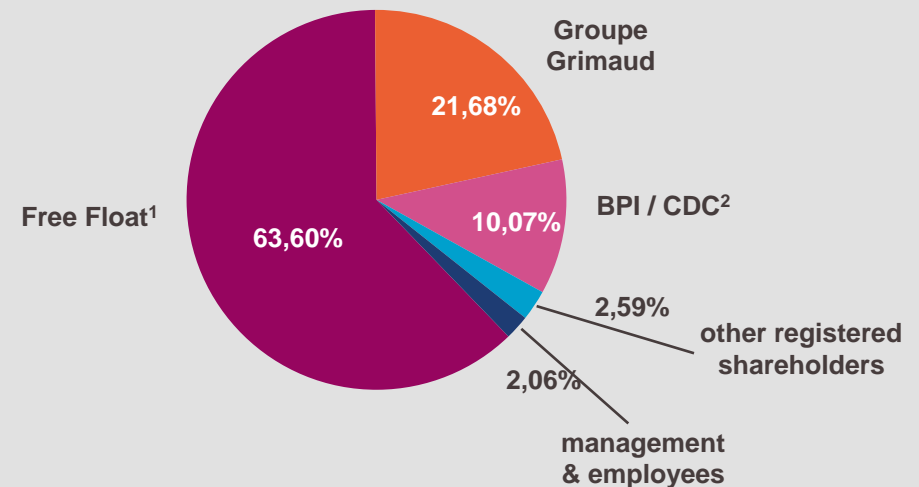


Corporate profile

- + Created in May 2013 through the merger of Vivalis SA and Intercell AG
- + Focus on antibody discovery and vaccine development and commercialization
- + Headquartered in Lyon, France
- + Approximately 360 employees
- + Principal sites in:
 - Vienna, Austria (140 employees),
 - Livingston, Scotland (100 employees),
 - Nantes & Lyon, France (90 employees);
 - presence in US and Japan
- + Listed on NYSE Euronext Paris and Vienna Stock Exchange

Stock information

- + Number of ordinary shares*: 54,621,480
- + Market cap: ~ EUR 180m
- + ISIN: FR0004056851
- + Shareholder Structure*:



¹ Shareholders holding less than 5%, including Novartis

² BPI France Participations SA (formerly FSI) / Caisse des Dépôts et Consignations

* Excluding 17.8m preferred shares which convert into 8.6m ordinary shares upon approval of the Pseudomonas vaccine candidate



February 2013

+ **Signing of several new agreements for the licensing of the EB66[®] cell line**

March 2013

+ **Expanded development of EB66[®] cell line as part of the GlaxoSmithKline (GSK) – Texas A&M University system influenza vaccine program in the United States.**

April 2013

+ **NDA filed in for the first human vaccine produced in EB66[®] cell line.**

May 2013

+ **Pediatric approval of Japanese encephalitis vaccine in the U.S**

+ **Completion of merger between Vivalis and Intercell to form Valneva SE**

June 2013

+ **Sale of Nantes clinical manufacturing operations (CMO) to Biological E**

+ **ACIP unanimously votes to extend recommendations for pediatric use of IXIARO[®] vaccine**

+ **Completion of a fully underwritten EUR 40,2m capital increase with preferential subscription rights**



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Key financial figures HY1 2013

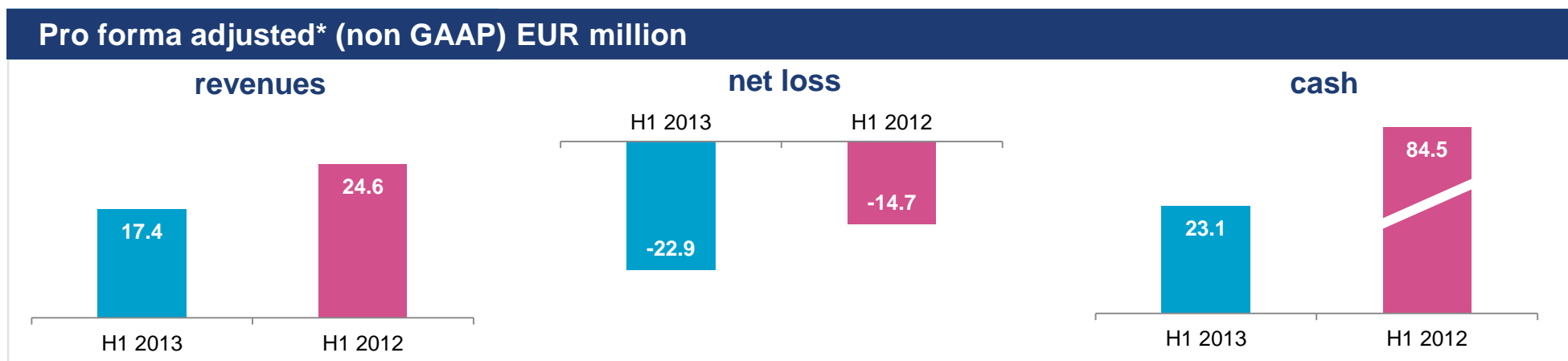
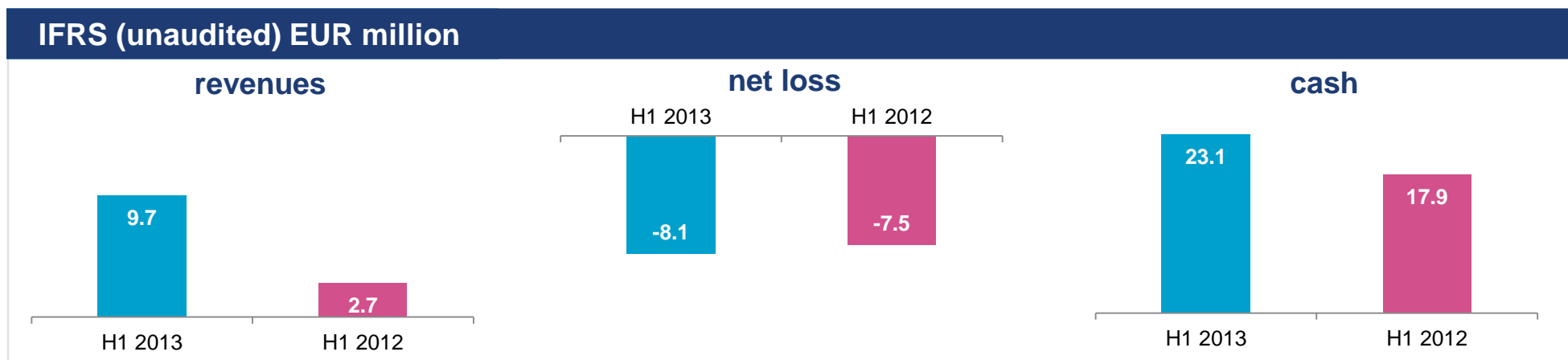


in EUR '000	Six months ended June 30,	
	2013*	2012*
Revenues and Grants	9,671	2,746
R&D expenses	(7,026)	(6,226)
Net loss	(8,114)	(7,502)
Net operating cash flow	(7,105)	(7,605)
Cash, short-term deposits and financial assets at end of period	23,108	17,974

Valneva H1 report combines Vivalis' financial results in the first 5 month of 2013 and Valneva's results in June, as the merger between Vivalis and Intercell became effective on May, 28.

*unaudited

H1 2013 Key Figures



* Excluding non-recurring merger transaction costs and costs related to repayment of debt in connection with the merger



H1 2013 Analysis

P&L

+ Revenues

- › IXIARO/JESPECT[®] product sales became principal source of revenue;
- › Decrease in H1 sales performance expected to be compensated by highest quarterly sales since launch in Q3
- › EB66[®] and Viva|Screen[®] revenues showed double-digit growth of 23.1% and 21.4%, respectively

+ Cost of goods sold

- › Relate to IXIARO/JESPECT[®] produced in Scottish manufacturing facility
- › 33% gross margin on reported H1 sales (excluding amortization charges)

+ Research and development expenses

- › Resulting from in-house and partnered R&D programs
- › EUR 1.5m contributed by ex-Intercell business

+ S,G&A costs

- › Impacted by merger transaction costs
- › Implementation of costs-synergies on track

+ Amortization of intangible assets

- › Non-cash amortization charges of EUR 1.4m resulting from acquired intangible assets (mainly JEV)

+ Net loss

- › 8,2% increase in net loss due to merger (EUR 1.6m contributed by ex-Intercell business)



H1 2013 Analysis

Balance Sheet

+ Merger effects and Purchase Price Allocation (PPA) fully reflected in June 30, 2013 balance sheet

+ Equity

- › fair value of purchase consideration amounted to EUR 103.5m
(for new ordinary and preferred shares)

+ PPA – acquired assets

- › EUR 87.4m tangible & financial assets
(property & equipment, inventory, cash & receivables, etc.)
- › EUR 111.8m intangible assets
(mainly allocated to JEV and Pseudomonas, no good will)

+ PPA – acquired liabilities

- › EUR 45.8m long-term liabilities
(mainly finance lease obligations, „soft“ loans)
- › EUR 50.0m trade payables and other current liabilities
(partly repaid in Q3)



Full Year 2013

- + Revenues & grants
EUR 30m-35m
- + Net loss*
EUR 20m-25m
- + Cash position
> EUR 40m

Mid-term

- + EUR 60-70m revenues
- + EUR 5-6m annual merger synergies
- + 2015 break-even
- + Financial self-sustainability

* Excluding any potential impairment on intangible assets



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Successful completion of merger

striving to become a leading European Biotech company in Vaccines and Antibodies

Merger successfully completed on May 28, 2013

- + Valneva shares listed on NYSE Euronext in Paris & Vienna Stock Exchange
- + Valneva market capitalization of EUR 183m, as of August 12, 2013

All stock merger between Vivalis and Intercell

- + Exchange ratio of 13 Vivalis shares and 13 Valneva listed preferred shares for every 40 Intercell shares
- + Post-merger Valneva ownership split: 55% Vivalis / 45% Intercell
- + Pseudomonas earn-out for Intercell shareholders through issuance of preferred shares



Successful completion of capital increase

a stronger financial position to implement the group's strategy

**Successful EUR40,2m
capital increase –
oversubscribed by 146%**

- + Final gross proceeds amount to EUR 40,187,819.75 with the issuance of 15,165,215 new shares.
- + Subscription orders amounted to approximately EUR 58.7 million, a subscription rate of approximately 146%.

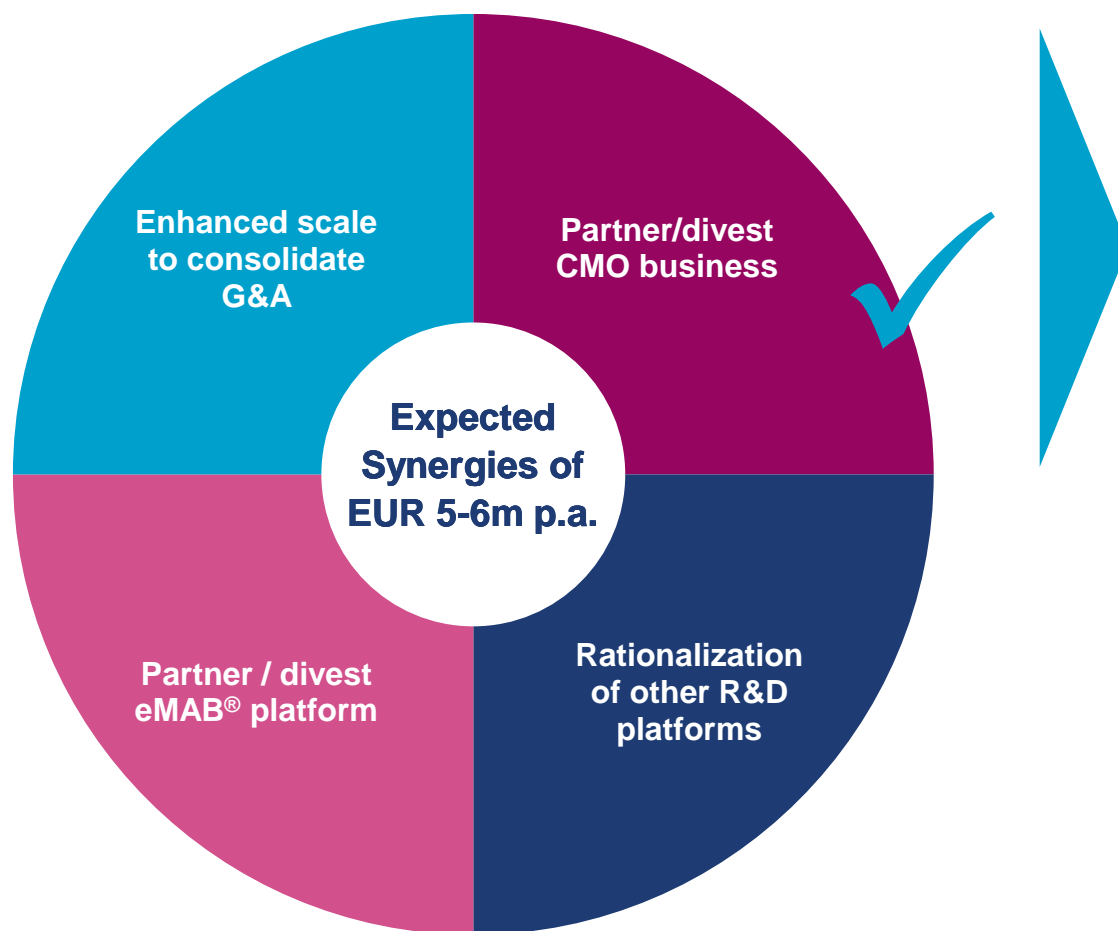
**A new Shareholders'
structure**

- + Upon completion of the capital increase, the FSI held 10,07 % of the share capital of the Company
- + Groupe Grimaud became Valneva's single largest shareholder with a 21,68 % stake in the Company.



Integration progressing well: on track to deliver on expected cost synergies

Expected synergies achieved within 2 years



Sale of Nantes CMO facility to Biological E

- + Up to EUR 3 million cost savings annually
- + Undisclosed selling price, exceeding the current book value of facility

Implementation of additional synergies initiated

- + Integration of G&A functions
- + Spin-off of eMAB® platform into “Elatos” subsidiary for venture financing
- + Insourcing of external R&D services to enhance cost-efficiency

✓ *Completed*



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IXIARO®/ JESPECT®:

a marketed, unique product licensed in 35+ countries

Japanese Encephalitis: Most Common Viral Encephalitis in Asia¹

- + JEV is a Flavivirus (like Dengue, Yellow Fever, Tick-borne Encephalitis)
- + JE is the leading cause of viral neurological disease & disability in Asia²
- + JE results in 68,000 estimated symptomatic cases in Asia each year³
- + Between 1 in 25 and 1 in 1,000 infections lead to clinical disease⁴
- + Currently there is no effective treatment for JE¹
- + JE is fatal in 20-30% of symptomatic cases and leaves half of the survivors with neurological sequelae¹


The Product

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

Global Marketing and Distribution Agreements

US, EU, Asia⁵ 

Australia, New Zealand 

India, Indian subcontinent⁶
(local manufacturing based on Intercell's technology) 



1 CDC. MMWR 2010;59:1-27; 2 Solomon T et al. J. Neurol. Neurosurg. Psychiatry 2000;68:405-415; 3 WHO. Bull World Health Organ 2011; 89:766-774E.; 4 van den Hurk AF et al. Annu Rev Entomol 2009;54:17-35; 5 M&D rights, not yet approved or launched; 6 trade name JEEV®

* 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®:

H1 sales impacted by stocks reduction, strong Q3 expected

H1 sales update

- + H1 sales of EUR 9.3m compared to EUR 14.7m in H1 2012
- + Growth on in-market sales:
 - › Novartis' in-market sales are up 8% in H1 2013 compared to H1 2012
 - › Sales to the U.S. Military are up 11% in H1 2013 compared to H1 2012:
- › Novartis decided to reduce its stock levels across the IXIARO® related supply chain
- + Q3 expected as strongest quarter since launch of the product:
 - › Single largest order from the U.S. military

Business potential

- + Military business expected to grow as military population deployed in Asia increases to 250,000 people
- + Travel markets penetration rate to increase mid-term to 2.5% from approximately 1% today
- + Total mid-term net sales potential of ~EUR 50m
- + Gross margin target of ~50% mid-term
- + Long term business potential of ~EUR 200m in market corresponding to net sales of ~EUR 100m

Key growth drivers

- + Increase awareness and marketing
- + Adopt recommendations for broad military use
- + Global roll out of travel guidelines to all "at-risk" travelers
- + Promote label for pediatric use
- + Continue geographical expansion
- + Enhance commercialization capabilities and infrastructure



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Valneva's R&D programs

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

	Product Candidate	Discovery	IND ¹ enabling	PH I	PH II	PH III	Approved/Marketed	Partner	
Vaccines	Japanese Encephalitis (incl. pediatric)	[Solid blue arrow]							Novartis, CSL, Biological E. Ltd.
	EB66 [®] partnered veterinarian program	[Solid blue arrow]							Kaketsuken
	EB66 [®] pandemic flu	[Hatched blue arrow]					*		GSK / Kaketsuken
	Pseudomonas aeruginosa	[Solid blue arrow]				IC43			Novartis
	IC31 [®] partnered programs (including tuberculosis vaccine)	[Hatched blue arrow]					*		Novartis, Sanofi, SSI, AERAS, others
	EB66 [®] partnered human Programs	[Hatched blue arrow]				*			GSK(flu), Kaketsuken (flu)
	C. difficile	[Solid blue arrow]				IC84			In-house, Novartis option
	Borrelia	[Solid blue arrow]			IC15				In-house, Novartis option
	Other EB66 [®] based vaccines	[Hatched blue arrow]					*		Sanofi Pasteur, Delta-Vir, Transgene, Geovax, Merial Merck Animal Health
Antibodies	VIVA SCREEN™ partnered human anti-infective mAbs	[Hatched blue arrow]						Sanofi Pasteur (> 3 disease targets)	
	Proprietary antibody programs	[Solid dark blue arrow]						In-house	

* see license overviews

¹ Investigational New Drug

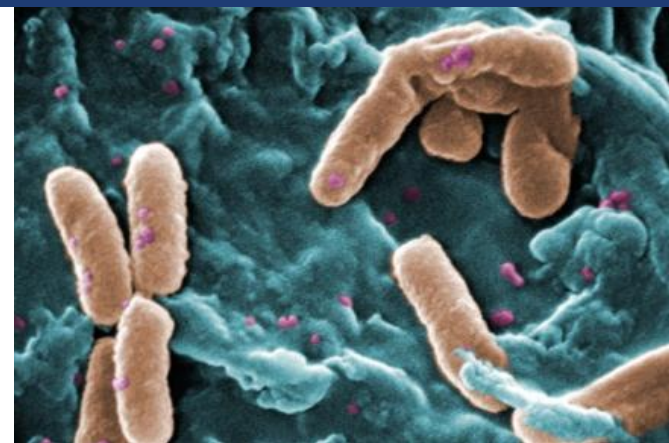


IC43:

Pseudomonas aeruginosa infections: A high unmet medical need

IC43 vaccine candidate (Phase II/III)

- + Causes ~20% of nosocomial infections
- + No. 1 cause of ICU-related pneumonia
- + No. 2 cause of all nosocomial pneumonia
- + Pseudomonas aeruginosa colonization of ventilated patients is associated with increased mortality rate



Our product candidate

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

Current development

- + Currently in Phase II/III pivotal efficacy trial
- + 800 subjects with reduction in mortality as primary endpoint
- + Interim analysis (futility) after 50% of subjects expected in H2/ 2013



Pseudomonas aeruginosa:

Upcoming futility analysis results in Ph II/III trial

H1 Update

- + Phase II showed lower all-cause mortality rates in Vaccines groups compared to controls
- + Study enrolment for a futility analysis completed (approximately 50% = 400 patients)
- + Independent Data Monitoring Committee (DMC) will conduct futility analysis data review
 - › Interim safety data
 - › Efficacy data, e.g., Day 28 mortality
- + DMC will give a recommendation + rationale to a Steering Committee composed out of members from Novartis and Valneva
- + Subsequently next development decisions will be taken

- + Interim analysis (futility) after 50% of subjects expected in H2 2013**
- + Program is co-financed by Novartis and Valneva (Strategic Alliance Agreement)**

EB66[®]: An emerging industrial standard for vaccines production

over 30 agreements with the world's biggest pharmaceutical companies



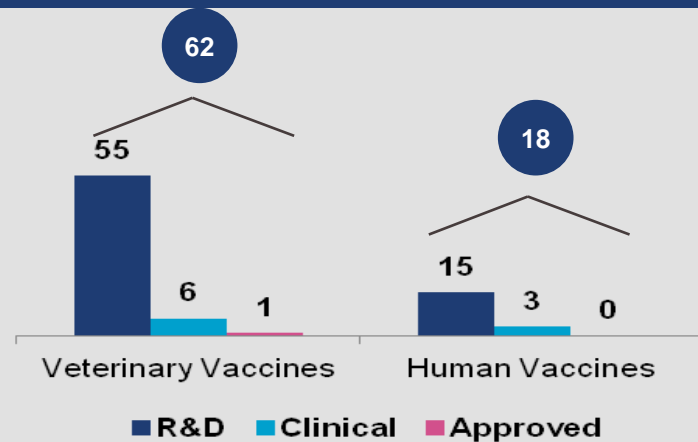
EB66[®] cell line

- + Avian embryonic stem cell derived technology
- + The alternative to chicken eggs for large scale manufacturing of human and veterinary vaccines
- + Biological master file accepted by the US FDA

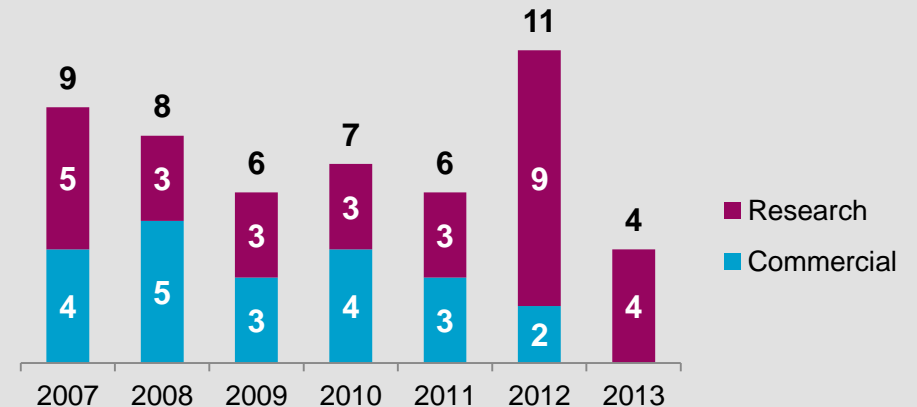
A growing franchise generating revenues

- + To date, 18 commercial licenses and 17 research licenses and agreements
- + 11 new agreements in 2012, 7 licenses signed on average every year
- + Already 5 agreements signed in 2013

Number of EB66[®] based vaccines



Number of licenses signed per year



- + **First veterinary vaccine (to prevent Egg Drop Syndrome) approved in 2012**
 - + **EUR 30m in upfront, milestones and research fees received to date**
- + **Additional EUR 80m milestones potential from existing licenses & future royalty**



EB66[®] cell line:

Significant newsflow in H1, new agreements expected in H2

On track to deliver 2013 objectives: 6 new licenses including 2 commercials

- + New Drug Application (NDA) filed in Japan for the first EB66[®] human vaccine - GSK's partner Kaketsuken.
- + GSK's H5N1 pandemic - US Department of Health and Human Services (HHS) approved establishment of a USD 91m of influenza-vaccines manufacturing facility in Bryan-College Station, Texas.
- + Four new EB66[®] agreements:
 - 1) new agreement signed with GSK for production of a new viral vaccine;
 - 2) research license with one of the world's largest vaccine developer;
 - 3) research license with Italian company FATRO;
 - 4) signing of a research license with a US Veterinary vaccine company.
- + **Continuous assessment of Valneva's proprietary cell line**
- + **Additional commercial license agreements expected**



Tuberculosis:

different clinical developments in area of highest medical need

Tuberculosis (Phase II – partner development)

- + Most common in developing countries
- + Caused by two different bacteria: Mycobacterium tuberculosis and Mycobacterium bovis
- + WHO estimates that one third of the world's population is infected
- + TB causes up to 1.7m deaths per year

Our investigational vaccine

- + Recombinant subunit vaccine based on IC31® in combination with SSI antigens
- + Partnered with SSI and Sanofi, supported by Aeras
- + Broad program with 3 clinical vaccine candidates currently in phase II and phase I studies (data expected in 2014)

H1 Update

- + 3 clinical vaccine candidates currently in phase II and phase I studies
- + Two trials expected to deliver data in 2014
- + 3rd Candidate, Partnered with SSI and Sanofi-Pasteur, currently in 2 phase I clinical studies (supported by Aeras and the SATVI)

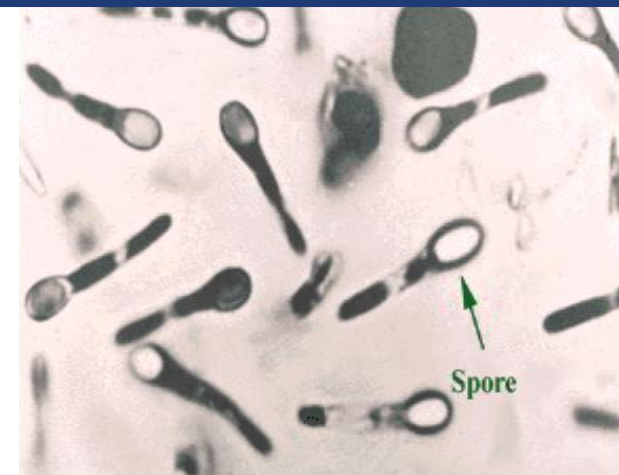


IC84:

Clostridium difficile: leading cause of nosocomial Diarrhea

IC84 vaccine candidate (Phase I)

- + Leading cause of nosocomial diarrhea in the U.S. and Europe
- + Estimated 0.5 - 3m cases annually in the U.S.
- + Commensal bacterium of the healthy adult human intestine in 2-5% of the population
- + Up to 60% of healthy neonates and infants are colonized without clinical symptoms
- + Toxin mediated disease where anti-toxin immunity can be protective



Our investigational vaccine

- + Recombinant fusion protein of relevant parts of toxins A and B
- + Alum-adjuvanted (if needed)
- + 3 injections in adults on days 0, 7 and 21 for Part A
- + 4 injections in elderly on days 0, 7, 28 and 56 for Part B

Picture: www.amozeshonline.com/bacteriology



Clostridium difficile:

Results from Ph I (b) imminent

H1 Update

- + Phase I (a) showed good safety and immunogenicity and indicated functionality in adults
- + Phase I (b) in target population – 80 subjects (> 64 years of age)
- + Phase I (b) study completed to confirm dosing and potential adjuvantation, in addition to safety and immunogenicity
- + Data release imminent
- + Subsequently next development decisions will be taken
- + **Phase I nearing finalization**
- + **Program partnered with Novartis (Strategic Alliance Agreement)**

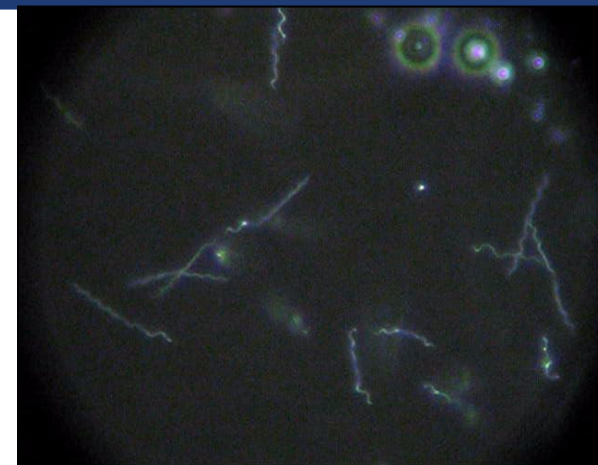


IC15:

Borrelia: Lyme borreliosis, a second threat which comes with ticks

IC15 vaccine candidate (pre-clinical development)

- + Lyme borreliosis is the most common vector borne illness in the Northern Hemisphere
 - + Europe: ~85,000* cases annually (WHO)
 - + US: ~ 300,000** cases annually (CDC)
- + Only transmitted by Ixodes ticks
- + The vaccine targets the outer surface protein A (OspA) of Borrelia; several serotypes are present



Our product

- + Protein-based vaccine protective against the 3 major Borrelia species causing disease in EU

H1 update

- + Pre-clinical testing nearing completion
- + Process industrialization initiated
- + Next clinical in-house development candidate (H2 2014)

* 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.

** latest data from the CDC (PR on Aug 19, 2013) claims 300,000 cases per year in the US annually

Photo: PHIL – Public Health Photo Library



VIVA|Screen[®] :

Partnership with Sanofi-Pasteur progressing well

VIVA Screen [®]	H1 Update
<ul style="list-style-type: none">+ A monoclonal antibody microarray-based platform+ Allows for the rapid high throughput discovery of rare fully human therapeutic antibodies directly from human donors+ License agreement with Sanofi-Pasteur since 2010 in a number of selected infectious disease targets	<ul style="list-style-type: none">+ Successful completion of antibody discovery work+ Delivery of antibody candidates to partner Sanofi-Pasteur in 3 indications for further evaluations.+ Decision by Sanofi-Pasteur to progress towards development expected at end of Q3 / beginning of Q4

- + Fourth antibody discovery program expected to be launched at the end of 2013**
- + First potential milestone in Q1 / Q2 2014 triggered by Sanofi-Pasteur's decision**



IC31[®] Adjuvant for Vaccines

Novartis' Phase I ongoing, additional collaborations initiated

IC31 [®] Adjuvant	H1 Update
<ul style="list-style-type: none">+ A unique synthetic adjuvant which stimulates strong T-cell immune responses and shows protective efficacy.+ 8 clinical trials have proven IC31[®] to be a very safe and immunogenic adjuvant in humans.+ Novartis has exclusive license for the use of IC31[®] in selected new vaccines.	<ul style="list-style-type: none">+ Novartis: Phase I clinical trial initiated in 2011 still ongoing (trial combines an undisclosed vaccine candidate with the IC31[®] adjuvant).+ Valneva maintains research collaborations with various partners to evaluate IC31[®] in new vaccine formulations+ Additional collaborations have been initiated in the field of cancer.

+ Potential of EUR 100m in milestones and future mid-digit royalties on sales



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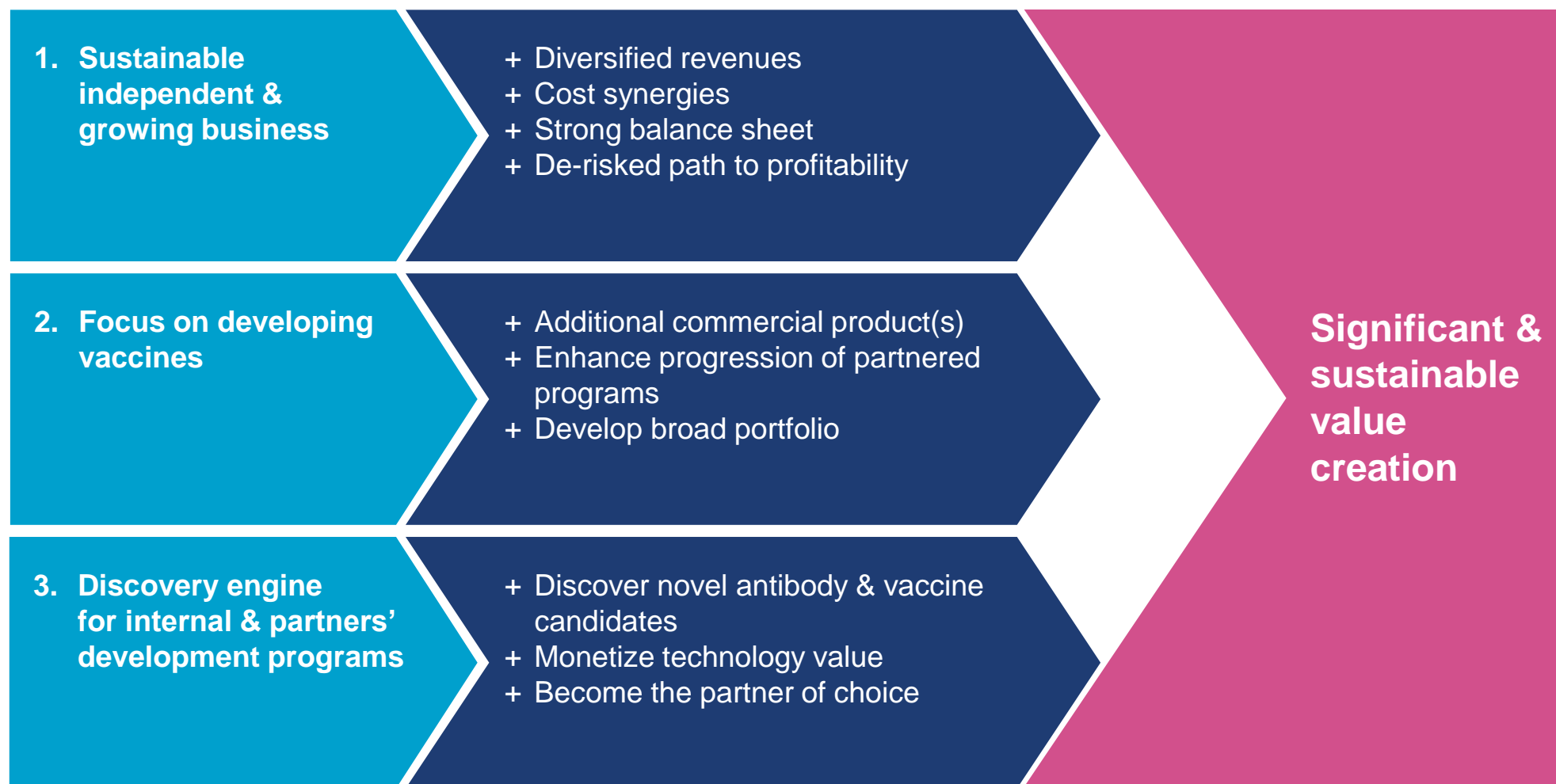
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Valneva's strategy and objectives

building a European biotech leader





Valneva's expected 2013/14 key milestones

significant potential value inflection points

2013

✓ *Completed*

- + IXIARO[®] pediatric label extension granted by EMA and in the US ✓
- + First NDA submission filed for a human product using the EB66[®] cell line ✓
- + Sale of CMO in Nantes (France) ✓
- + Completion of a EUR 40.2m rights offering ✓
- + Phase I B results *C. difficile*
- + New EB66[®] licenses agreements
- + Phase II/III interim results *Pseudomonas*
- + Fourth antibody programs with Sanofi Pasteur using the VIVA|SCREEN[®] Platform

2014

- + Further IC31[®] / Tuberculosis data
- + Market approval and launch of EB66[®] cell-based pandemic influenza vaccine in Japan
- + Sanofi opt-in milestone for 1st Program
- + Next approval of a veterinary product produced in the EB66[®] cell line
- + Phase II/III final results *Pseudomonas**
- + Phase I initiation *Borrelia* vaccine
- + Phase II trial start *C. difficile**

* Subject to positive clinical data in 2013 and respective program progression



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Merci
Danke
Thank you

