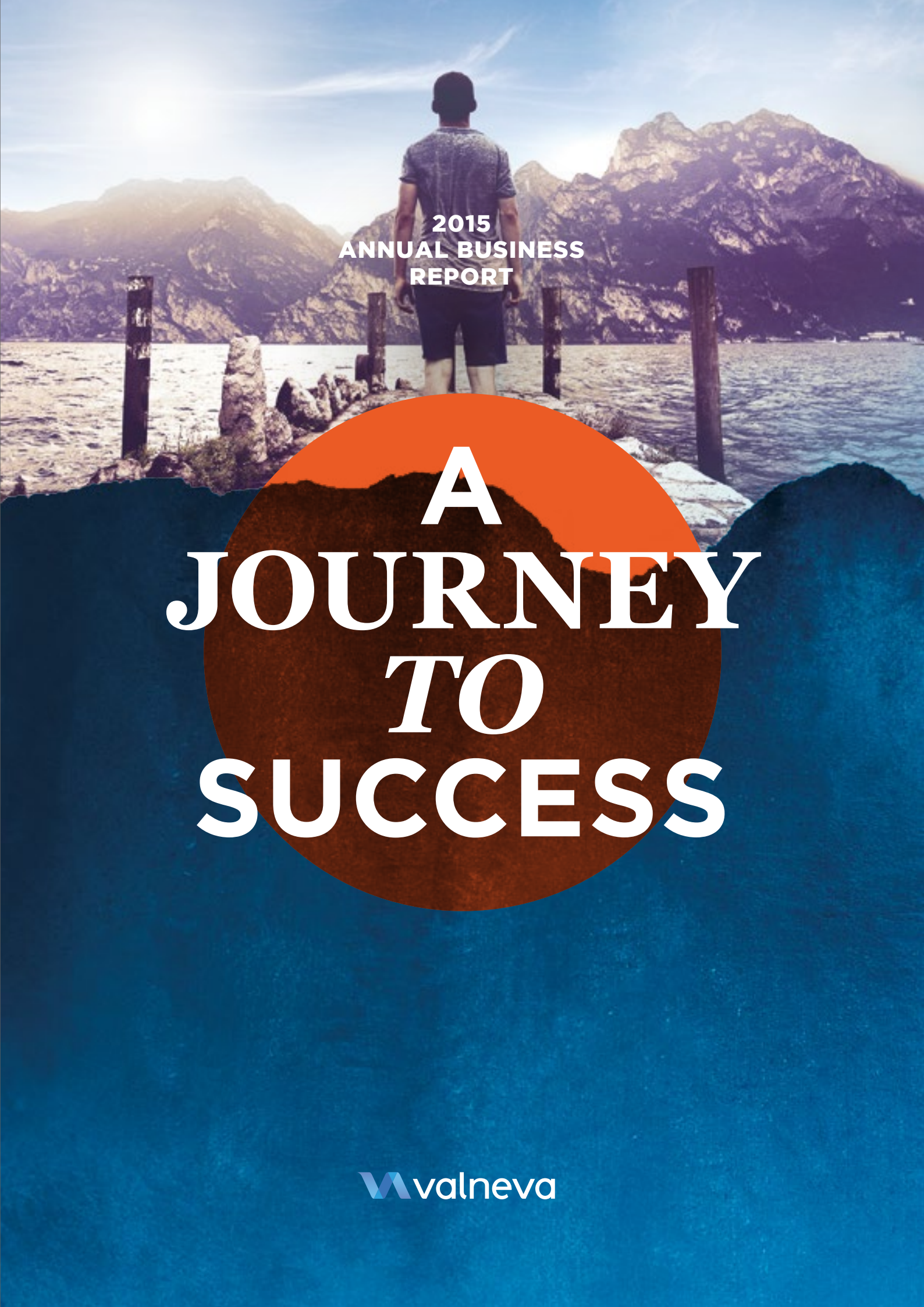


2015
ANNUAL BUSINESS
REPORT

A JOURNEY *TO* SUCCESS

valneva

ADVANCING VACCINES FOR BETTER LIVES

AS AN INDEPENDENT AND FULLY-INTEGRATED VACCINE COMPANY THAT SPECIALIZES IN THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF INNOVATIVE VACCINES, VALNEVA'S MISSION IS TO PROTECT PEOPLE FROM INFECTIOUS DISEASES. WITH TWO VACCINES ON THE MARKET, PROMISING PRODUCT CANDIDATES IN CLINICAL DEVELOPMENT AND TWO VALIDATED TECHNOLOGIES, VALNEVA FOCUSES ON SEGMENTS WHERE INNOVATIVE VACCINES ARE URGENTLY NEEDED.


30
COMMITMENTS
36
FINANCIAL REVIEW
32
KEY FIGURES
A JOURNEY TO SUCCESS
14
PRODUCTS
28
CORPORATE GOVERNANCE
17
VACCINE CANDIDATES
37
FINANCIAL OUTLOOK

LETTER FROM THE *MANAGEMENT* BOARD

Valneva's business year 2015 was marked by excellent operational performance and major strategic steps on our path to further build a leading independent vaccine company.

We acquired and successfully integrated DUKORAL®, a vaccine to protect against cholera and, in some countries, against diarrhea caused by LT-ETEC[1]. With this well established product, we expanded our commercial vaccine portfolio of travel vaccines. DUKORAL® generated €21.0 million in product sales in 2015 for Valneva. The newly acquired business, including the DUKORAL® manufacturing site and an R&D service unit in Sweden, along with a Nordics vaccine distribution business, is expected to be financially sustainable and to contribute positive cash flows.

With two global brands, we took the important strategic decision in 2015 to build our own commercial infrastructure to support our commercial portfolio. Consequently, we terminated the IXIARO®-related marketing and distribution agreement with GlaxoSmithKline (GSK) in order to take direct control over marketing and distribution of IXIARO®. Although we had initially anticipated a temporary negative transition effect, it did not materialize. From 2016 onwards the new distribution and marketing network will allow us to leverage synergies with our second vaccine DUKORAL® and to increase IXIARO®'s margins and profitability. The combination of strong-in-market sales growth and a very collaborative and professional transition with GSK resulted in net product sales of €30.6 million in 2015, in line with prior guidance.
In addition to the Nordic sales and marketing team that became part of Valneva through the acquisition of DUKORAL® and the Swedish operations, we built two new dedicated sales and marketing organizations in Montreal, Quebec and London, UK. Our US office was also expanded in order to support our IXIARO® sales business to the US Military, our single largest customer. To complement our own commercial sales infrastructure and ensure broad geographic availability of our products, we entered into a number of country-specific marketing and distribution agreements

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, LT-ETEC = Heat-labile toxin producing enterotoxigenic *E.coli*

with leading local partners including VaxServe, Inc., a Sanofi Pasteur company (US private market) and GSK (Germany, Austria, France). The successful establishment of Valneva's new global marketing and distribution network is expected to deliver product sales in the range of €70 to €80 million in 2016 – representing up to 30% growth over 2015 with more than 60% of the 2016 product sales forecast for Valneva's own commercial teams.

Our two technology platforms, EB66® and IC31®, are offering the basis for internal programs and partnerships. Valneva signed 10 new license agreements on the EB66® vaccine production cell line in 2015. Our key partners in the veterinarian and human vaccine industry continue to develop and license EB66®-based products. A significant upfront payment from the first Chinese licensing agreement and an increasing revenue stream from EB66® royalties have helped the technology business segment develop into a positive cash generator.

Valneva's aggregate revenues and grants for 2016 are expected to be close to €100 million. While we focus on growing revenues and profitability of the cash-generating commercial part of our business, our vaccines research & development efforts are given equal strategic importance in order to generate long-term returns. Our R&D efforts concentrate on the identification and development of innovative vaccines that can address unmet medical needs.

In 2015, Valneva further progressed its two late-stage clinical development candidates which address hospital and healthcare-associated infections against *Pseudomonas aeruginosa* and *Clostridium difficile* infections. Our *Clostridium difficile* vaccine candidate has generated positive top-line data in a Phase II study conducted in the US and Europe, and we aim for a Phase III partnership agreement in 2016 to further progress this vaccine into Phase III. For our *Pseudomonas aeruginosa* Phase II/III trial, we successfully completed enrollment of approximately 800 patients in 2015. Results of this trial are expected in the second quarter of 2016 and represent a significant pipeline catalyst. We will also add a new program to our clinical portfolio this year as our Lyme borreliosis vaccine candidate is expected to enter Phase I in 2016. Valneva also has a broad portfolio of research-stage candidates, including vaccines against chikungunya, yellow fever, Zika and human metapneumovirus (hMPV), from which we have selected chikungunya as the next program for clinical entry.
Total revenues and grants were €83.3 million in 2015 (compared to €42.4 million in 2014) and EBITDA for the year was minus €8.5 million, supporting our positive trajectory towards break-even. For 2016, we expect to further reduce our EBITDA loss and see the possibility of reaching EBITDA break-even in the second half while continuing to invest around €25 million in R&D. Our long-term goal is to grow revenues to around €250 million by 2020 from existing and future products while delivering positive cumulative cash-generation.
The Company will continue to build on R&D value growth and anticipates investing at least 20% of its revenues annually in an innovative R&D pipeline with at least one clinical candidate at each stage of product development. To deliver on these goals, Valneva's strategy is to complement its profitable organic growth with opportunistic M&A that could generate additional revenue streams. In these exciting times, we reinforce our commitment to our employees who are our single largest asset.

We are proud of Valneva's enthusiastic working culture that is marked by innovation, flexibility and strong execution. We are one team that stands and works together.

Developing a business is an endeavor, like a journey that takes us to summits and sometimes over rough terrain, but at Valneva we strongly believe that this is a journey of continued success.

THOMAS LINGELBACH
President and CEO

FRANCK GRIMAUD
Deputy CEO

REINHARD KANDERA
CFO

BUSINESS HIGHLIGHTS

February *2015*

Valneva expands its travel vaccine portfolio through the acquisition of DUKORAL® and also acquires a vaccine distribution business in the Nordic countries

Valneva announces the successful completion of its €45 million capital increase

June *2015*

Valneva takes direct control over marketing and distribution of IXIARO® to increase margin and profitability

July *2015*

Valneva and PaxVax enter into marketing and distribution agreement

November *2015*

Valneva announces US marketing and distribution services agreements with VaxServe for Japanese encephalitis vaccine IXIARO®

January *2016*

Valneva successfully established a global marketing and distribution network with new offices in the UK and Canada

March *2016*

Valneva announces up to $42 million IXIARO® supply contract with US government

R&D HIGHLIGHTS

January
2015

Valneva grants exclusive worldwide license to Altimmune for the development of hepatitis B vaccines in combination with the IC31® adjuvant

March
2015

Valneva signs an exclusive license agreement with Jianshun Biosciences to commercialize the EB66® cell line in China and receives a €2.5 million upfront payment

Valneva announces the approval of an EB66®-based prototype influenza vaccine in Japan

Valneva signs two new EB66® agreements with Merial and an undisclosed European company for the development of veterinary vaccines

July
2015

Valneva completes patient enrollment for Pseudomonas aeruginosa Phase II/III trial

August
2015

Valneva announces two new EB66® agreements with Italian firm Fatro and Japanese pharmaceutical company Kaketsuken

November
2015

Valneva reports positive Phase II results for its Clostridium difficile vaccine candidate

December
2015

Valneva announces DUKORAL® label change in Canada and a €25 million reduction of the purchase consideration

February
2016

Valneva announces it is evaluating the development of a Zika vaccine candidate

A GROWTH STRATEGY ***BASED ON THREE*** PILLARS

COMMERCIALIZED ***VACCINES***

VACCINE ***CANDIDATES***

TECHNOLOGIES AND ***SERVICES***

Valneva's strategy is to become the world's largest independent and fully-integrated vaccine company by growing revenues from commercialized vaccines, both through organic growth and opportunistic M&A, and by focusing R&D investments in promising product candidates to generate long-term financial returns.

With a portfolio of two commercialized vaccines, Valneva has gained a decisive foothold in the travelers' vaccine segment:

IXIARO® is an intramuscular vaccine indicated for active immunization against the Japanese encephalitis virus.
DUKORAL® is an oral vaccine indicated for active immunization against cholera. The indication in some countries also includes diarrhea caused by LT-ETEC[1], the most frequent cause of travelers' diarrhea.
THIRD-PARTY PRODUCTS: Valneva also commercializes third-party products in certain territories like typhoid vaccine Vivotif® for example.

Valneva conducts clinical trials to develop new vaccines against the life-threatening hospital-acquired bacteria, ***Pseudomonas aeruginosa*** and ***Clostridium difficile*****.**
The Company also focuses on the research and development of other emerging diseases in areas of need for efficacious vaccines. Its vaccine candidate against **Lyme borreliosis** is expected to enter into a Phase I study in 2016 and its **chikungunya** vaccine candidate in 2017. Other pre-clinical projects focus on vaccine development against **Zika, yellow fever and human metapneumovirus (hMPV).**

Valneva's two proprietary technologies, the **EB66® cell line** and the **IC31® adjuvant,** help the Company and its partners to improve the effectiveness in vaccine development and manufacturing, and deliver growing cash contributions from licensing.

Valneva has entered into strategic partnerships and collaborations with large vaccine manufacturers and distributors, including GSK, Sanofi-Pasteur, the Statens Serum Institut, Merial or Kaketsuken, to develop new vaccines using the EB66® cell line and the IC31® adjuvant.

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, LT-ETEC = Heat-labile toxin producing enterotoxigenic *E.coli*

2016 OUTLOOK

Financial guidance

+ Valneva expects 2016 revenues to reach €90 to €100 million with product sales in the expected range of €70 to €80 million, reflecting up to 30% growth over 2015 product sales.

+ Improved revenues due to Valneva's new global marketing & distribution network are expected to lead to a gross margin on product sales of approximately 50% in 2016.

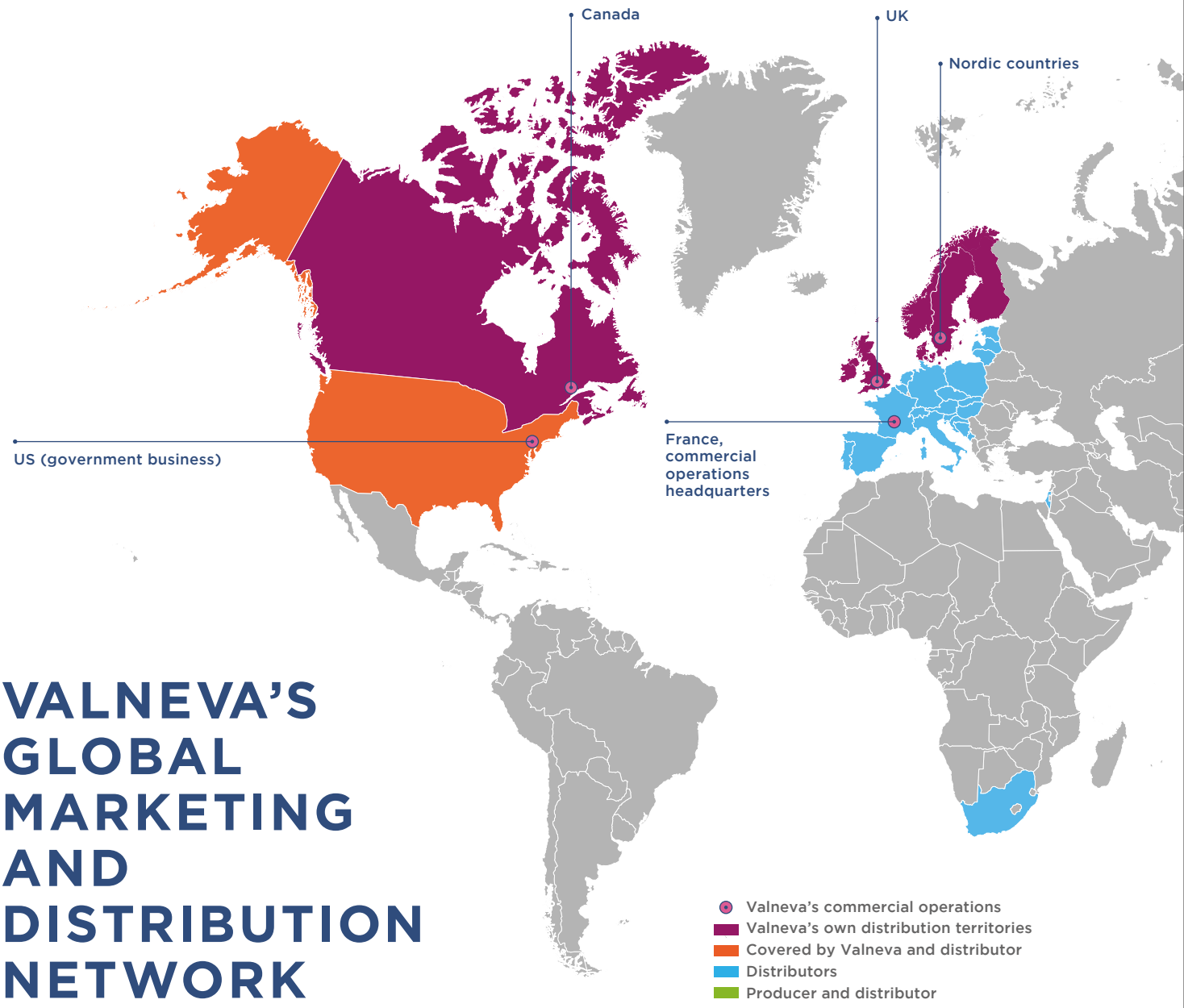
+ Valneva will continue to strive towards financial self-sustainability and expects to reduce its EBITDA loss to less than €5 million in 2016 while investing around €25 million in R&D.

Significant pipeline catalysts in 2016

+ Phase II/III results of *Pseudomonas aeruginosa* vaccine candidate in the second quarter of 2016.

+ Expected partnership agreement for Phase III trial of *Clostridium difficile* vaccine candidate before the end of 2016.

+ Clinical entry of Lyme borreliosis vaccine candidate expected in the second half of 2016.



VALNEVA'S GLOBAL MARKETING AND DISTRIBUTION NETWORK

With commercial operations in the US, Canada, UK and the Nordic countries, Valneva is well positioned to directly serve key markets for its current products.

In 2015, Valneva decided to take direct control over the marketing and distribution of its Japanese encephalitis vaccine IXIARO® by terminating the marketing and distribution agreement with GlaxoSmithKline related to IXIARO®, initially signed in 2006 with Novartis Vaccines. Subsequently, we launched our own global marketing and distribution network in order to improve our margins and profitability and leverage synergies with our second travel vaccine DUKORAL®, and to build commercial capabilities in order to position Valneva as a vertically integrated vaccine player capable of rolling-up vaccine assets.

For the time being, Valneva decided to establish commercial operations in four countries, estimated to represent approximately 60% of the Company's 2016 expected product sales.

Valneva acquired a sales and marketing team in the Nordic countries in 2015 and recently established two new dedicated sales and marketing organizations with offices in Montreal, Canada and London, UK, which will focus on developing IXIARO® and DUKORAL® sales, in addition to third party products. In the US, Valneva will distribute IXIARO® directly to the US military, the Company's largest customer for this vaccine.

Valenva's commercial teams have extensive expertise in the sale, marketing and distribution of vaccines, gained through prior experience both in leading pharmaceutical and biotech companies.

Nordic countries

Valneva's sales and marketing team in the Nordic countries has well-established commercial operations and intends to further expand its presence by broadening its current portfolio with complementary customer products. The team currently distributes Valneva's vaccines IXIARO® and DUKORAL®, and third-party vaccines including the typhoid travel vaccine Vivotif®. This market represents approximately 24% of our expected European travel vaccine sales for 2016.

UK

In early 2016, Valneva launched new commercial operations in the UK to further develop the sales of the Company's travel vaccines IXIARO® and DUKORAL®, in addition to selling third-party products. Sales from the UK operations represent approximately 13% of expected European travel vaccines sales for 2016.

Canada

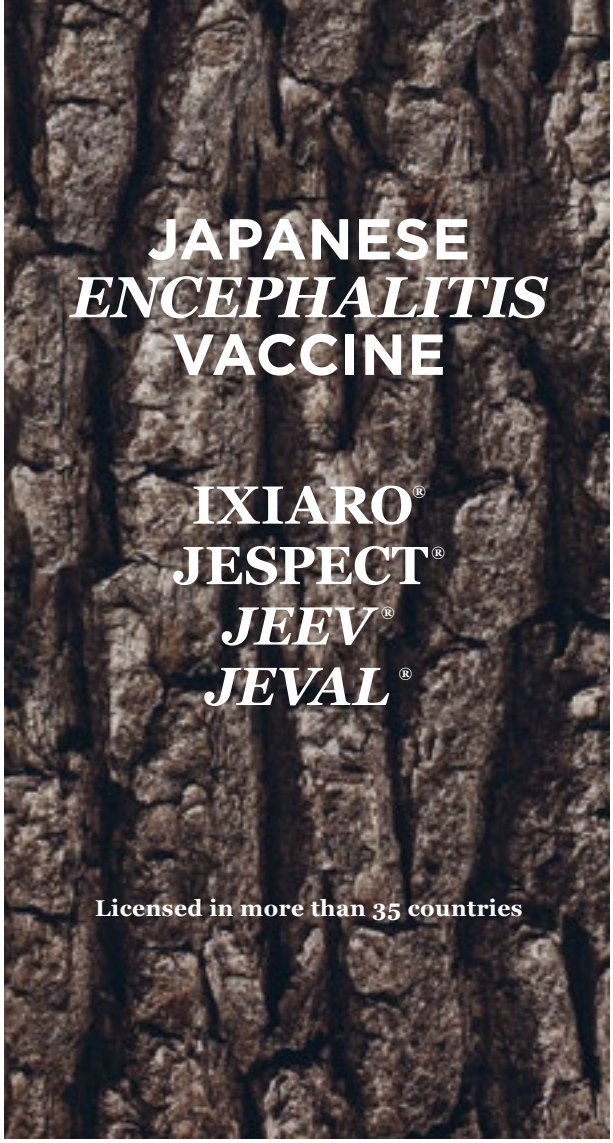
The Canadian team is focused on the marketing and distribution in Canada of Valneva's vaccines IXIARO® and DUKORAL®, and of third-party vaccines including the typhoid travel vaccine Vivotif®. Canada represents the single largest market for DUKORAL®, accounting for more than 50% of estimated 2016 sales.

US

Located to the northwest of Washington D.C. in Gaithersburg, the US team focuses on the marketing and sales of IXIARO® to the US military, and on sales through distribution partners in the private travel market. Sales to the US military represent more than 40% of expected 2016 IXIARO® sales.

To ensure broad geographic availability of IXIARO® and DUKORAL®, Valneva signed several country-specific marketing and distribution agreements with leading local players.

GlaxoSmithKline (GSK)	Germany, Austria, France	IXIARO® and DUKORAL®
VaxServe Inc (a Sanofi Company)	US private market	IXIARO®
PaxVax	Italy, Spain, Portugal	IXIARO® and DUKORAL®
Seqirus (formerly BioCSL)	Australia, New Zealand	JESPECT® and DUKORAL®
Biological E	India and certain other Asian countries	JEEV®
Adimmune	Taiwan	JEVAL®
IMED	Poland and certain Eastern European markets	IXIARO® and DUKORAL®
Pro Farma	Switzerland	IXIARO® and DUKORAL®
Kamada	Israel	IXIARO® and DUKORAL®
Other partners	The Asia Pacific region incl. Hong Kong, Korea, Malaysia, Philippines, Singapore and Thailand	IXIARO® and DUKORAL®



Aimed to protect travelers, military and populations in endemic regions against Japanese encephalitis

- An inactivated, alum-adjuvanted Vero-cell derived vaccine
- Indicated for active immunization against Japanese encephalitis in adults, adolescents, children and infants aged two months and older[2]

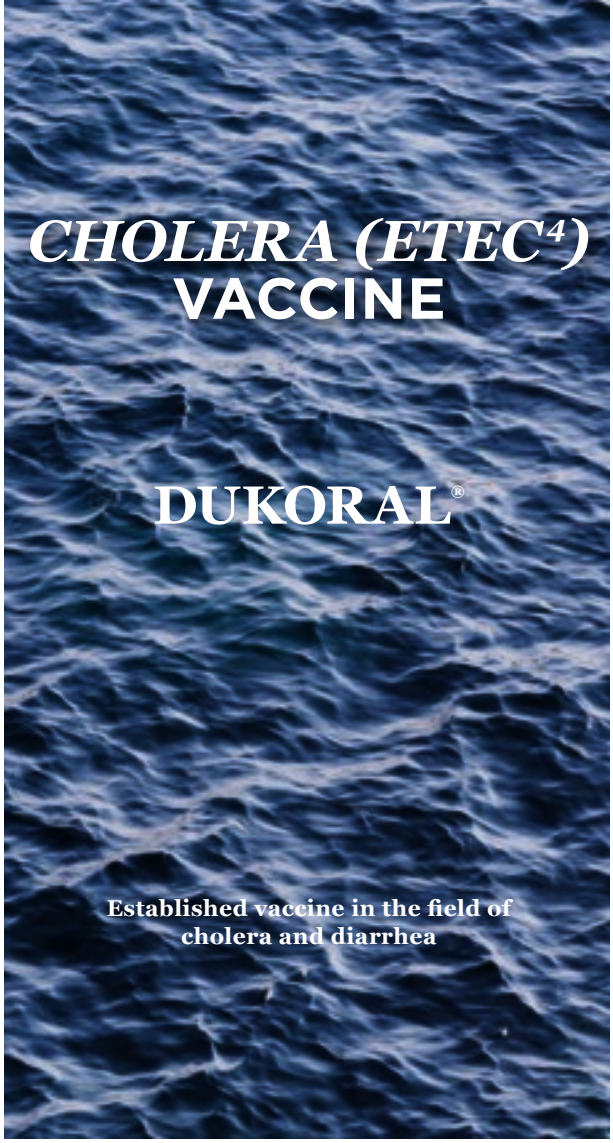
Key revenue drivers 2016

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

€ 30.6M[3]
ANNUAL PRODUCT SALES
2015

2016
EXPECTED SALES DEVELOPMENT
in € million

2 Age indication differs by territories
3 Consolidated Valneva product sales



DUKORAL® is the only approved cholera vaccine available for European, Canadian and Australian travelers

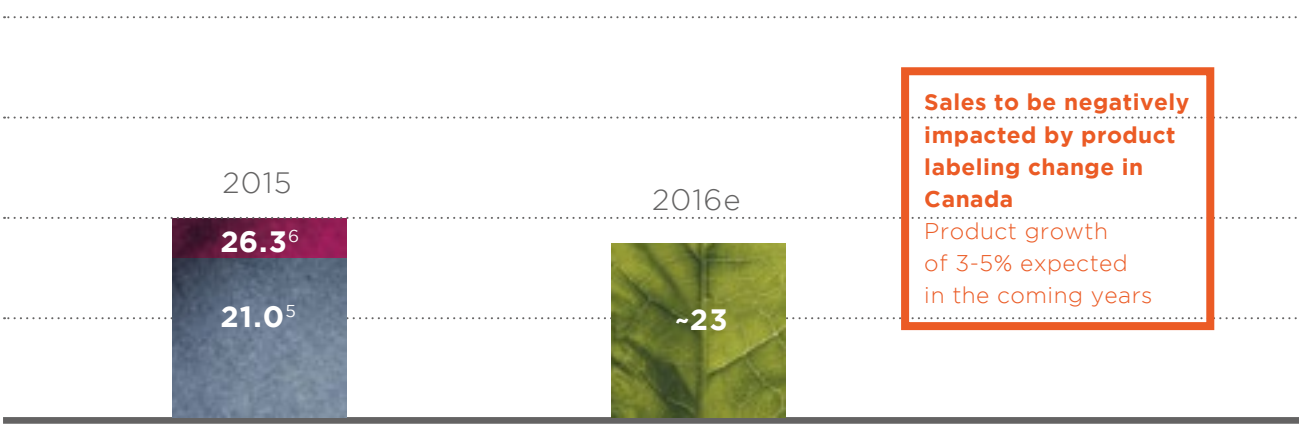
- An oral vaccine containing four different inactivated strains of the bacterium V. cholerae serotype O1 and a recombinant B subunit of the cholera toxin
- The vaccine is indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by LT-ETEC[4]

Key revenue drivers 2016

- Continue to implement new commercialization strategy
- Support label harmonization across all key countries
- Reinforce KOL management
- Explore further product life cycle possibilities
- Unlock growth potential
- Ongoing travel to risk regions, improved awareness and updating travel recommendations
- 347 million travelers to Asia/South America/ Africa in 2014[7]

€ 21.0M[5]
ANNUAL PRODUCT SALES
2015

2016
EXPECTED SALES DEVELOPMENT
in € million



4 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, LT-ETEC = Heat-labile toxin producing enterotoxigenic *E.coli* **5** Valneva product sales between February 10 and December 31, 2015 **6** Pro forma sales including €5.3m under previous owner **7** UNWTO Tourism Highlights 2015

ABOUT *JAPANESE* ENCEPHALITIS

Japanese encephalitis (JE) is a potentially deadly infectious disease and is the most important cause of viral encephalitis in many Asian countries with nearly 68,000 clinical cases every year.

According to WHO, 24 countries in Asia and the Western Pacific regions have endemic JE transmission, exposing more than 3 billion people to a risk of infection. The disease is caused by a mosquito-borne flavivirus related to dengue, yellow fever, Zika and West Nile viruses. There is no cure for the disease, which highlights the importance of vaccination. About 1:25 to 1:1000 persons who are infected with the virus will develop symptomatic disease, an inflammation of the brain. It is fatal in approximately 30% of individuals who show symptoms, and results in permanent disability in half of the survivors. The WHO recommends strong prevention activities, including JE immunization in all regions where the disease is a recognized public health problem[8].

ABOUT *CHOLERA*

Cholera is an acute diarrheal infection caused by ingestion of food or water contaminated with the bacterium *vibrio cholerae*. An estimated 3 – 5 million cholera cases and 100,000 – 120,000 deaths[9] due to cholera occur every year.

The short incubation period of two hours to five days enhances the potentially explosive pattern of outbreaks. WHO recommends immunization with currently available cholera vaccines in areas where cholera is endemic and in areas at risk of outbreaks.

ABOUT *ETEC*

Enterotoxigenic *Escherichia coli* (ETEC) is the most prevalent cause of diarrhea among travelers to developing countries. ETEC is estimated to affect about 11 million[10] travelers every year.

Similarly to cholera, an *E. coli* infection is usually transmitted through consumption of contaminated water or food and is the leading bacterial cause of diarrhea in developing countries. It is the most common cause of travelers' diarrhea and also afflicts military personnel deployed to endemic areas.
The ETEC bacteria colonize the small intestine and cause severe diarrhea, dysentery, abdominal cramps and fever. Prevention through vaccination is part of the strategy to reduce the incidence and severity of diarrheal disease due to ETEC.

8 WHO factsheet No 386 March 2014 **9** WHO Cholera factsheet February 2014 **10** Lundkvist J, Steffen R, Jonsson B. Cost-benefit of WC/rBS oral cholera vaccine for vaccination against ETEC-caused travelers' diarrhea J Travel Med 2009; 16(1):28-34

We are dedicated to the research and development of vaccines in areas of important medical need.

Valneva conducts clinical trials to develop new vaccines with novel, innovative approaches.

Currently we are focusing on nosocomial or healthcare associated infections — partnered for late stage development — and mostly emerging, insect-transmitted infectious diseases.

	PRODUCT CANDIDATE	DISCOVERY RESEARCH	PRE-CLINICAL RESEARCH	IND ENABLING	PHASE I	PHASE II	PHASE III	PARTNER
CLINICAL VACCINE CANDIDATES	PSEUDOMONAS AERUGINOSA							Co-development with GSK
	CLOSTRIDIUM DIFFICILE							TBD
	LYME BORRELIOSIS							TBD
PRE-CLINICAL VACCINE CANDIDATES	CHIKUNGUNYA							Proprietary
	YELLOW FEVER							Proprietary
	ZIKA							Proprietary
	HMPV							Proprietary

Pseudomonas aeruginosa is a leading cause of life-threatening, hospital-acquired infections worldwide

PSEUDOMONAS AERUGINOSA

- *Pseudomonas aeruginosa* is one of the most common pathogens isolated from hospitalized patients and a frequent cause of severe nosocomial infections[11].

- *Pseudomonas* infections are complicated and can be life-threatening due to the increasing antibiotic resistance of these bacteria.

- The bacterium is the N° 1 cause of ventilator-associated pneumonia in intensive care patients and the second most frequent cause of hospital-acquired pneumonia[12]. Targeted groups include up to one million patients in Europe and the US[13].

Currently, no vaccine is available against *Pseudomonas aeruginosa* and the estimated market potential could be as significant as $1 billion annually.

11 Soo Hoo, MD, Wen, MD, Ngyuyen, MD, Goetz, MD. Impact of Clinical Guidelines in the Management of Severe Hospital-Acquired Pneumonia. Chest 2005; 128:2778-2787 **12** Selina SP Chen MD, Pseudomonas Infection; http://emedicine.medscape.com/article/970904-overview#a0199 **13** McConville, M.D., John P. Kress, M.D. Weaning Patients from the Ventilator, N Engl J Med 2012; 367:2233-2239 **14** Vincent et al. JAMA 1995; 274:639-644;

VALNEVA'S *MOST ADVANCED VACCINE* CANDIDATE

VLA43 – PHASE II/III

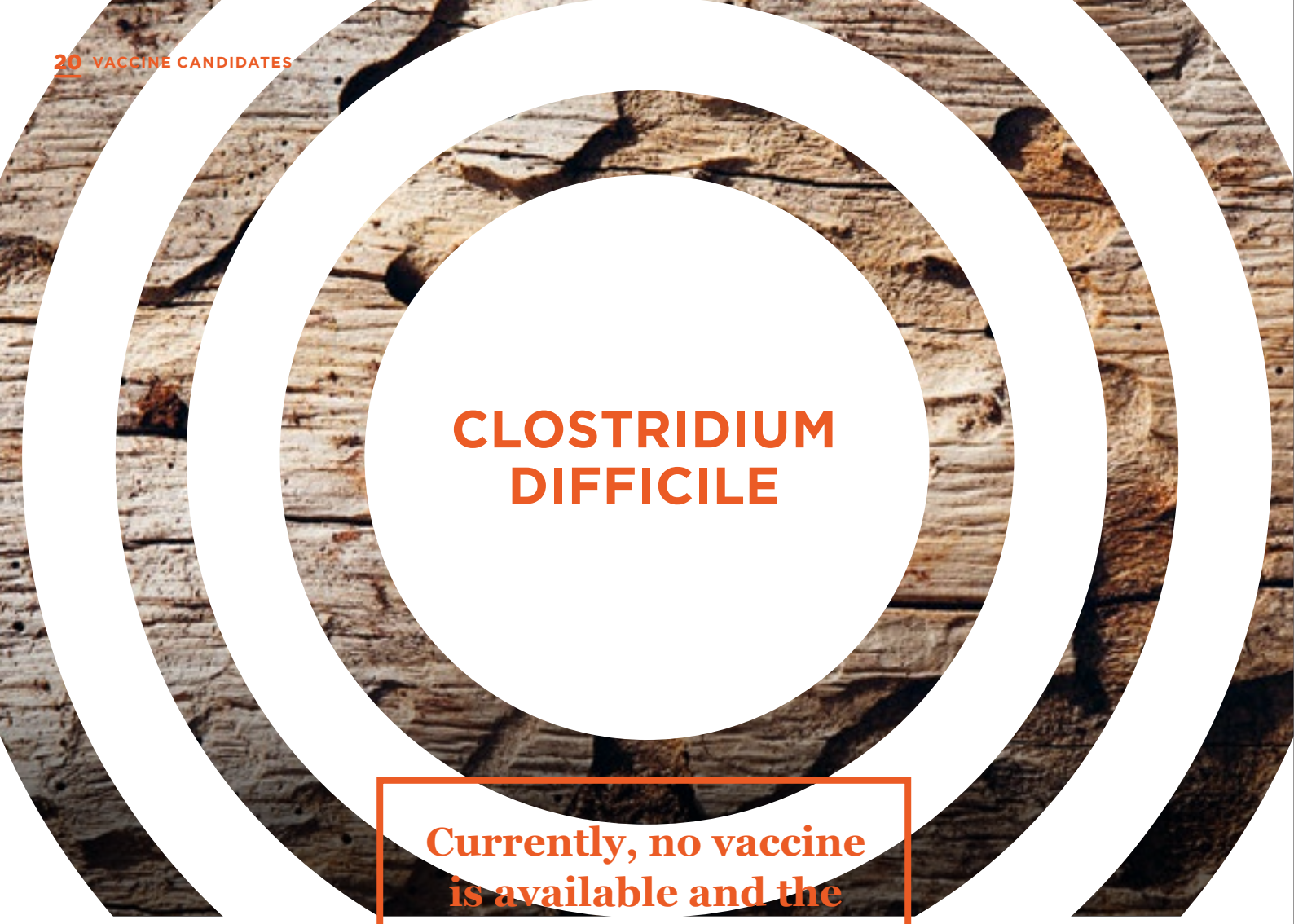
Valneva's vaccine candidate is designed for patients in intensive care units on mechanical ventilation.
In 2015, Valneva completed enrollment of its Phase II/III efficacy trial with a total of 800 ventilated intensive care unit patients recruited across approximately 50 different study sites.

Results of the ongoing Phase II/III pivotal efficacy study are expected in the second quarter of 2016.

– The data will determine next clinical development steps and potential routes to first licensure. Based on the program's Phase II data and the interim analysis for the current Phase II/III confirmatory efficacy trial, various outcomes would be considered as successful.

Valneva's program is the only clinical development program worldwide of a vaccine against *Pseudomonas aeruginosa*.

Hospital-acquired pneumonia is a major healthcare burden with additional costs of estimated ~ $10,000 per case [14]



CLOSTRIDIUM DIFFICILE

Currently, no vaccine is available and the total market potential for a prophylactic vaccine may exceed $1 billion annually[15].

***Clostridium difficile* is a leading cause of life-threatening, healthcare-associated infections worldwide and an increasing threat to elderly.**

As the *Clostridium difficile (C. difficile)* bacteria overgrow, they release toxins that attack the intestine linings, causing diarrhea and more serious intestinal conditions such as colitis.
The *C. difficile* bacteria are an increasing threat to elderly patients and those with elective hospital admissions and long-term care facility residence. In the US alone, there were approximately 29,000 deaths within 30 days after diagnosis of a *C. difficile* infection in 2011[16].
Antibiotic treatments have significant limitations and incidence is steadily increasing, resulting in a significant economic burden notably due to prolonged hospitalization[17].

15 Valneva's assumption **16** Lessa et al, Burden of *Clostridium difficile* Infection in the United States. N Engl J Med 2015;372:825-34 **17** Dubberke ER, Clinical Infectious Diseases 55, no. suppl 2 (2012): S88-S92 **18** Clostridium difficile infection in Europe. A CDI Europe Report – April 2013
19 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

There is an urgent need to develop a vaccine against the leading cause of healthcare-associated diarrhea in Europe[18], and the most common pathogen of acute healthcare-associated infections in the US [19].

VALNEVA'S PROPHYLACTIC VACCINE CANDIDATE VLA84 - PHASE II

DESIGNED TO PRODUCE AN IMMUNE RESPONSE TO NEUTRALIZE THE EFFECTS OF C. DIFFICILE TOXINS A AND B

The vaccine candidate has delivered positive Phase II results:

- Vaccine candidate was highly immunogenic in all age groups tested and induced strong immune responses to both *Clostridium difficile* Toxins A and B (primary endpoint met)

- Good safety and tolerability profile of vaccine candidate confirmed (secondary endpoint met)

- Level of seroconversion considered broadly in-line with published data from comparable prophylactic *C. difficile* vaccine trials

- Randomized, placebo-controlled and observer-blinded Phase II study enrolled 500 healthy volunteers aged 50 years and older and confirmed the optimal dose and formulation of the vaccine

- Study design was agreed with regulators in Europe and the US with the aim of potentially supporting a subsequent progression into Phase III

- Closing of the Phase II study is expected mid 2016

Valneva aims to sign a Phase III partnership agreement in 2016.

LYME BORRELIOSIS

Tick-transmitted infection that is increasingly common in the US and Europe

Each year, 300,000 Americans[20] and 85,000 Europeans[21] are diagnosed with Lyme borreliosis (LB). LB is caused by Borrelia bacteria which are transmitted by infected ticks. Delayed or inadequate treatment of a Borrelia infection can lead to very serious symptoms, involving the joints, heart, and central nervous system, and can be disabling.

Currently no LB vaccine is available for humans, although it has been shown that the disease can be prevented by immunization with an Outer surface protein A (OspA)-based vaccine.

"The high incidence of Lyme disease is perhaps the greatest failure of contemporary public health in the United States and perhaps also in Europe, considering that we know the immunologic basis of control but have no licensed vaccine. A new vaccine would protect people of all ages from serious complications of this bacterial infection."
— Stanley A. Plotkin, Emeritus Professor, University of Pennsylvania

Valneva estimates that the market potential for a LB prophylactic vaccine exceeds €500m.

LYME BORRELIOSIS VACCINE
VLA15

Valneva has developed a multivalent vaccine (VLA15) which is based on OspA, one of the most dominant proteins expressed by the bacteria when present in a tick. The target indication for Valneva's vaccine candidate is the prophylactic active immunization against Lyme borreliosis in individuals ≥ 5 years of age.

Pre-clinical results indicated that VLA15 can provide protection against the majority of Borrelia species[22].

Valneva expects to commence a Phase I trial in the US and Europe in 2016 with the primary objectives of evaluating safety, tolerability and immunogenicity specific for six OspA serotypes.

20 Mead 2015. Infect Dis Clin N Am 29:187–210 **21** Estimation 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 Euro pe Lyme Report; ECDC tick-borne-diseases-meeting-report **22** Comstedt et al.2014. PLoS ONE 9:e113294

PRE-CLINICAL PROGRAMS

CHIKUNGUNYA

The virus reemerged from East Africa in 2014 to cause devastating epidemics of debilitating and often chronic arthralgia that have affected millions of people in the Indian Ocean Basin and Asia.

Most advanced pre-clinical project

Target group:
Primary prevention for travelers, military personnel, and residents in endemic areas

Market:
No antiviral treatment and no licensed vaccine to prevent the disease are available.

Valneva's approach:
Valneva is working on a live attenuated, prophylactic vaccine candidate and expects to enter Phase I clinical development in 2017.

ZIKA

The most common symptoms of Zika virus infection are mild fever, skin rash and conjunctivitis (red eye) lasting between two to seven days. Global health officials are alarmed because of its link to brain defects in infants as well as the rare Guillain-Barré syndrome that can lead to paralysis.

Target group:
Primary prevention for travelers, military personnel, and residents in endemic areas (priority for young/pregnant women).

Market:
The World Health Organization (WHO) declared Zika an international health emergency in February 2016 when it estimated that as many as 4 million people could be affected by the virus as it spreads through Latin America and the Caribbean to North America.

Valneva's approach:
Valneva launched a pre-clinical proof of concept program based on its experience with the related JE virus vaccine and has initiated discussions with WHO, BARDA and WRAIR to potentially join forces to accelerate the development of a Zika vaccine.

From our broad portfolio of research-stage candidates, we are preparing the next program for clinical entry.

YELLOW FEVER

Yellow fever is an acute viral disease spread by the bite of an infected female mosquito which causes 200,000 infections and 30,000 deaths every year. The disease originated in Africa, from where it spread to South America and Europe.

Target group:
Primary prevention for travelers, military personnel, and residents in endemic areas.

Market:
Although a live attenuated vaccine has been used to prevent yellow fever for more than 70 years, frequent supply problems and potential adverse reactions underline the necessity of a new, modern and well tolerated yellow fever vaccine.

Valneva's approach:
Valneva is developing a cell based second-generation, prophylactic vaccine candidate.

HUMAN METAPNEUMOVIRUS

hMPV is one of the most significant and common human viral infections. Although the virus was primarily known as a causative agent of respiratory tract infections in children, it has become an important cause of respiratory infections in adults as well.

Target group:
Prevention of respiratory tract infections in infants and children and at risk adults.

Market:
To date, no vaccine is available and treatment is supportive.

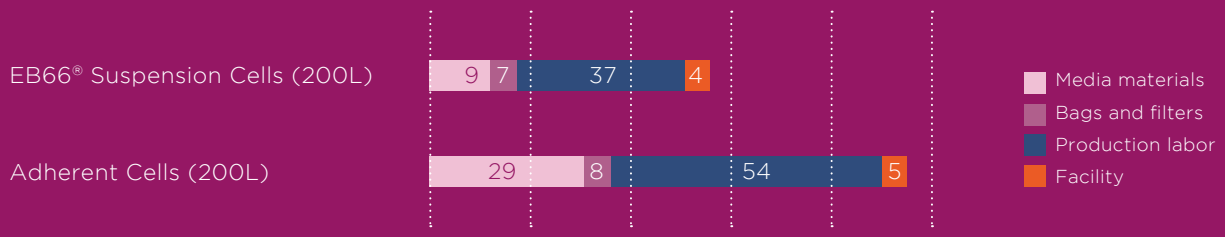
Valneva's approach:
Valneva is currently evaluating different vaccine candidates for the development of a prophylactic hMPV vaccine.

VALNEVA'S EB66® CELL LINE

A VALIDATED CELL LINE FOR A MORE EFFICIENT VACCINE MANUFACTURING PROCESS

- The EB66® cell line can be used for the manufacture of different types of human and veterinary vaccines.
- Easy to handle, able to grow in suspension without serum, the EB66® cell line is an ideal "substrate" for industrialization.
- Perfectly adapted to respond to sudden increases in demand in case of flu outbreaks. Influenza is today the principal segment of the vaccine market: each year the manufacture of more than 400 million doses is required and manufacturers have approximately six months to produce the vaccines, a time period that is impossible to shorten and which constitutes a problem for the production of influenza vaccines using eggs.

COST OF EACH GMP CELL CULTURE CAMPAIGN [23]
(from cell thawing to virus infection) with EMD Millipore Mobius single-use assemblies and EB66® cells (calculated with BioSolve software)



The cell culture process is suitable for large-scale manufacture of vaccines.

They eliminate the need for embryonated chicken eggs from managed, biosecure flocks.

They eliminate the four to six months' lead time for the organization of egg supplies.

Cell lines have higher initial purity than eggs.

They have faster, high-volume start-up times for production.

They are much easier to handle and industrialize.

They reduce the potential for contamination by viable and non-viable particulates.

THE PROCESS PARAMETERS CAN BE RAMPED UP AND RUN ROUTINELY AND COST EFFECTIVELY.

23 Source: BioProcessInternational 13(3)s, March 2015

EB66®

With 3 approved veterinarian vaccines, 2 approved human vaccines and upcoming marketing approvals, EB66® is becoming a cash generator.

– More than €30m of royalty payments from existing licenses received to date

– Potential additional milestones of up to €80m

Our key partners in the veterinarian and human vaccine industry continue to progress EB66®-based product developments and marketing approvals.

To date, Valneva has more than 35 EB66® agreements with the world's largest pharmaceutical companies.

The Company has signed 10 new agreements in 2015 (5 research and 5 commercial agreements).

Two exclusive partnerships:

1. Exclusive agreement signed in 2007 with GSK for the development of EB66®-based pandemic and seasonal influenza vaccines

- Valneva to receive potential milestone payments and royalties on future sales under this agreement

- New R&D collaboration agreement signed in 2015 leading to additional research fees

- GSK's EB66®-based H5N1 pandemic influenza vaccine candidate has successfully completed a Phase I clinical trial in the US

2. Exclusive agreement with Chinese company Jianshun Biosciences Ltd to commercialize EB66® in China

- JSB to sublicense EB66® cells for development, manufacturing and commercialization of human and veterinary viral vaccines (excluding influenza)

- Valneva received €2.5m upfront payment in 2015, and €0.5m in 2016. The Company is also entitled to annual fees and 50% of total revenues payable to JSB

- Valneva remains full owner of the EB66® cell line

A NOVEL SYNTHETIC VACCINE ADJUVANT TO ENHANCE IMMUNE RESPONSES

IC31®

IC31® has demonstrated good activity in clinical trials supported by a very good safety and tolerability profile.

Adjuvants in vaccination enhance and shape the immune response to specific antigenic components of vaccines through targeted activation of the immune system.

The technology has been partnered with various vaccine companies, including GSK, the Statens Serum Institut and Sanofi Pasteur to evaluate IC31® in new vaccine formulations against infectious diseases.

In 2015, Valneva granted an exclusive worldwide license to Altimmune for the development of hepatitis B vaccines in combination with the IC31® adjuvant. Patient enrollment for Phase I clinical trial is ongoing.

In the field of tuberculosis, three clinical vaccine candidates formulated with Valneva's IC31® adjuvant are currently in Phase I and II clinical trials. The Statens Serum Institut's novel tuberculosis vaccine candidate H1/IC31® formulated with the adjuvant IC31® showed good safety and immunogenicity in a Phase II clinical trial in HIV-infected adults[24].

24 Reither et al. 2014. PLoS One 9:e114602

With the conviction that strong corporate governance is the basis for the trust that our investors, employees and institutions have placed in us, we maintain our efforts to build confidence as we continue to grow.

As part of Valneva's two-tier corporate governance system, the Supervisory Board, acting in the interests of the shareholders, participates actively in reviewing and directing the Company's strategic options together with the Management Board.

THE SUPERVISORY BOARD BRINGS IN BUSINESS EXPERIENCE WITHIN THE HEALTHCARE INDUSTRY COMBINED WITH EXPERTISE IN THE VACCINE BUSINESS.

JAMES SULAT
Served as CFO for Chiron and CEO of Maxygen

ALAIN MUNOZ
Former vice-president of international product development at Sanofi

PROF HANS WIGZELL
Former president of the Karolinska Institute and currently active on the board of Karolinska Development AB

***FRÉDÉRIC* GRIMAUD**

Chairman of Valneva's Supervisory Board, President and CEO of Groupe Grimaud

MICHEL GRECO
Served as deputy CEO and Management Board member of Aventis Pasteur

ANNE-MARIE GRAFFIN
Served as European vice-president at Sanofi Pasteur MSD

PROF ALEXANDER VON GABAIN
Co-founder of Intercell, deputy vice-chancellor for Innovation and Commercial Outreach at the Karolinska Institute in Stockholm

THOMAS LINGELBACH

President & CEO
Président du Directoire

CEO of Intercell since 2011, Managing Director for Novartis Vaccines & Diagnostics Germany, Vice President Global Industrial Operations Chiron Vaccines, More than 20 years in vaccine industry

FRANCK GRIMAUD

Deputy CEO
Directeur Général

CEO and co-founder of Vivalis since 1999, Formerly responsible for Groupe Grimaud's development in China, Malaysia and Thailand, More than 20 years in Business Development and Life Sciences

REINHARD KANDERA

CFO
Directeur financier

CFO of Intercell since 2009, Formerly at Deutsche Bank, More than 20 years in Financial Management and Life Sciences

VALNEVA'S MANAGEMENT BOARD IS A COMPLEMENTARY AND DEDICATED TEAM, WITH DIVERSE EDUCATIONS, EXPERIENCES, NATIONALITIES AND INTERPERSONAL SKILLS.

A group of highly skilled professionals support the Management Board in the execution of Valneva's strategy with regards to performance management, operational oversight and review of key partnering activities. Together, they form the Executive Committee. The EC operates cross-functionally and oversees the execution of Valneva's strategy.

FRÉDÉRIC JACOTOT
General Counsel, VP, 28 years as a legal expert within the pharma industry

ANDREAS MEINKE
PhD, VP Pre-clinical & Translational Research, expert in micro & molecular biology and infectious diseases, more than 17 years of experience in vaccine R & D

FRÉDÉRIC LEGROS
PhD, VP Business Development, 12 years' experience in Business Development, licensing in & out

JASON GOLAN
VP Sales & Marketing, 15 years' experience in the healthcare industry, including global vaccine commercialization

KLAUS SCHWAMBORN
PhD, VP Discovery Research & Innovation, 21 years' experience in research and drug discovery

OLIVIER JANKOWITSCH
VP Corporate Development, 16 years' experience in pharma operations and management roles

MANFRED TIEFENBACHER
VP Finance, 23 years international experience in finance roles in R&D, manufacturing and sales organizations

Our employees are our single largest asset.

Valneva's success stems from the work and expertise of more than 400 employees. We are an international and multicultural company that provides our employees the opportunity for personal growth and development. Our culture is marked by enthusiasm, innovation and strong execution, creating a unique identity.

- Valneva promotes equal opportunity and maximization of talent. A management review and a personal development plan are in place for all our employees. Our learning initiatives are mainly driven by the need to develop job related expertise skills and to reinforce leadership and communication competencies.

- As a global company that respects all cultures, we are convinced that the rich diversity of our workforce and the talents they offer make us more innovative, effective and competitive.

Valneva is engaged in the research, development and distribution of vaccines with the aim of protecting people from severe infections and reducing morbidity and mortality.

- Valneva contributes to society by using its vaccine know-how to tackle global health-threats, protecting lives and reducing global healthcare costs.

- Valneva is committed to developing urgently needed vaccines against life-threatening diseases caused by pathogens such as *Pseudomonas aeruginosa* and *Clostridium difficile*.

- Valneva's leading commercial vaccine IXIARO® addresses Japanese encephalitis, of which about 70,000 new cases are recorded every year. Through our partner Biological E., the vaccine is available in India, where Japanese encephalitis is endemic, under the trade name JEEV®.

- At Valneva, we apply the highest standards of integrity in our ambition to serve the medical community's needs through continued pursuit of excellent science for the fight against infectious diseases.

Code of Conduct
Valneva recognizes that a culture of integrity and ethical behavior is one of the cornerstones of its success and that doing business in accordance with high ethical standards is important in securing and maintaining strong business relationships. Valneva's Code of Conduct applies to all Supervisory Board Members, Management Board Members, directors and employees of Valneva SE and its affiliates.

United Nations Global Compact
In 2015, Valneva joined the United Nations Global Compact, the world's largest corporate sustainability initiative to align strategies and operations with universal principles on human rights, labor, environment and anti-corruption.

UN GLOBAL COMPACT
WE SUPPORT

Community engagement
Valneva supports social engagement at local level. Valneva believes in the importance of social engagement and encourages its employees to participate in charity events or volunteer in the local community. Several initiatives took place in 2015 to raise money for local charities.

COMMITMENT *TO THE ENVIRONMENT*

Valneva is committed to the protection of the environment by applying standards to prevent pollution, manage waste and control energy consumption.

Environmental sustainability is a guiding principle at Valneva. We aim to use natural resources efficiently and minimize the environmental impact of our activities and products during their lifecycles. We integrate sustainable operations & supply chains, innovative products & packaging, and environmental sustainability into our business decision process.

A policy for waste separation, recycling and monitoring has been adopted at Valneva. We highlight the importance of this policy as a major priority for all sites. It consists of four key areas:

1. Formal environmental management system based on strict procedures and compliance with regulations

2. Pollution prevention and waste management

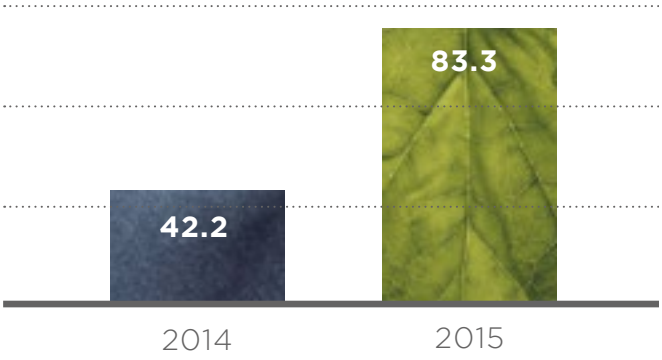
3. Improvement of energy consumption management

4. Information and training programs on environmental protection, health and safety

Valneva publishes a yearly Corporate Social Responsibility report.

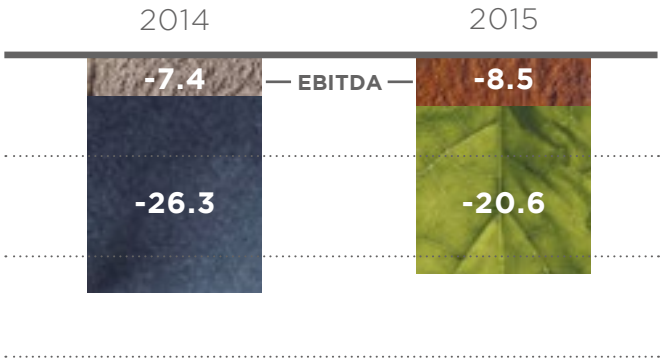
TOTAL REVENUES & GRANTS ALMOST DOUBLED

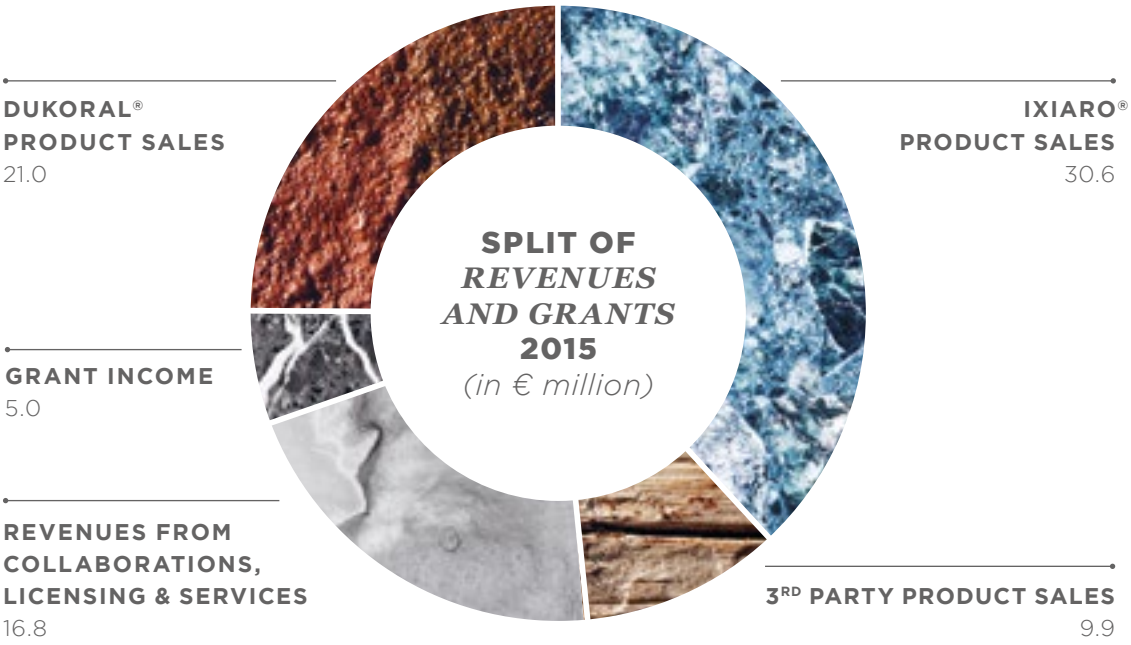
in € million



NET LOSS IMPROVED BY 21.5% IN 2015

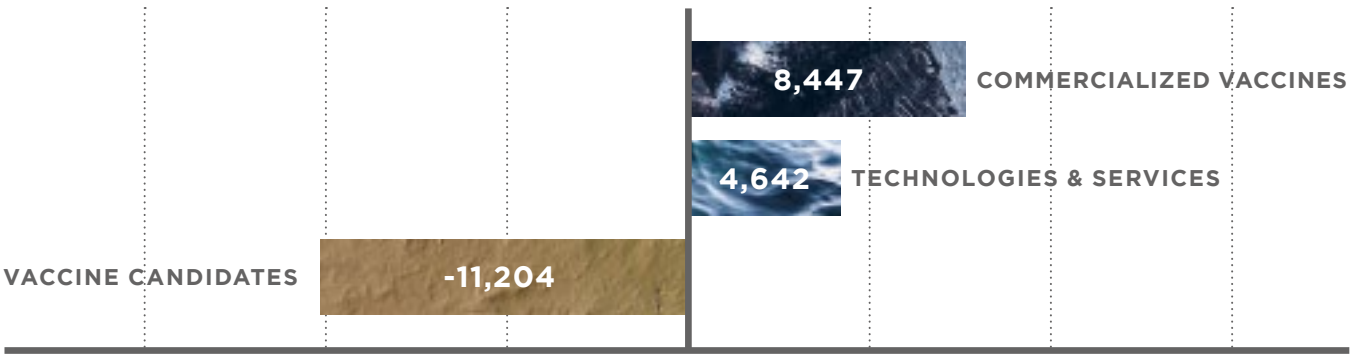
in € million





OPERATING PROFIT PER SEGMENT

before amortization of intangible assets and before overheads in € thousand



€ in thousand *(except per share amounts)*	Year ended December 31,	
	2015	2014
Product sales	61,545	28,124
Revenues from collaborations, licensing and services	16,814	8,799
Revenues	**78,360**	**36,922**
Grant income	4,975	5,506
Revenues and grants	**83,335**	**42,429**
Cost of goods and services	(46,961)	(17,144)
Research and development expenses	(25,367)	(22,242)
Distribution and marketing expenses	(9,121)	(2,065)
General and administrative expenses	(14,394)	(12,077)
Other income and expenses, net	(152)	(395)
Amortization and impairment of fixed assets/intangibles	(7,273)	(12,323)
OPERATING LOSS	**(19,934)**	**(23,817)**
Finance income	5,073	2,273
Finance expenses	(9,716)	(4,394)
Result from investments in affiliates	(8,999)	-
Gain on bargain purchase	13,183	-
LOSS BEFORE INCOME TAX	**(20,393)**	**(25,938)**
Income tax	(224)	(334)
LOSS FOR THE YEAR	**(20,617)**	**(26,272)**
Loss per share *for loss from continuing operations attributable to the equity holders of the Company, expressed in EUR per share (basic and diluted)*	(0.28)	(0.47)
EBITDA	(8,492)	(7,364)

"In 2015, Valneva recorded solid financial performance despite the integration of the acquired Swedish activities and the transfer of IXIARO®'s commercialization. Our total revenues almost doubled while our net loss showed an improvement of 21.5% and our technology segment became profitable."

— Reinhard Kandera, CFO

€ in thousand	At December 31,	
	2015	2014
ASSETS		
Non-current assets	**158,804**	**166,567**
Intangible assets and goodwill	98,567	105,204
Property, plant and equipment	42,439	41,611
Other non-current assets	17,797	19,753
Current assets	**116,383**	**52,967**
Inventories	26,687	7,282
Trade receivables	15,754	6,850
Other current assets	31,374	9,366
Cash, cash equivalents, short-term deposits and current financial assets	42,567	29,468
Assets held for sale	**–**	**7,982**
TOTAL ASSETS	**275,187**	**227,517**
EQUITY		
Capital and reserves attributable to the Company's equity holders	**144,335**	**124,444**
Share capital	11,205	8,453
Share premium and other regulated reserves	245,965	206,707
Retained earnings and other reserves	(92,219)	(64,444)
Net result for the period	(20,617)	(26,272)
LIABILITIES		
Non-current liabilities	**84,489**	**75,704**
Borrowings	76,568	66,036
Deferred tax liability	112	103
Other non-current liabilities and provisions	7,810	9,564
Current liabilities	**46,363**	**26,387**
Borrowings	25,687	7,117
Trade payables and accruals	10,698	10,734
Current tax liability	425	275
Tax and employee-related liabilities	6,889	5,398
Other current liabilities and provisions	2,664	2,862
Liabilities held for sale	**–**	**982**
TOTAL LIABILITIES	**130,852**	**103,073**
TOTAL EQUITY AND LIABILITIES	**275,187**	**227,517**

€ in thousand	Year ended December 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss for the year	(20,617)	(26,272)
Depreciation and amortization	11,442	12,359
Impairment fixed assets/intangibles	-	4,095
Share-based payments	1,018	530
Income tax	238	334
Other adjustments for reconciliation to cash used in operations	2,829	(2,439)
Changes in working capital	(14,585)	(938)
Cash used in operations	**(19,674)**	**(12,332)**
Interest paid	(4,506)	(2,227)
Income tax paid	(153)	(385)
Net cash used in operating activities	**(24,334)**	**(14,944)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of other businesses, net cash acquired	(22,181)	-
Purchases of property, plant and equipment	(1,854)	(946)
Proceeds from sale of fixed assets	128	1,712
Purchases of intangible assets	(792)	(2,792)
Purchases of financial assets	-	(13,616)
Proceeds from sale of financial assets	-	17,130
Investments in associated companies	(1,999)	-
Interest received	133	505
Net cash generated from investing activities	**(26,565)**	**1,993**
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of costs of equity transactions	42,010	8,632
Disposal/(Purchase) of treasury shares	63	69
Proceeds from borrowings	26,472	1,656
Repayment of borrowings	(4,350)	(5,083)
Net cash generated from financing activities	**64,195**	**5,274**
Net change in cash and cash equivalents	**13,296**	**(7,677)**
Cash at beginning of the year	28,857	36,509
Exchange gains/(losses) on cash	(246)	25
CASH AT END OF THE YEAR	**41,907**	**28,857**
CASH, CASH EQUIVALENTS, AND FINANCIAL ASSETS AT END OF THE YEAR	**42,567**	**29,468**

FINANCIAL REVIEW 2015

Valneva's aggregate revenues and grants increased to €83.3 million in 2015 from €42.4 million in 2014 benefiting from the acquisition of Crucell Sweden AB and an 8.8% increase in IXIARO®/JESPECT® product sales.

IXIARO®/JESPECT® product sales increased to €30.6 million compared to €28.1 million in 2014 while DUKORAL® product sales, which were included from the acquisition date on February 10, 2015, reached €21.0 million and third party product distribution contributed €9.9 million to 2015 product sales.

Revenues from collaborations and licensing increased to €16.8 million in 2015 from €8.8 million in 2014 and grant income amounted to €5.0 million in 2015 representing a reduction of €0.5 million compared to 2014.

Valneva's 2015 net loss improved by 21.5% to €20.6 million compared to €26.3 million in 2014 positively impacted by a €13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of Crucell Sweden AB.

Valneva's operating loss decreased by 16.3% to €19.9 million in 2015 compared to €23.8 million in 2014. Valneva's EBITDA loss was €8.5 million in 2015, compared to a €7.4 million loss in 2014, driven by R&D spending in new vaccine candidates.

The Commercialized Vaccines segment showed an operating profit of €1.7 million in 2015, compared to an operating profit of €1.1 million in 2014 and the Technologies and Services segment showed an operating profit of €4.1 million in 2015 compared to €7.3 million operating loss in 2014.

Liquid funds stood at €42.6 million on December 31, 2015, compared to €29.5 million on December 31, 2014 and consisted of €38.2 million in cash and cash equivalents, €3.7 million in short-term bank deposits and €0.7 million in restricted cash.

FINANCIAL OUTLOOK 2016

REVENUES

€90–100M

total revenues
(up to 20% growth vs. 2015)

R&D INVESTMENTS

€25M

expenses
(at 2015 level)

COMMERCIAL PRODUCTS

€70–80M

product sales (up to 30% growth vs. 2015)
50% gross margin on product sales (vs. 32% in 2015)

EBITDA

Close to operational break-even

LESS THAN €5M EBITDA LOSS
(VS. €8.5M IN 2015)

CONTACT INFORMATION

VALNEVA SE
World Trade Center Lyon
10-12 Boulevard Vivier Merle
69003 Lyon, France

Investor Relations & Corporate Communications
France: T +33-2-2807-3710
Austria: T +43-1-206 20-1116
communications@valneva.com
investors@valneva.com

www.valneva.com

VALNEVA SE
Campus Bio-Ouest, 6 Rue Alain Bombard
44821 Saint-Herblain
Nantes, France

VALNEVA AUSTRIA GMBH
Campus Vienna Biocenter 3
1030 Vienna, Austria

VALNEVA SCOTLAND LTD.
Oakbank Park Road
Livingston EH53 0TG, Scotland

VALNEVA SWEDEN AB
SE–105 21 Stockholm, Sweden

VALNEVA CANADA INC.
3535 Saint-Charles Blvd., Suite 600
Kirkland (Québec) H9H 5B9, Canada

VALNEVA UK LTD
Centaur House, Ancells Business Park
Ancells Road / Fleet
Hampshire GU51 2UJ, United Kingdom

INTERCELL USA, INC.
910 Clopper Road, Suite 160S
Gaithersburg, MD
20878 United States

CREDITS

Published by
Valneva SE
World Trade Center Lyon
10-12 Boulevard Vivier Merle
69003 Lyon, France

Editorial
Corporate Communications Valneva SE

Concept & design
REACH Partners AG
Zurich, Switzerland

Printed by
Gugler GmbH
Melk/Donau, Austria

Publication date
May 2016

Disclaimer

www.valneva.com

valneva