

# Q3 Analysts Presentation

November 5, 2013





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### Forward Looking Statements

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# Valneva:

## Analysts Presentation Q3 2013

**1. Introductory note – *Thomas Lingelbach***

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**2. Financial Report Q3 – *Reinhard Kandra***

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**3. IXIARO®/JESPECT® Update – *Franck Grimaud***

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**4. R&D Programs Update – *Thomas Lingelbach***

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**5. Outlook – *Thomas Lingelbach***

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**6. Q & A**

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## July 2013

- + Successful completion of a EUR 40.2m capital increase, oversubscribed by 146%
- + New EB66<sup>®</sup> cell Line Research license agreement with Boehringer Ingelheim
- + Biological E's Japanese Encephalitis vaccine prequalified by WHO

## August 2013

- + Passing of CSO and Management Board Member Majid Mehtali
- + First combined figures following merger effective date in May

## September 2013

- + Positive Phase I results for Clostridium difficile vaccine candidate
- + New EB66<sup>®</sup> cell line agreement with Delta-Vir
- + IXIARO<sup>®</sup>/JESPECT<sup>®</sup> posts best quarterly sales since product launch

## October 2013

- + New EB66<sup>®</sup> clinical development license agreement with IAVI for HIV Vaccine
- + Orphan Drug confirmation for the pediatric Indication of IXIARO<sup>®</sup> in the US
- + Phase II/III interim results for Pseudomonas vaccine candidate



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## Key financial figures Q3 / 9 months 2013



in EUR '000	Three months ended Sept. 30		Nine months ended Sept. 30	
	2013	2012	2013	2012
Revenues and Grants	14,680	1,750	24,351	4,496
R&D expenses	(7,816)	(2,558)	(14,841)	(8,783)
Net loss	(9,968)	(2,428)	(18,082)	(9,931)
Net operating cash flow	(14,928)	(1,175)	(22,033)	(8,780)
Cash, short-term deposits and financial assets at end of period	18,179	15,589	18,179	15,589

# Q3 2013 Key Figures



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

# Q3 / 9 months 2013 Analysis & Outlook



## + Revenues

- › IXIARO/JESPECT® quarterly net sales revenues of EUR 11.4m in Q3; nine months pro forma sales increased by 13.7% to EUR 20.7m
- › Increase in total revenues, both on reported and pro forma basis for Q3 and 9 months

## + Cost of goods sold

- › EUR 6.6m in Q3 – IXIARO/JESPECT® yields 41.7% gross margin (excluding amortization charges)

## + Research and development expenses

- › EUR 7.8m R&D expenses in Q3 resulting from in-house and partnered R&D programs

## + S,G&A costs

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

## + Net loss

- › Q3 net loss increased to EUR 10.0m due to merger; pro forma Q3 net loss flat to Q3 2012

## + Other expenses

- › Negatively impacted by non-cash valuation effects from exchange rate fluctuations



# Q3 / 9 months 2013 Analysis & Outlook – continued



## + Amortization of intangible assets

- › Non-cash amortization charges of EUR 2.0m in Q3 resulting from acquired intangible assets (mainly JEV)

## + Cash & securities

- › EUR 18.2m liquid funds at quarter end
- › To be further strengthened by
  - Ongoing debt-refinancing of > EUR 20m
  - Collection of receivables of > EUR 12m
  - Completion of CMO facility sale

## + FY2013 outlook confirmed

- › Revenues and grants: EUR 30-35m
- › Net loss at high end of EUR 20-25m range
- › Cash position: > EUR 40m



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# IXIARO®/ JESPECT®:

a marketed, unique product licensed in 35+ countries

## Japanese Encephalitis: Most Common Viral Encephalitis in Asia<sup>1</sup>

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

## 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, Asia<sup>5</sup> 

Australia, New Zealand 

India, Indian subcontinent<sup>6</sup>  
(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®

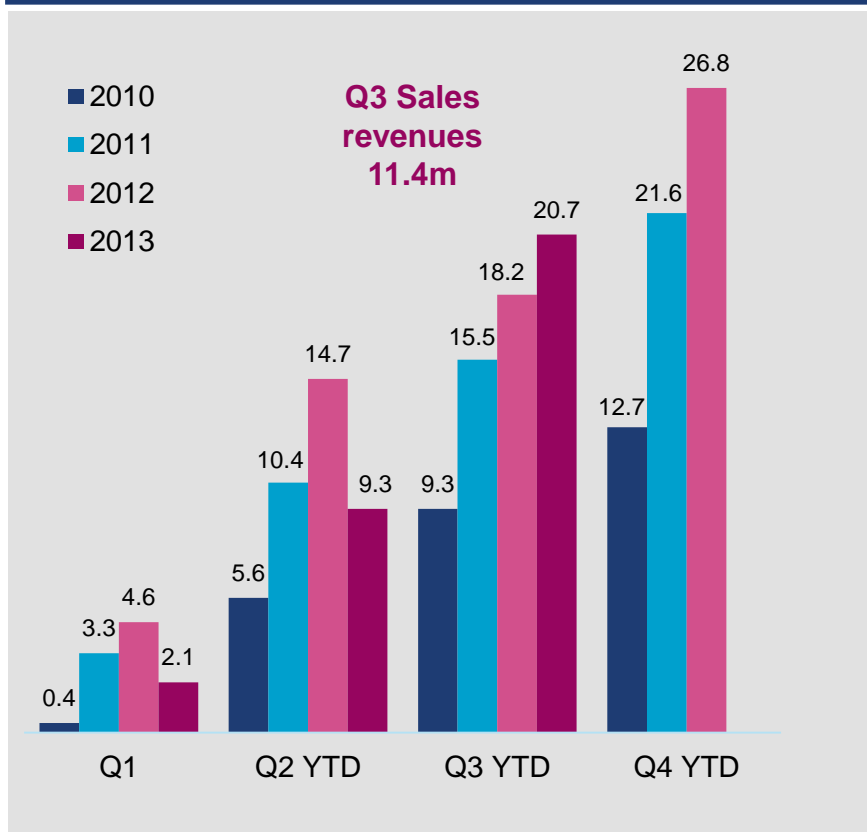
\* Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed. The currently available presentation for IXIARO can be used in children from 3 years of age. 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®:

## Best quarterly sales for Valneva since launch

### Product sales revenues in EUR m



### Q3 sales analysis

- + Sales revenues +13,7% (9months 2013 vs 9months 2012)
- + In-market sales growth trend double-digit largely confirming
- + Single largest military order (approx. 100kds)

### Outlook

- + Following Novartis' decision to reduce its stock levels, full year sales expected in range of 2012
- + Positive impact of pediatric licensure and updated recommendations expected for 2014
- + Military expected to grow as deployed population increases to 250.000 people

# IXIARO®/ JESPECT®:



Valneva obtains market exclusivity for Pediatric Indication in the US\*

## September 2012

- + US Food and Drug Administration (FDA) grants Orphan drug status for Ixiaro® pediatric indication

## May 2013

- + FDA approves the pediatric indication of Ixiaro® for use in children from the age of 2 months

## October 2013

- + FDA grants a 7 years orphan drug market exclusivity to Ixiaro®
- + Exclusivity period began on May 17, 2013
- + \*: No other pediatric JE vaccine can be approved during 7 years except if clinically superior



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# Valneva's R&D programs

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

	Product Candidate	Discovery	IND <sup>1</sup> enabling	PH I	PH II	PH III	Approved/Marketed	Partner
Vaccines	EB66 <sup>®</sup> partnered veterinarian program	[Progress bar: Discovery to PH III]					*	Kaketsuken
	EB66 <sup>®</sup> pandemic flu	[Progress bar: Discovery to PH II]					*	GSK / Kaketsuken
	Pseudomonas aeruginosa	[Progress bar: Discovery to PH II, labeled IC43]						Novartis
	IC31 <sup>®</sup> partnered programs (including tuberculosis vaccine)	[Progress bar: Discovery to PH II]					*	Novartis, Sanofi, SSI, AERAS, others
	EB66 <sup>®</sup> partnered human Programs	[Progress bar: Discovery to PH I]					*	GSK(pandemic flu)
	C. difficile	[Progress bar: Discovery to PH I, labeled IC84]						In-house, Novartis option
	Borrelia	[Progress bar: Discovery to PH I, labeled IC15]						In-house, Novartis option
	Other EB66 <sup>®</sup> based vaccines	[Progress bar: Discovery to PH I]					*	Sanofi Pasteur, Delta-Vir, Transgene, Geovax, Merial Merck Animal Health
Antibodies	VIVA SCREEN <sup>®</sup> partnered human anti-infective mAbs	[Progress bar: Discovery]					*	Sanofi Pasteur (> 3 disease targets)
	Proprietary antibody programs	[Progress bar: Discovery]						In-house

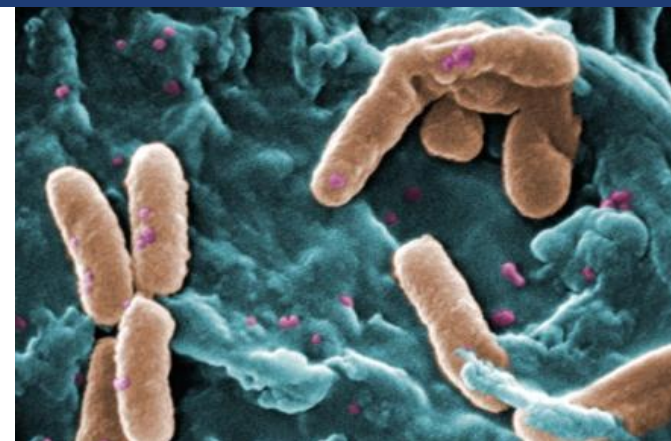
\* Partner programs

<sup>1</sup> Investigational New Drug

# Pseudomonas aeruginosa: targeting 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 after approx. 50% = 400 patients
- + Royalties and potential development milestones of up to EUR 120m

\*: co-financed by partner Novartis

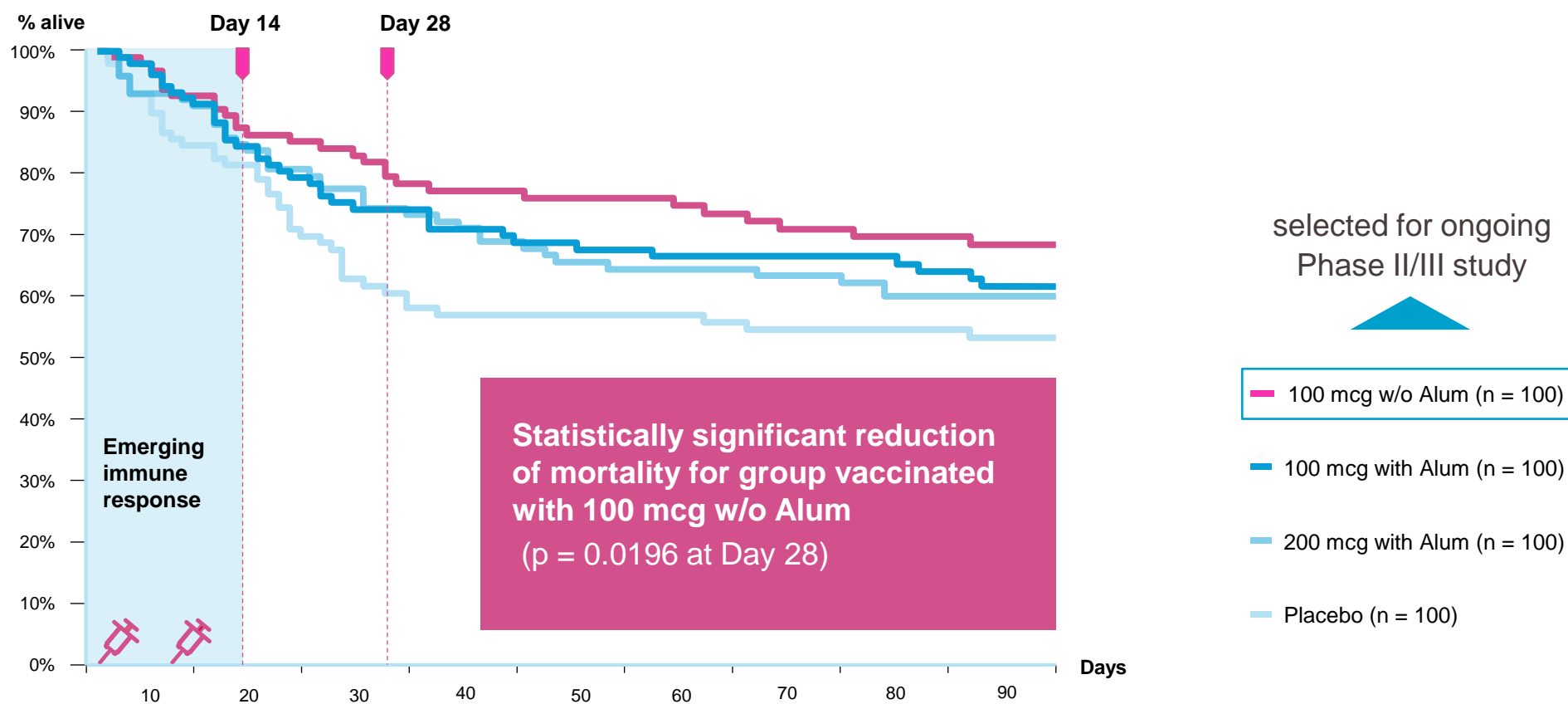




# Pseudomonas aeruginosa:

key findings in Phase II: reduction of mortality in all Pseudomonas vaccine groups vs. placebo

## Survival Rates IC43-201





# Pseudomonas aeruginosa: key development results to date

Current PhII/III interim analysis indicates further confirmation of previous findings

## Previous Key Findings

### Pre-clinical:

- + Protective in a murine lethal *P. aeruginosa* challenge model

### Phase I (163 subjects):

- + Immunogenic in healthy volunteers
- + Safe and well tolerated

### Phase II (400 patients):

- + 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):

- + 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) seems to be confirmed

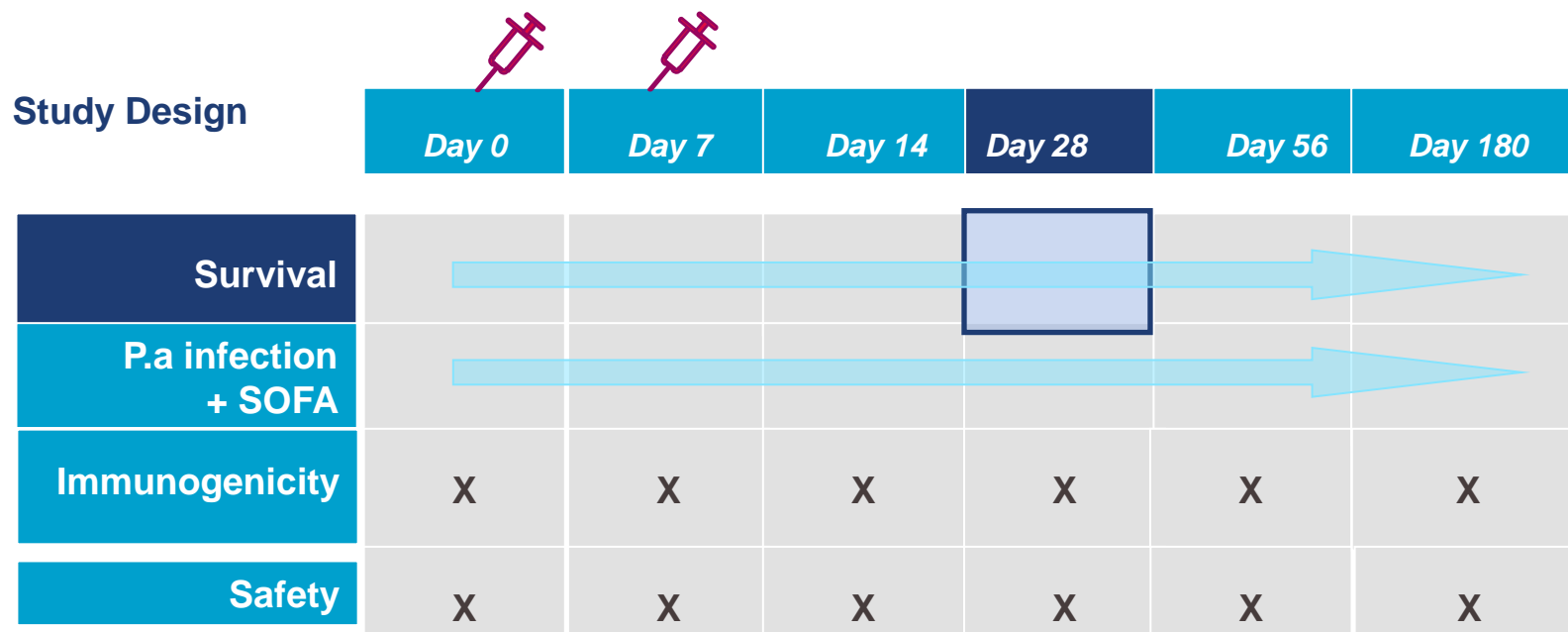
\*: Statistically significant reduction of mortality for group vaccinated with 100mcg w/o Alum (formulation chosen for ongoing phase II/III trial)

\*\* fully blinded / Analysis conducted by Data Monitoring Committee



# Pseudomonas aeruginosa: Phase II/III pivotal efficacy trial – next steps

- + Development partners evaluating different trial progression scenarios
- + DMC will be consulted for potential modification of trial protocol
- + Trial continuation decision (further enrolment possible as of Q1 2014\*)



\* subject to potential regulatory authorizations (if needed)

# Clostridium difficile:

## leading cause of nosocomial Diarrhea

### IC84 vaccine candidate (Phase I)

- + 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](http://www.amozeshonline.com/bacteriology)



## **Clostridium difficile:** positive Phase I results obtained

**Phase Ia and Ib completed with 81 healthy elderly subjects and 60 healthy adults**

- + All trial endpoints met
- + Favorable safety and tolerability profile
- + Immunogenicity in elderly similar to responses to C.Diff toxins A and B observed in adults

**+ Next development steps (Phase II initiation) to be agreed after final study close-out**



## VIVA|Screen®:

### Partnership with Sanofi-Pasteur progressing well

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

- + Fourth antibody discovery program expected to be launched at the end of 2013**
- + First potential milestone payment early 2014 based on Sanofi-Pasteur's decision**



## IC31<sup>®</sup> Adjuvant for Vaccines

Novartis' Phase I ongoing, additional collaborations initiated

### IC31<sup>®</sup> Adjuvant

- + A unique synthetic adjuvant which stimulates strong T-cell immune responses and shows protective efficacy.
- + 8 clinical trials have proven IC31<sup>®</sup> to be a very safe and immunogenic adjuvant in humans.
- + Novartis has exclusive license for the use of IC31<sup>®</sup> in selected new vaccines.

### Q3 Update

- + Novartis: Phase I clinical trial (combines an undisclosed vaccine candidate with the IC31<sup>®</sup> adjuvant) still ongoing
- + Additional research collaborations with various partners to evaluate IC31<sup>®</sup> in new vaccine formulations

**+ Potential new partnerships based on availability of additional clinical data (2014)**



## **EB66<sup>®</sup> cell line for vaccine production:**

2 new EB66<sup>®</sup> agreements in Q3, 7 signed in 2013 to date

### **Q3 Update:**

**+ Delta-Vir GmbH (Newcastle Disease Virus)**

- › Expect to file Clinical Trial Application (EU) in H2/2014

**+ Boehringer Ingelheim**

- › Research agreement for Animal Health Vaccines

**+ Additional commercial license agreements expected in 2013**

- + Expected approval in Japan of H5N1 Pandemic influenza vaccine by GSK's co-development partner Kaketsuken in Q1 2014**





# Tuberculosis and Borrelia vaccine candidates: towards next development stages

## Tuberculosis (Phase II – partner development)

- + 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)
- + TB causes up to 1.7m deaths per year

## IC15 Borrelia vaccine candidate (pre-clinical)

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





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# 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 rights offering ✓
- + Phase I B results C. difficile ✓
- + New EB66® licenses agreements (✓)
- + Phase II/III interim results Pseudomonas (✓)
- + Re-financing of an approx. EUR 20m loan
- + Fourth antibody program with Sanofi Pasteur using the VIVA|SCREEN® platform

### 2014

- + Market approval and launch of EB66® cell-based pandemic influenza vaccine in Japan
- + Sanofi opt-in milestone for first VIVA|SCREEN® antibody program
- + Next approval of a veterinary product produced in the EB66® cell line
- + Phase I initiation Borrelia vaccine
- + Phase II trial start C. difficile\*
- + Further IC31® / Tuberculosis data
- + Phase II/III final results Pseudomonas\*

\* Subject to trial continuation



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Merci  
Danke  
Thank you

