Valneva presents its Q2/H1 2016 financial results

Analyst Presentation
August 31, 2016

valneva

Forward-looking statements

This presentation contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this presentation, those results or developments of Valneva may not be indicative of their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva 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 expectations of Valneva 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, currency fluctuations, the impact of the global and European credit crisis, and the 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. Valneva is providing the information in these materials as of this presentation, and 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 – Newsflow – Thomas Lingelbach

2. Financial report Q2/H1 2016 – Reinhard Kandera

3. Commercialized products & EB66® – Franck Grimaud

4. R&D programs – Thomas Lingelbach

5. 2016 outlook – Thomas Lingelbach

6. Q&A

Valneva's newsflow

August 2016
+ Signing of Marketing & Distribution agreement for Seqirus' flu vaccines in Austria

July 2016
+ Successful completion of Phase II for *Clostridium difficile* vaccine candidate
+ Signing of new EB66® agreements including commercial EB66® license agreement with the Canadian subsidiary of IDT Biologika GmbH
+ European Investment Bank grants Valneva a €25 million loan to fund R&D activities
+ Successful generation of a highly-purified Zika vaccine candidate
+ Valneva appoints two leading pharma executives to its Supervisory Board

June 2016
+ First sales of flu vaccines produced on Valneva's EB66® cell-line
+ *Pseudomonas aeruginosa* candidate did not confirm positive vaccine effect in Ph II/III trial

March 2016
+ Valneva signed $42 million IXIARO® supply contract with US Government

February 2016
+ New R&D collaboration with GlaxoSmithKline for the EB66® cell line

January 2016
+ Successful establishment of new global marketing and distribution network
+ Approval of Japanese encephalitis vaccine in Taiwan through commercial partner Adimmune

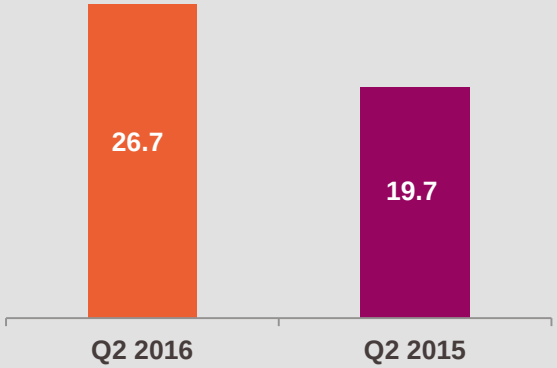
Agenda

1. Introduction – Newsflow – Thomas Lingelbach
2. **Financial report Q2/H1 2016 – Reinhard Kandera**
3. Commercialized products & EB66® – Franck Grimaud
4. R&D programs – Thomas Lingelbach
5. 2016 outlook – Thomas Lingelbach
6. Q&A

Q2 2016 financial results

Compared to Q2 2015 (IFRS, € million, unaudited*)

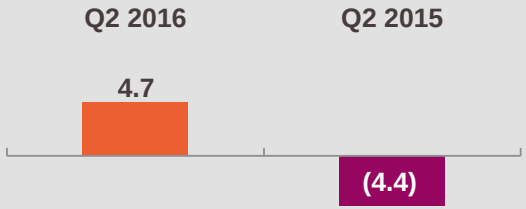
Revenues & Grants



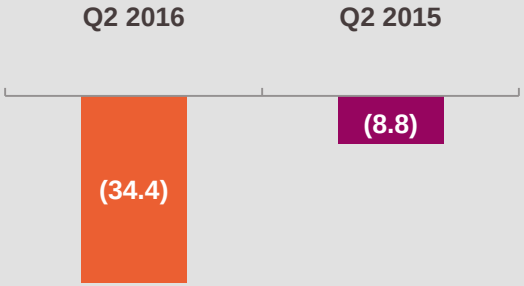
COGS

R&D Expenses

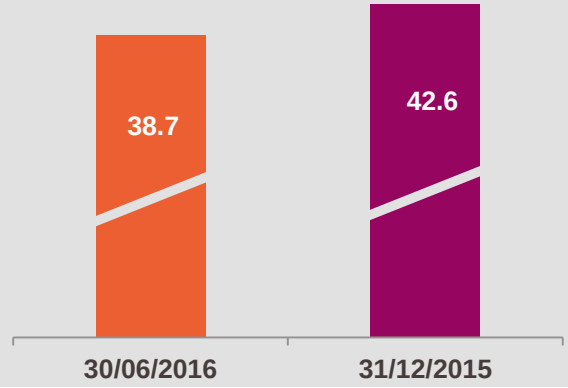
EBITDA**



Net profit/loss



Cash position



* However auditors performed a limited review

**Calculated by excluding Q2 2016 amortization, depreciation and impairment of €37.0m (Q2 2015: €2.9m) from the Q2 2016 operating loss of €32.3m (Q2 2015: €7.3m)

Q2/H1 2016 profit & loss (unaudited)

€ in thousand

	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
Revenues and grants	**26,700**	**19,713**	**51,387**	**39,214**
Cost of goods and services	(8,770)	(11,547)	(21,691)	(23,658)
R&D expenses	(6,658)	(6,985)	(12,457)	(12,489)
Distribution and marketing expenses	(4,061)	(2,274)	(7,356)	(3,492)
General and administrative expenses	(3,558)	(4,316)	(7,323)	(7,083)
Other income / (expense)	(48)	(6)	43	146
Amortization and impairment	(35,939)	(1,844)	(37,658)	(3,638)
Gain on bargain purchase	-	-	-	13,183
OPERATING LOSS	**(32,334)**	**(7,259)**	**(35,054)**	**2,183**
Finance results and tax	(2,089)	(1,587)	(4,406)	(1,237)
LOSS FOR THE PERIOD	**(34,422)**	**(8,846)**	**(39,460)**	**946**
EBITDA*	**4,658**	**(4,384)**	**4,672**	**(5,346)**

* Calculated by excluding amortization, depreciation, impairments and gains from bargain purchase from the operating profit/loss

Business segment overview H1

Two profitable segments funding R&D pipeline

	Revenues	Operating profit/loss (before amortization*)
Commercial products	**€41.0m**	**€13.4m**
	56% gross margin	33% operating margin
Technologies & services	**€6.5m**	**€2.1m**
	46% gross margin	32% operating margin
Proprietary R&D	**€3.9m**	**(€5.4m)**
		€9.2m R&D expenses
Overhead		**(€7.5m)**
		15% of operating expenses
Subtotal		**€2.6m**
Amortization & Impairment*		**(€37.7m)**
Total Operating Loss		**(€35.1m)**

*of merger/acquisition related intangible assets – non cash

Financial analysis H1 2016

Product sales	48.8% increase to €40.9m Driven by strong IXIARO®/JESPECT® sales (up 100.2% compared to H1 2015)
Total revenues & grants	€51.4m (up 31.0% compared to H1 2015) - on track to meet €90-100m revenue goal for FY 2016
COGS	€21.7m total COGS yielding 57.8% gross margin, including 55.7% gross margin on product sales
R&D expenses	Driven by R&D pipeline expansion while spending on late stage programs is decreasing (€12.5m)
Distribution & marketing expenses	Increase to €7.4m (vs. €3.5m in H1 2015) driven by establishment of own sales & marketing organization
G&A expenses	3.4% increase to €7.3m due to full inclusion of acquired Swedish business and broadened geographical presence

Financial analysis H1 2016 (continued)

Amortization of intangible assets	€37.7m non-cash amortization charges on acquired intangible assets (includes one-time impairment charges of €34.1m related to the *Pseudomonas aeruginosa* project)
Financial income and expenses	Negative effects from EUR/GBP exchange rates following “Brexit” included; However, operating results are benefitting from weak GBP
EBITDA	H1 2016 EBITDA of €4.7m showing strong improvements and confirms trend towards operational break-even
Net Loss	€39.5 million net loss (includes one-time impairment charges of €34.1m related to the *Pseudomonas aeruginosa* project)
Cash	€38.7 million net cash at quarter-end; €25m loan agreement with EIB provides additional financial flexibility;

2016 financial outlook confirmed

Strong revenue growth and positive trend towards EBITDA break-even

Revenues	€90 – 100m total revenues (up to 20% growth vs. 2015)
Commercial products	€70 – 80m product sales (up to 30% growth vs. 2015) 50% gross margin on product sales (vs. 32% in 2015)
R&D investments	€25m R&D expenses (at 2015 level)
EBITDA	Close to operational break-even Less than €5m EBITDA loss (vs. €8.5m in 2015)

Agenda

1. Introduction – Newsflow – Thomas Lingelbach
2. Financial report Q2/H1 2016 – Reinhard Kandera
3. **Commercialized products & EB66® – Franck Grimaud**
4. R&D programs – Thomas Lingelbach
5. 2016 outlook – Thomas Lingelbach
6. Q&A

Leading commercial product: Japanese encephalitis vaccine

Protecting travelers from the most common encephalitis in Asia[1]

Japanese Encephalitis vaccine

+ Designed to protect travelers, military personnel and populations in endemic regions against Japanese encephalitis (JE)
+ Indicated for active immunization against JE in adults, adolescents, children and infants aged two months and older[1]

Commercial position

+ Currently, no effective treatment for the disease[2]
+ Valneva's vaccine is the only approved vaccine available for US and EU travelers ≥ 2 month of age[1]
+ Exclusive supplier agreement in place with US military
+ Asian manufacturers mainly serve local public markets

Growth drivers

Increased product adoption by travelers through reinforced product awareness and improved usage with rapid-immunization-schedule

Improved recommendations

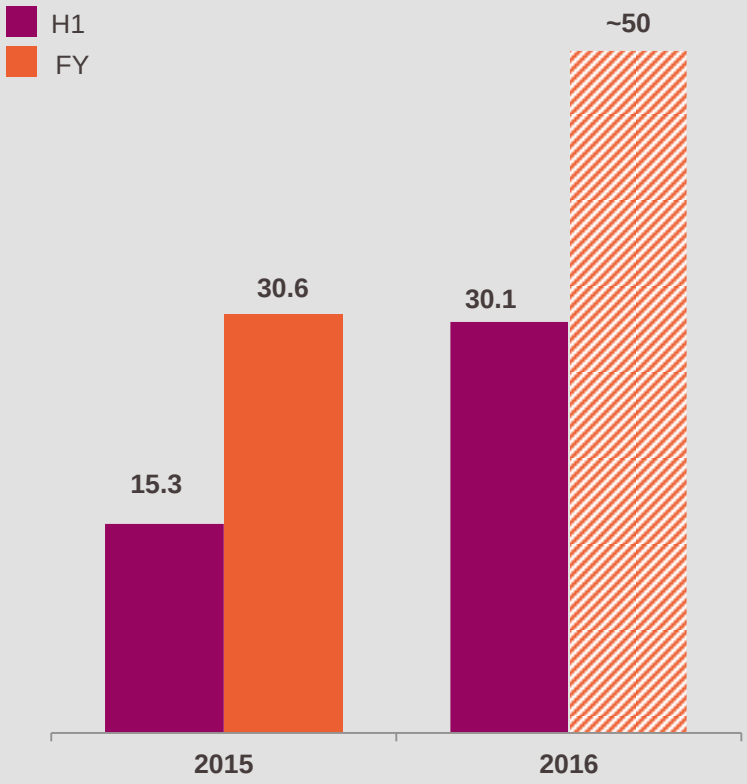
Geographical expansion

1 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; **2** CDC. MMWR 2010;59:1-27

Leading commercial product: Japanese encephalitis vaccine

IXIARO®/JESPECT®: significant growth driven by improved margins and strong demand from US military, Germany, UK and Canada

Product sales revenues in € million



IXIARO®/JESPECT® Q2/H1 2016 sales analysis

H1 2016 product sales doubled to €30.1m
(compared to €15.3m in H1 2015)

Q2 2016 product sales reached €15.6m
(compared to €5.3m in Q2 2015)

Significant growth was driven by:

+ Improved margin structure through Valneva's new distribution network
+ Policy adoption by USM and full revenue recognition
+ Increased penetration in key traveler markets

Outlook

Valneva will supply IXIARO® doses to US military for a total value of $42m over a two-year period

Valneva is confident it can meet its FY 2016 guidance of ~€50m product sales

+ Based on observed demand pattern in the travelers' markets and supplies to the US military

Commercial product: Cholera/ (ETEC[1]) vaccine

Established vaccine in the field of diarrhea

DUKORAL®

+ For the prevention of diarrhea caused by Vibrio cholera (cholera) and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)[1]
+ In a number of countries including the EU, indicated to protect against cholera only
+ Designed to protect adults and children from 2 years of age who will be visiting endemic areas

Commercial position

+ Only approved cholera vaccine available for European, Canadian and Australian travelers
+ WHO pre-qualification; widely used in other countries
+ Asian manufacturers predominantly serve local markets and primarily for cholera only

Growth opportunities

Support label harmonization across all key countries

Increased communication with medical community

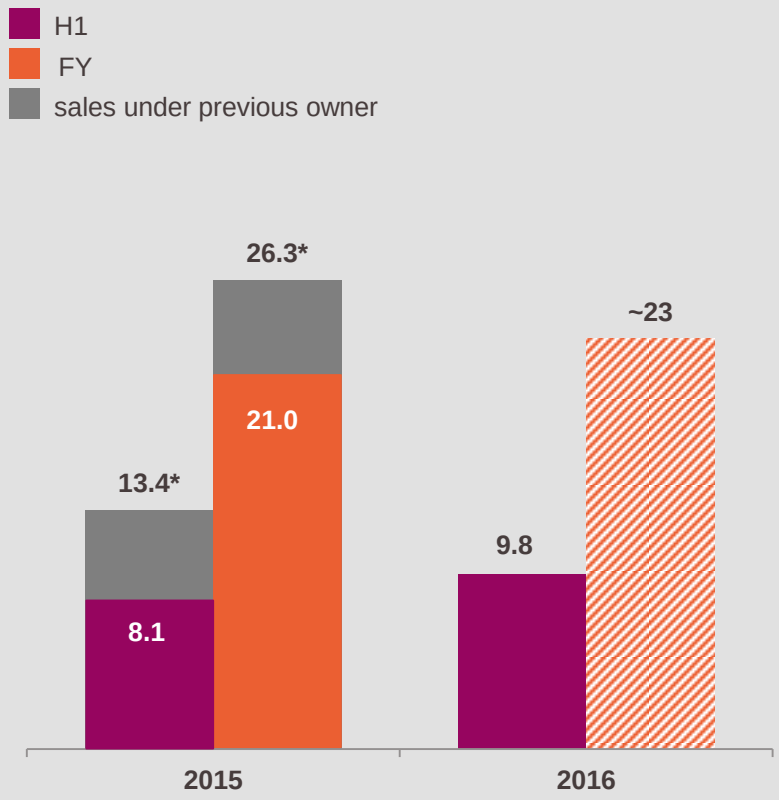
Product life cycle management

TV campaign in Canada starting Q4

1 Indications differ by country - 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, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

Commercial product: Cholera/ (ETEC[1]) vaccine
DUKORAL® update

Product sales revenues in € million



DUKORAL® Q2/H1 2016 sales analysis

H1 product sales reached €9.8m in H1 2016

(Compared to €8.1m of Valneva sales in H1 2015)

Q2 2016 sales amounted to €4.4

(Compared to €3.6m in Q2 2015)

In-market sales growth demonstrated in key markets (Nordics, AUS, DE, ES). Significant disease and product awareness campaign ongoing in Canada following update to product monograph.

Outlook

Product sales in line to meet Company expectations of ~€23m product sales in 2016

Growing DUKORAL® by way of promotional efforts, geographic expansion, and potential further product life cycle management

1 Indications differ by country - 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, ETEC = Enterotoxigenic Escherichia coli (E. Coli);
***** pro-forma sales incl. €5.3m under previous owner;

New M&D agreement for third-party distribution

Valneva to distribute Seqirus' flu vaccines Sandovac® and Fluad® in Austria

Seqirus is the second largest flu company in the world that combines strength and expertise of bioCSL Inc. and the influenza vaccines business formerly owned by Novartis AG

+ Yearly influenza epidemics are a serious public health problem worldwide
+ Valneva will start distributing Seqirus' vaccines beginning with the 2016-2017 flu season in Austria

Sandovac®

+ Inactivated seasonal flu vaccine
+ Licensed for individuals 6 months of age and older

Fluad®

+ Adjuvanted, inactivated seasonal flu vaccine
+ Approved for use in persons 65 years of age and older

This step supports our strategy to leverage our sales and marketing infrastructure and expand our commercial footprint worldwide

+ Valneva expects to sign additional agreements for the marketing and distribution of third-party vaccines

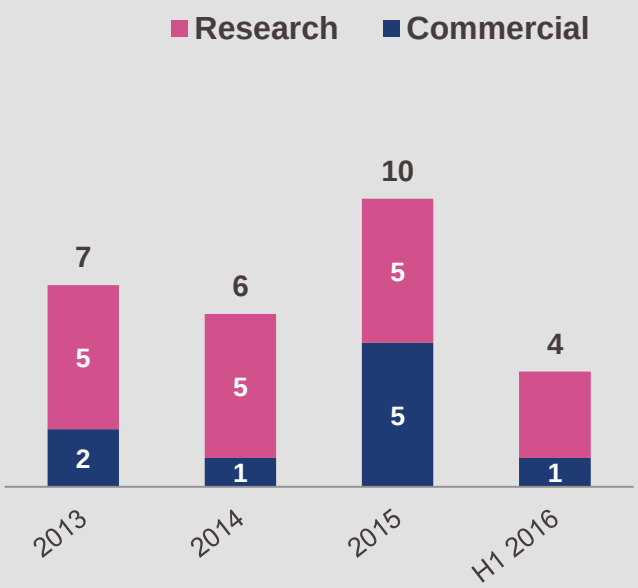
EB66® platform for efficient large scale vaccine production

The technology is becoming increasingly profitable

Revenue generating platform

+ **Fully characterized cell-line** (**avian** embryonic stem cell derived) with **low production costs**
+ **Over 35 agreements with the world's largest pharma cos**
+ **~ 7 new licenses per year**
+ **€34m** in upfront, milestones & research fees **received to date**
+ **Exclusive license to**:
  - › **GSK** for EB66®-based pandemic and seasonal influenza vaccines
  - › **Jianshun Biosciences** to commercialize EB66® in China

5 new agreements signed in 2016



Recent highlights

Valneva recorded first royalties from the sale of EB66® based pandemic influenza vaccine under its partnership with GSK

New commercial license agreement with Gallant Custom Laboratories Inc., a Canadian subsidiary of the German animal health firm IDT Biologika GmbH

+ To develop, manufacture and commercialize vaccines for the prevention of influenza virus in poultries and fowl adenovirus

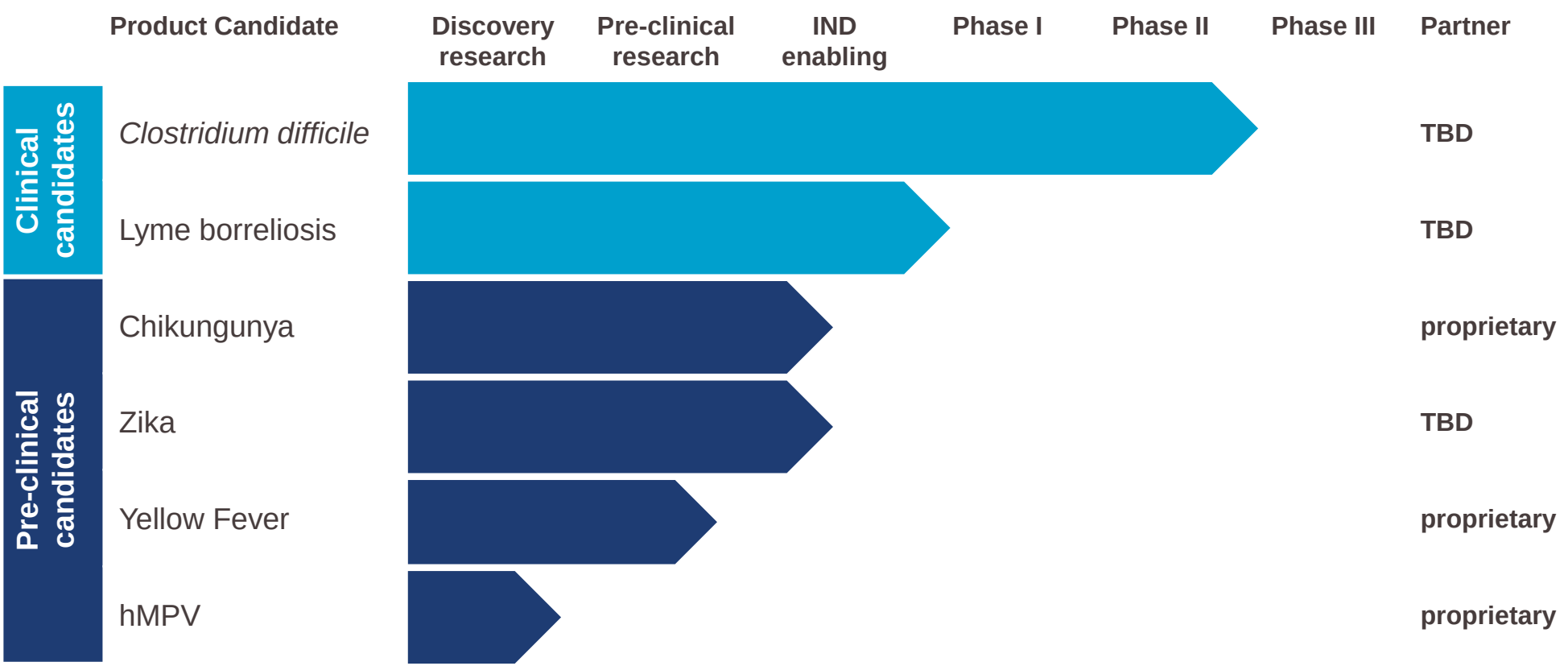
Several research licenses with European companies

Agenda

1. Introduction – Newsflow – Thomas Lingelbach
2. Financial report Q2/H1 2016 – Reinhard Kandera
3. Commercialized products & EB66® – Franck Grimaud
4. **R&D programs – Thomas Lingelbach**
5. 2016 outlook – Thomas Lingelbach
6. Q&A

Valneva's pipeline of vaccine candidates

New pre-clinical candidates for future clinical development



Pre-commercial product: Clostridium difficile vaccine

Vaccine targeting healthcare-associated diarrhea, an increasing threat to elderly

Clostridium difficile (C. diff)

- **Single most common pathogen of acute healthcare-associated infections in the US[1] (~ 450,000 cases of annually and ~ 30,000 deaths[2])**
- **~ 172,000 cases in EU member states per year[3]**
- **Targeting primary prevention of *C. difficile***
  - Current antibiotic treatments have significant limitations with recurrence in ~20% of cases[4]

Valneva's vaccine candidate

- **Vaccine targeting primary prevention**
- **One of three clinical programs**
- **Expected to enter market as number two**
- **Total market estimate of >USD 1 bn/year target groups[5]**

Current development status VLA84

- **Final positive Phase II results announced in July 2016**
- **Vaccine dose confirmed in older adults and elderly**
- **Highly immunogenic in all age groups tested (strong immune responses to both C. diff toxins A & B)**
- **Good safety and tolerability profile confirmed**

Valneva aims for a licensing agreement in 2016

- **GSK waived option rights for strategic reasons ahead of final data analysis**
- **Discussions with potential partners ongoing**

Source picture: www.123rf.com; **1** 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; **2** Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34. **3** Clostridium difficile infection in Europe. A CDI Europe Report.; **4** Leffler et al, Clostridium difficile infection. N Engl J Med 2015;372:1539-48; **5** VacZine Analytics Clostridium difficile prophylactic vaccines Market View, January 2014;

Pre-commercial product: *Clostridium difficile* vaccine

Next steps

Phase II study close-out

+ **Final Phase II results of Valneva's Clostridium difficile vaccine candidate confirmed positive initial Phase II data that were released at the end of 2015**

VLA 84 – ready for Phase III

+ **The study design was agreed with regulators in Europe and the US with the aim of supporting a subsequent progression into Phase III.**

Licensing agreement

+ **Discussions with potential partners ongoing and the Company reaffirms its expectation to enter into a partnering agreement for this program by the end of this year**

Pre-commercial product: Lyme borreliosis vaccine

Targeting Lyme borreliosis, with market potential of above €500m[4]

Lyme borreliosis

+ **Transmitted by Ixodes ticks[1], causing Lyme**
+ **Most common vector borne illness in the Northern Hemisphere (~300,000 cases per year in US[3] and ~85,000 cases per year in Europe[2])**
+ **Delayed or inadequate treatment can lead to disabling sequels**

Valneva's vaccine candidate

+ **Only active clinical program, no vaccine on the market**
+ **Multivalent, protein subunit-based vaccine**
+ **Targets the outer surface protein A (OspA) of Borrelia**

Current development status VLA15 (Pre-clinical)

+ **Pre-clinical testing completed**
  - › Data showed that the vaccine has the potential to provide protection against the majority of Borrelia species pathogenic for humans
+ **IND submission initiated**

Phase I to commence in 2016

+ **Priority in EU markets where high awareness on tick transmitted diseases exists**
+ **Expected penetration rates of up to 10% in high-incidence territories 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** Estimate of Valneva, concentrated in private markets

Pre-clinical candidate: Chikungunya vaccine

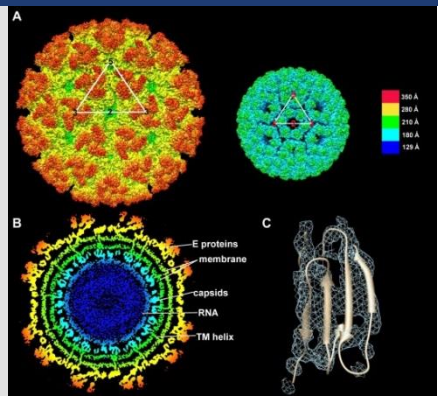
Targeting Chikungunya, an emerging outbreak disease

Chikungunya virus

+ **Transmitted by Aedes mosquitoes, causing Chikungunya disease**
+ **Outbreaks in Asia, Africa & Europe, most recent spread to the Americas (> 180,000 reported cases in 2016) [1]**
+ **Outbreak disease with large attack rates, up to 50% of those infected experience prolonged or long term symptoms**

Valneva's vaccine candidate

+ **Monovalent, single dose, live attenuated virus vaccine**
+ **Grown on Vero cells**
+ **Protective against various CHIKV outbreak phylogroups & strains [2]**



Current development status VLA1553 (Pre-clinical)

+ **Pre-clinical testing completed**
  - › Data from non-human primates (NHP) showed that the vaccine was safe and has the potential to provide long term protection against Chikungunya after a single immunization
+ **Pre-clinical development initiated**

Phase I to be initiated in H2 2017

+ **Priority for travelers to endemic regions, also interesting for military; larger traveler market than JE**
+ **Public endemic market and emergency stockpiling as secondary target populations**

Picture source: Sun et al. 2013, eLife 2:e00435; **1** PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016); **2** Hallengärd et al. 2013. J Virology 88:2858–2866.

Pre-clinical candidate: Zika virus vaccine

Targeting a Public Health Emergency of International Concern

Zika virus disease

- Transmitted mostly by Aedes species mosquito, same species also transmits Dengue, Yellow Fever etc.
- Zika infection is associated with microencephaly, severe brain defects and Gullian-Barre syndrome (GBS)
- Economic impact of Zika estimated $3.5 billion in 2016[1]
- No vaccine available

Valneva's vaccine candidate

- Vero cell based, highly purified, inactivated, whole-virus ("PIV"), alum adjuvanted
- Biological, chemical & physical profile similar to IXIARO®
- Two injections expected to generate full protection in humans

Current development status VLA1601 (Pre-clinical)

- **Pre-clinical proof of concept achieved**
  - Animal data generated in validated mouse-model used as correlate of protection (PRNT)
  - Vaccine elicts high titered antibodies that also cross neutralize various Zika virus strains
- **Preliminary discussions held with European Medicines Agency**

Phase I could commence early 2017

- Valneva intends to leverage IXIARO® production facility - Clinical trial material manufacturing possible in short term
- Competitive advantage on regulatory pathway and full industrialization foreseen given full application of JEV technology
- Partnering evaluations initiated

1 http://pubdocs.worldbank.org/en/410321455758564708/The-short-term-economic-costs-of-Zika-in-LCR-final-doc-autores-feb-18.pdf

Event calendar and anticipated newsflow 2016

Commercialized products	+ FY 2016 product sales in the expected range of €70 to €80m (up to 30% growth) + Successful implementation of own global marketing & distribution network leading to IXIARO®/JESPECT® sales of ~€50m in 2016 + Expected gross margin on product sales of approximately 50% in 2016
Technologies & Services	+ Additional EB66® and IC31® licensing agreements
Vaccine candidates	+ Phase III partnering for the *Clostridium difficile* vaccine candidate + Lyme borreliosis Phase I clinical trial to commence end 2016 + Decision on progression of second clinical candidate for 2017

Agenda

1. Introduction – Newsflow – Thomas Lingelbach
2. Financial report Q2/H1 2016 – Reinhard Kandera
3. Commercialized products & EB66® – Franck Grimaud
4. R&D programs – Thomas Lingelbach
5. 2016 outlook – Thomas Lingelbach
6. **Q&A**

Thank you.

valneva