

**VALNEVA SE**

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## Valneva Reports Strong Q1 Revenue Growth and Positive EBITDA Reaffirms Financial Guidance and Pipeline Outlook for 2017

### Robust Q1 financial results – confirming financial self-sustainability strategy

- + Total revenues and grants of €29.1 million in Q1 2017 (vs €24.7 million in Q1 2016) driven by a strong increase in vaccine sales;
- + Q1 product sales performance up 26.7% compared to Q1 2016, mainly driven by IXIARO<sup>®</sup> sales to the US military and strong sales in the travel market;
- + EBITDA of €3.4 million and operating profit of €0.5 million in Q1 2017 compared to an operating loss of €2.7 million in Q1 2016;
- + Net loss reduced to €1.7 million in Q1 2017 compared to a net loss of €5.0 million in Q1 2016;
- + Cash position at €45.2 million at end of March 2017.

### 2017 outlook confirmed

- + Valneva confirms it expects 2017 overall IFRS revenues to reach €105 to €115 million, reflecting up to 17% total revenue growth compared to 2016, driven mainly by IXIARO<sup>®</sup>/JESPECT<sup>®</sup> and DUKORAL<sup>®</sup> sales;
- + The Company confirms it intends to invest between €21 million and €23 million in R&D in 2017, corresponding to approximately 20% of annual revenues;
- + Valneva confirms it expects an EBITDA of €5 to €10 million in 2017.

### R&D Highlights

- + Patient recruitment for the Phase I trials of Valneva's Lyme vaccine candidate in the US and EU is advancing in accordance with the study protocol and the Company intends to accelerate the program's progression towards Phase II;
- + Valneva plans to advance its Chikungunya vaccine candidate into Phase I in the second half of 2017;
- + Valneva also seeks to partner its Phase III-ready *Clostridium difficile* vaccine candidate in 2017.

**Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented,** *"We are very pleased with our first-quarter operational performance which validates our financial guidance for the full year. We will continue to focus on commercial execution while at the same time allocating our capital to promising R&D projects that we believe will create substantial value and patient benefit, such as our Lyme disease vaccine candidate".*



## Key Financial Information

€ in thousand	3 months ending March 31 (unaudited)	
	2017	2016
Revenues & grants	29,122	24,687
Net profit/(loss)	(1,657)	(5,037)
EBITDA <sup>1</sup>	3,359	14
Net operating cash flow	12,131	(6,602)
Cash, short-term deposits and marketable securities, end of period	45,208	33,408

**Lyon (France), May 11, 2017** – Valneva SE (“Valneva” or “the Company”), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, reported today its consolidated financial results for the first quarter ended March 31, 2017. The condensed consolidated interim financial report is available on the Company’s website at [www.valneva.com](http://www.valneva.com).

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00 pm (CET). A replay will be available on the Company’s website. Please refer to this link: <http://edge.media-server.com/m/p/axsxyw36>.

### Commercialized vaccines

#### **JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)**

##### **Strong sales growth driven by US military supply**

In the first quarter of 2017, IXIARO®/JESPECT® revenues increased to €15.6 million compared to €14.6 million in the first quarter of 2016, mainly driven by strong sales to the US military. This sales increase follows an update in the US Navy medical guidance at the end of 2016, stating that Japanese Encephalitis vaccination is now required for all Navy personnel and DoD employees assigned to Japan or the Korean peninsula for over 30 days. At the time of this update, vaccination against Japanese encephalitis was already required for U.S Air Force personnel and the Marine Corps so assigned. Based on first quarter revenues, Valneva confirms it expects IXIARO®/JESPECT® revenues to reach between €58 and €62 million in 2017, through continued marketing and sales activities and an increase in product adoption by travelers.

<sup>1</sup> EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets from the operating loss.

## **CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL<sup>®2</sup>)**

### **Strong sales performance in Canada, the UK and the Nordics**

DUKORAL<sup>®</sup> revenues grew to €9.8 million in the first quarter of 2017 compared to €5.4 million in the first quarter of 2016, primarily due to increased sales in Canada (which accounts for more than 50% of global revenue for this product), the United Kingdom and the Nordics. Valneva will continue to invest in growing the DUKORAL<sup>®</sup> vaccine through promotional activities and geographic expansion and expects DUKORAL<sup>®</sup> sales to grow by approximately 10% in 2017 to €27 million.

## **Technologies and services**

### **EB66<sup>®</sup> CELL LINE**

In the first quarter of 2017, Valneva signed 5 new EB66<sup>®</sup> agreements including a research license with MSD Animal Health for the development of new EB66<sup>®</sup>-based veterinary vaccines and a commercial license with Bavarian Nordic.

Under the terms of the commercial agreement signed with Bavarian Nordic, the Danish biotech company has the rights to develop and commercialize multiple poxvirus-based vaccines on the EB66<sup>®</sup> cell-line. The deal also includes the possibility for Bavarian Nordic to transfer, upon regulatory approvals, some of its existing product candidates produced on chicken embryonic fibroblast (CEF) onto Valneva's EB66<sup>®</sup> technology.

Valneva expects to sign additional agreements for the licensing of its EB66<sup>®</sup> vaccine platform in the coming quarters.

## **Vaccine Candidates**

### **CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE– VLA 84**

#### **Partnering agreement sought in 2017**

*Clostridium difficile* (*C. difficile*) is the most common infectious cause for nosocomial diarrhea in Europe and the US. There are an estimated 450,000 cases of *C. difficile* in the US annually<sup>3</sup> and no vaccine against the disease is commercially available.

Valneva seeks to partner its *Clostridium difficile* vaccine candidate and has ongoing discussions with interested parties. Published Phase II data<sup>4</sup> from the most advanced vaccine program targeting primary prevention of *Clostridium Difficile Infections* (CDI) indicates that Valneva's VLA84 provides an immunological profile comparable to that other product.

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<sup>2</sup> Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, including dosing, safety and age groups in which this vaccine is licensed. ETEC: Enterotoxigenic *Escherichia coli* (*E. Coli*) bacterium

<sup>3</sup> Lessa et al, Burden of *Clostridium difficile* Infection in the United States. *N Engl J Med* 2015;372:825-34

<sup>4</sup> G. de Bruyn et al. *Vaccine* 34 (2016) 2170-2178

## **LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15**

### **Patient recruitment progressing in the US & EU**

Following clearance from the Food & Drug Administration (FDA) and the Belgian authorities at the end of 2016, Valneva has initiated Phase I clinical trials in the US and Europe, and vaccinated the first subject at the end of January 2017.

Patient recruitment for the Phase I trials is advancing in accordance with the study protocol and the Company intends to accelerate the program's progression with a view to starting Phase II in early 2018.

Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection affecting more than 300,000 Americans each year. The global market for a vaccine against Lyme disease is estimated at approximately €700 - €800 million annually<sup>5</sup>.

## **CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553**

### **Expected to enter Phase I in the second half of 2017**

Valneva is also working actively on the development of a Chikungunya vaccine and expects to enter Phase I clinical development in the second part of 2017. Pre-clinical data has shown that Valneva's live attenuated vaccine candidate has a good safety profile and the potential to provide long term protection against Chikungunya after a single immunization. The Chikungunya virus (CHIKV) re-emerged from East Africa in 2014, causing devastating epidemics of debilitating and often chronic arthralgia, and is now considered as a major health threat with 180,000 reported cases in the Americas in 2016<sup>6</sup>. There is currently no antiviral treatment for CHIKV infection and no licensed vaccine to prevent the disease. The global market for a Chikungunya vaccine is estimated at approximately €500 million annually<sup>7</sup>.

## **Other Business Update**

### **VALNEVA SHARES NOW TRADABLE ON DEUTSCHE BÖRSE XETRA® PLATFORM**

Valneva's common shares have recently been accepted for continuous trading on the electronic trading platform Xetra® under the symbol VLA FP.

Xetra®, one of the biggest electronic and global trading systems, is a leading European trading venue operated by Deutsche Börse which handles over 90% of all of the stock trades for the Frankfurt Stock Exchange.

Valneva SE common shares will continue to trade in Segment B of Euronext Paris (ticker: VLA.PA) and on the Prime Market of the Vienna stock exchange (ticker: VALNEVA SE ST).

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<sup>5</sup> Company estimate supported by independent market studies

<sup>6</sup> PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016)

<sup>7</sup> Company estimate supported by independent market studies

## Financial Review

### FIRST QUARTER 2017 FINANCIAL REVIEW (unaudited)

#### Revenues and grants

Valneva's aggregate first quarter 2017 revenues and grants were €29.1 million compared to €24.7 million in the first quarter of 2016.

Product sales in the first quarter of 2017 increased by 26.7% to €25.9 million from €20.4 million in the same period of the previous year.

Revenues from collaborations and licensing in the first quarter of 2017 decreased to €2.5 million compared to €3.3 million in the first quarter of 2016. Grant income in the first quarter of 2017 decreased to €0.7 million from €0.9 million in the first quarter of 2016.

#### Operating result and EBITDA

Cost of goods and services sold (COGS) were €13.3 million in the first quarter of 2017 of which €5.7 million were related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 63.2%. €5.4 million of COGS were related to DUKORAL<sup>®</sup> sales, yielding a product gross margin of 44.7%. Of the remaining COGS for the first quarter of 2017, €0.4 million were related to the Third Party product distribution business and €1.8 million related to cost of services. In the comparative period of 2016, COGS were €12.9 million, of which €11.3 million were related to cost of goods and €1.6 million to cost of services.

Research and development expenses in the first quarter of 2017 decreased to €5.2 million from €5.8 million in the first quarter of the previous year. Distribution and marketing expenses in the first quarter of 2017 amounted to €4.3 million, compared to €3.3 million in the first quarter of 2016. General and administrative expenses amounted to €4.0 million compared to €3.8 million in the first quarter of 2016. Amortization and impairment charges in the first quarter of 2017 were €1.8 million compared to €1.7 million during the first quarter of 2016.

As a result of the increased revenues, Valneva realized in the first quarter of 2017 an operating profit of €0.5 million compared to an operating loss of €2.7 million in the first quarter of 2016. Valneva's first quarter 2017 showed a positive EBITDA of €3.4 million which compared to a balanced EBITDA result in the first quarter of 2016 due to the timing of sales to the US Military, the majority of which are made in the first half of the year. First quarter 2017 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €2.9 million from the operating profit of €0.5 million as recorded in the condensed consolidated income statement under IFRS.

#### Net result

Valneva's net loss in the first quarter of 2017 was €1.7 million compared to a net loss of €5.0 million in the first quarter of the prior year.

The finance loss for the first quarter of 2017 amounted to €2.0 million compared to €2.3 million in the first quarter of 2016.

### Cash flow and liquidity

Net cash generated by operating activities in the first quarter 2017 was €12.1 million compared to a net cash-flow used in operating activities of €6.6 million in the first quarter of 2016. This strong improvement resulted from the positive EBITDA development and was also helped by working capital effects.

Cash outflows from investing activities in the first quarter of 2017 amounted to €1.1 million and resulted primarily from purchase of equipment. Cash inflows from investing activities in the first quarter of 2016 amounted to €17.8 million and primarily were related to a re-payment received from Johnson & Johnson in connection with the adjustment of the purchase consideration for the acquisition of Crucell Sweden AB and the DUKORAL<sup>®</sup> business.

Cash out-flows from financing activities in the first quarter of 2017 amounted to €4.9 million and primarily were related to re-payment of borrowings. Cash outflows from financing activities in the first quarter of 2016 amounted to €19.8 million and included the re-payment of borrowings to Athyrium LLC as well as re-payments of loans in connection with grants.

Liquid funds on March 31, 2017 stood at €45.2 million compared to €42.2 million on December 31, 2016 and consisted of €41.5 million in cash and cash equivalents and €3.7 million in restricted cash.

## 2017 Financial Outlook

in million €	2016 Actual	2017 Estimates	Growth
<b>Total revenues &amp; grants</b>	97.9	<b>105 - 115</b>	up to 17%
<b>Product sales</b>	80.4	<b>88 - 92</b>	10 - 15%
IXIARO <sup>®</sup> /JESPECT <sup>®</sup> sales	53.0	58 - 62	10 - 15%
DUKORAL <sup>®</sup> sales	24.6	27	10%
<b>EBITDA</b>	2.8	<b>5 - 10</b>	80 – 250%
<b>R&amp;D expenses (20% of revenues)</b>	(24.6)	<b>(21) – (23)</b>	-

### **About Valneva SE**

Valneva is a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

Valneva's portfolio includes two commercial vaccines for travelers: IXIARO<sup>®</sup>/JESPECT<sup>®</sup> indicated for the prevention of Japanese encephalitis and DUKORAL<sup>®</sup> indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has proprietary vaccines in development including candidates against Clostridium difficile and Lyme Borreliosis. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66<sup>®</sup> vaccine production cell line, IC31<sup>®</sup> adjuvant).

Valneva shares are tradable on Euronext-Paris, the Vienna stock exchange and Deutsche Börse's electronic platform Xetra<sup>®</sup>. The Company has operations in France, Austria, Great Britain, Sweden, Canada and the US with over 400 employees. More information is available at [www.valneva.com](http://www.valneva.com).

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### **Forward-Looking Statements**

This press release 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 press release, those results or developments of Valneva may not be indicative of 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 press release 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.