

## Valneva Reports Robust H1 2017 Financial Results & Major R&D Progress Company Continues Delivering Strong Commercial Performance while Focusing on Advancing Leading R&D Programs

### Robust H1 2017 Financial Results

- Total revenues and grants of €55.4 million in H1 2017 (with total product sales growth of 17.5% compared to H1 2016)
- EBITDA increased strongly in H1 2017 reaching €7.6 million (vs. €4.7 million in H1 2016). Given supply and sales seasonality as well as external R&D costs expected later in the year, H2 EBITDA will be lower than H1
- Net loss was significantly reduced in H1 2017 to €4.4 million compared to a net loss of €39.5 million in H1 2016 which was impacted by the termination of the Pseudomonas program
- Positive operating cash flow amounted to €16.6 million in H1 2017 (vs. €3.9 million in H1 2016) bringing Valneva's cash position to €47.3 million at the end of June 2017

### Major R&D Progress – Lyme Phase I on track, two further programs to enter clinical development

- Valneva recently received FDA Fast Track designation for its Lyme disease vaccine candidate VLA15. Phase I study is now fully recruited and the Company expects to announce Phase I data in Q1 2018 followed directly by the launch of Phase II
- Valneva also granted Emergent BioSolutions an exclusive worldwide license for its Zika vaccine technology (ZIKV), including potential milestones of up to €44 million, plus royalties. Phase I is expected to commence late 2017 or early 2018
- The Company reiterates its intent to launch the Phase I development of its Chikungunya vaccine candidate late 2017 or early 2018.

### Valneva Continues to Deliver Strong Commercial Results – ongoing double digit growth

- 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 reaffirms it expects an EBITDA of €5 to €10 million in 2017; H2 will have lower EBITDA than H1 due to sales and R&D cost phasing
- Valneva confirms its strategic intention to grow its revenues – both organically as well as strategically – to approximately €250 million in the mid-term while advancing its promising vaccine towards market and/or targeted partnering.

**David Lawrence, Valneva's newly appointed Chief Financial Officer**, commented, *"It gives me great pleasure to report very positive results for the first half of 2017. Clearly these results come from the tremendous efforts of my colleagues and I look forward to working with them. Full year guidance remains unchanged noting the significant level of R&D activity and sales phasing in H2. Ongoing sales growth and R&D progression will be a feature of future reports. I expect that this combination will add significant value over time such that Valneva can achieve its goal to become the Leading, Commercial Stage Vaccine Biotech Company."*

## Key Financial Information

€ in thousands	3 months ended June 30,		6 months ended June 30,	
	2017	2016	2017	2016
Revenues & Grants	26,248	26,700	55,370	51,387
Net profit/(loss)	(2,705)	(34,422)	(4,362)	(39,460)
EBITDA	4,196	4,658	7,555	4,672
Net operating cash flow	4,456	10,475	16,587	3,888
Cash, cash equivalents and short-term deposits, end of period	47,313	38,657	47,313	38,657

**Lyon (France), August 31, 2017** – Valneva SE (“Valneva” or “the Company”), a fully integrated, commercial stage biotech company focused on developing innovative, life-saving vaccines, reported today its consolidated financial results for the first half ended June 30, 2017. The half year financial report, including the condensed consolidated interim financial report and the half year management report, is available on the Company’s website [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/aae6z69g>

## Commercial vaccines

### JAPANESE ENCEPHALITIS VACCINE (IXIARO<sup>®</sup>/JESPECT<sup>®</sup>) Continued sales growth

In the first half of 2017, revenues from IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales reached €31.5 million compared to €30.1 million in the first half of 2016. The increase was mainly driven by growth in the UK, German and Canadian private markets as well as U.S. military.

Based on first-half sales, Valneva confirms its full year 2017 guidance of IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenue reaching approximately €60 million (€58 to €62 million) compared to €53.2 million in 2016.

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

#### DUKORAL<sup>®</sup>’s revenues jump 57% in H1

In the first half of 2017, revenues from DUKORAL<sup>®</sup> sales reached €15.4 million compared to €9.8 million in the first half of 2016, representing substantial growth of 57%. In addition to Canada, where more than 50% of DUKORAL<sup>®</sup> global revenues are generated, the vaccine benefited from strong sales in the UK market.

Based on first-half sales, Valneva confirms its expectation to achieve its DUKORAL<sup>®</sup> full year 2017 revenue guidance of approximately €27 million (vs €24.7 million in 2016). The Company will continue to invest in growing the DUKORAL<sup>®</sup> vaccine by way of promotional efforts and geographic expansion.

## OTHER ADDITIONAL SOURCES OF REVENUES

### Third-party distribution

In the first half of 2017, total revenues from third party distribution were €1.2 million compared to €0.9 million in the first half of 2016.

Valneva's intends to continue entering into additional licensing, distribution and marketing agreements to further leverage its commercial infrastructure.

### Technologies and Services

In the first half of 2017, revenues from the Technologies and Services segment were €4.3 million.

Over the period, Valneva signed eight 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 also leverages its R&D capabilities by providing R&D services to third parties including Product development and Clinical trial material manufacturing, in-vivo and in-vitro testing, technical and facilities services based on cost plus agreements.

## Clinical vaccine candidates

Valneva has several promising, differentiated and valuable clinical stage vaccine candidates.

These include vaccine candidates against Lyme borreliosis, which was recently granted a fast track designation by the Food and Drug Administration (FDA), Chikungunya and Zika.

Valneva successfully completed Phase II development of its vaccine candidate against *Clostridium difficile* and is seeking a partner to take this program further into Phase III development which would require resources that are significantly above the R&D investment range within Valneva's business model.

### LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15

#### FDA fast track designation granted, Phase I subject enrollment completed

At the end of July 2017, the FDA granted Fast track designation to Valneva's Lyme disease vaccine candidate with a view to potentially accelerate the availability of the vaccine on the market. Fast Track designation is granted by the FDA to products that are under development for serious conditions and have the potential to fulfill an unmet medical need.

Valneva has now completed subject enrollment for the ongoing Phase I study and expects to announce data in the first quarter of 2018; this will be immediately followed by Phase II initiation.

Lyme borreliosis (LB) is a systemic infection caused by *Borrelia* bacteria, transmitted by infected ticks for which there is currently no human vaccine available. According to the Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans are diagnosed with Lyme disease each year with at least a further 180,000 to 200,000 cases in Europe.

Valneva's Phase I study is being conducted at three sites – two in the U.S. and one in Europe (Belgium) – and enrolled approximately 180 subjects aged between 18 and 40 years. The primary objective of the observer-blind, partially randomized, dose escalation study is to evaluate the vaccine candidate's safety and tolerability profile at different dose levels and formulations. Immunogenicity, measured by observing IgG antibodies against the six most prevalent serotypes of Lyme borreliosis in the US and Europe present in the vaccine, will also be monitored for different dose groups and formulations at different time-points.

The global market for a vaccine against Lyme disease is estimated at approximately €700 - €800 million annually<sup>1</sup>.

### **CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553** **Phase I initiation anticipated at the end of 2017 or beginning of 2018**

Valneva is working on the development of a monovalent, live attenuated Chikungunya vaccine candidate aimed to differentiate against other vaccines candidates under development through single-shot protection.

Preclinical data including studies in non-human primates showed a good safety profile and a good immunogenicity after a single immunization.

Based on preclinical results, the Company expects to initiate Phase I in the U.S. in late 2017 or early 2018. The study protocol is currently under finalization.

The Chikungunya virus (CHIKV) is a Togaviridae virus (identified in Tanzania in 1952) that re-emerged in 2014. There were about 180,000 reported cases in the Americas in 2016<sup>2</sup> and it is now considered a major public health threat. The incidence and geographic spread of CHIKV is expected to grow as the distribution of its primary mosquito vectors continue to broaden.

With no effective treatment available for CHIKV infection, there is a high unmet need for a vaccine and the global market is estimated at approximately €500 million annually<sup>3</sup>.

### **Zika VACCINE CANDIDATE – VLA 1601** **Partnered with Emergent Biosolutions, Phase I initiation anticipated at the end of 2017 or beginning of 2018**

At the end of July 2017, Valneva granted US Company Emergent BioSolutions an exclusive worldwide license for its Zika vaccine technology (ZIKV). Under the terms of the agreement, the parties will share all costs until Phase I completion with Valneva responsible for the program's execution. Upon availability of Phase I data, Emergent has an option to take the program over in exchange for an initial €5 million milestone payment, potential additional milestones of up to €44 million related to product development, approval, commercialization, and product sales, and future royalties on annual net sales.

The agreement also includes a technology transfer to Emergent's Bayview manufacturing facility in Baltimore, Maryland, in the US for Phase II/III and any future commercial manufacturing. Valneva retains a right of first negotiation for potential product commercialization in Europe.

<sup>1</sup> Company estimate supported by independent market studies

<sup>2</sup> PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016)

<sup>3</sup> Company estimate supported by independent market studies

Emergent and Valneva aim to initiate Phase I in the U.S. at the end of 2017 or early 2018 and anticipate Phase I data within six months after trial initiation. The study protocol is currently under finalization.

The Zika virus is a Flavivirus transmitted by Aedes mosquitos that usually either causes no symptoms or a mild flu-like syndrome in many infected persons. However, if women are infected during pregnancy, the virus is transmitted to the fetus and has been associated with the development of severe congenital abnormalities including microcephaly. Zika infection has also been linked with the risk of developing the autoimmune disorder Guillain-Barré syndrome. In 2015, a major Zika epidemic started in Brazil and spread to other parts of the Americas. Between 2015 and end of July 2017, 1 million cases of Zika infection and many cases of the congenital syndrome associated with Zika virus have been reported by countries and territories in the Americas, according to the World Health Organization<sup>4</sup>.

### **CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE – VLA 84** **Phase II successfully completed – Company seeking a partner for Phase III**

Following successful Phase II completion, Valneva seeks to partner its *Clostridium difficile* vaccine candidate and has ongoing discussions with interested parties. Published Phase II data<sup>5</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.

*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>6</sup> and no vaccine against the disease is commercially available.

## **Financial Review**

### **SECOND QUARTER 2016 FINANCIAL REVIEW** **(unaudited)**

#### **Revenues and grants**

Valneva's aggregate second quarter 2017 revenues and grants were €26.2 million compared to €26.7 million in the second quarter of 2016.

Product sales in the second quarter of 2017 increased by 8.3% to €22.2 million from €20.5 million in the same period of the previous year.

In the second quarter of 2017, revenues from collaborations and licensing decreased to €3.3 million from €5.4 million in the second quarter of 2016. Grant income amounted to €0.8 million in the second quarter of both 2017 and 2016.

#### **Operating result and EBITDA**

Cost of goods and services sold (COGS) were €11.1 million in the second quarter of 2017, representing an overall gross margin of 57.6% compared to 67.2% for the same period in 2016. €6.0 million of COGS was related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 62.3%. €3.1 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, €0.5 million was related to the Third Party product distribution business and €1.4 million was related to cost of services. In the

<sup>4</sup> [http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=12390&Itemid=42090&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en)

<sup>5</sup> G. de Bruyn et al. *Vaccine* 34 (2016) 2170-2178

<sup>6</sup> Lessa et al, Burden of *Clostridium difficile* Infection in the United States. *N Engl J Med* 2015;372:825-34

comparative period of 2016, COGS were €8.8 million, of which €6.9 million were related to cost of goods and €1.9 million to cost of services.

Research and development expenses in the second quarter of 2017 decreased to €4.5 million from €6.7 million in the second quarter of the previous year. This was due to timing of R&D activities. Distribution and marketing expenses in the second quarter of 2017 amounted to €3.9 million, compared to €4.1 million in the second quarter of 2016. In the second quarter of 2017, general and administrative expenses amounted to €3.4 million compared to €3.6 million in the second quarter of 2016. Amortization and impairment charges in the second quarter of 2017 were €1.8 million compared to €35.9 million during the second quarter of 2016 (which included non-cash impairment charges of €34.1 million for the *Pseudomonas aeruginosa* project).

In the second quarter of 2017, Valneva realized an operating profit of €1.3 million compared to an operating loss of €32.3 million in the second quarter of 2016. This is largely explained by the one-off impairment charge in 2016 for the *Pseudomonas* project. Valneva's second quarter 2017 showed a positive EBITDA of €4.2 million which compared to an EBITDA of €4.7 million in the second quarter of 2016. Second quarter 2017 EBITDA was calculated by excluding depreciation and amortization amounting to €2.9 million from the operating profit of €1.3 million as recorded in the condensed consolidated income statement under IFRS.

### **Net result**

Valneva's net loss in the second quarter of 2017 was €2.7 million compared to a net loss of €34.4 million in the second quarter of the prior year.

Finance costs and currency effects for the second quarter of 2017 amounted to a net finance expense of €3.0 million compared to a net finance expense of €1.8 million in the second quarter of 2016.

### **Cash flow and liquidity**

Net cash generated by operating activities in the second quarter 2017 was €4.5 million compared to €10.5 million in the second quarter of 2016.

Cash outflows from investing activities in the second quarter of 2017 amounted to €1.5 million and resulted primarily from purchase of equipment and software. Cash outflows from investing activities in the second quarter of 2016 amounted to €0.4 million.

Cash outflows from financing activities in the second quarter of 2017 amounted to €0.6 million and were related to re-payment of borrowings largely offset by an initial drawing from the EIB loan facility. Cash outflows from financing activities in the second quarter of 2016 amounted to €4.5 million and included the re-payment of borrowings and loans in connection with grants.

## **HALF YEAR 2017 FINANCIAL REVIEW (unaudited)**

### **Revenues and grants**

Valneva's aggregate first half 2017 revenues and grants were €55.4 million compared to €51.4 million in the first half of 2016. This represents growth of almost 8%. Most of this growth was driven by increased product sales in the first half of 2017, which grew to €48.1 million from €40.9 million in the same period of the previous year representing growth of 17.5%.

Revenues from collaborations and licensing in the first half of 2017 decreased to €5.8 million compared to €8.7 million in the first half of 2016. Grant income in the first half of 2017 decreased to €1.5 million from €1.8 million in the first half of 2016.

### **Operating result and EBITDA**

Cost of goods and services sold (COGS) were €24.4 million in the first half of 2017 representing an overall gross margin of 55.9% compared to 57.8% in the first half of 2016. €11.8 million of COGS

was related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 62.7%. €8.5 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 half of 2017, €0.9 million were related to the Third Party product distribution business and €3.2 million related to cost of services. In the comparative period of 2016, COGS were €21.7 million, of which €18.2 million was related to cost of goods and €3.5 million to cost of services.

Research and development expenses in the first half of 2017 decreased to €9.7 million from €12.5 million in the first half of the previous year. This relates to the timing of R&D activities. Distribution and marketing expenses in the first half of 2017 amounted to €8.2 million, compared to €7.4 million in the first half of 2016. General and administrative expenses were steady at €7.4 million (compared to €7.3 million in the first half of 2016). Amortization and impairment charges in the first half of 2017 were €3.6 million compared to €37.7 million during the first half of 2016 (which included non-cash impairment charges of €34.1 million for the *Pseudomonas aeruginosa* project).

Primarily, as a result of the strong product sales growth and the one-off impairment charge relating to *Pseudomonas*, Valneva realized an operating profit of €1.8 million in the first half of 2017 compared to an operating loss of €35.1 million in the first half of 2016.

Valneva's first half in 2017 shows an EBITDA of €7.6 million compared to an EBITDA of €4.7 million in the first half of 2016. First half 2017 EBITDA was calculated by excluding depreciation and amortization amounting to €5.7 million from the operating profit of €1.8 million as recorded in the condensed consolidated income statement under IFRS.

### **Net result**

Valneva's net loss in the first half of 2017 was €4.4 million compared to a net loss of €39.5 million in the first half of the prior year.

Finance costs and effects for the first half of 2017 amounted to a net finance expense of €5.1 million compared to a net finance expense of €4.1 million in the first half of 2016. This largely relates to the impact of currency movements amounting to €2.4 million.

### **Cash flow and liquidity**

Net cash generated by operating activities in the first half of 2017 was €16.6 million compared to €3.9 million in the first half of 2016. This strong improvement resulted from increased product sales and was also supported by working capital effects.

Cash outflows from investing activities in the first half of 2017 amounted to €2.6 million and resulted primarily from purchase of equipment and software. Cash inflows from investing activities in the first half of 2016 amounted to €17.4 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 outflows from financing activities in the first half of 2017 amounted to €5.5 million being primarily related to re-payment of borrowings. Cash outflows from financing activities in the first half of 2016 amounted to €24.3 million and included the re-payment of borrowings to Athyrium LLC (in connection with the adjustment of the purchase consideration for the acquisition of Crucell Sweden AB and the DUKORAL<sup>®</sup> business), as well as re-payments of loans in connection with grants.

Liquid funds on June 30, 2017 stood at €47.3 million compared to €42.2 million on December 31, 2016 and consisted of €43.9 million in cash and cash equivalents and €3.4 million in restricted cash.

### **About Valneva SE**

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

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 a unique vaccine against Lyme disease. 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 and 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 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 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 during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, 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.