

## Valneva Reports Nine Month Results for 2018, Confirms Guidance, Strengthens Balance Sheet with €50m Financing

### On track to deliver on multiple key business and R&D milestones

- €50 million raised in oversubscribed placement led by blue-chip US healthcare investors.
- Alignment obtained with FDA and EMA on Lyme vaccine development strategy; Phase 2 initiation on track to commence at the end of the 2018.
- Phase 1 study of Chikungunya vaccine transitioned into re-vaccination phase. Primary endpoint data expected by the end of the year.
- Data analysis for Phase 1 study of Zika vaccine candidate initiated. Primary endpoint data expected within the next few weeks.
- New IXIARO® supply contract with US Department of Defense expected before the end of 2018.

### On track to deliver against full year revenues and EBITDA guidance

- FY product sales revenues to exceed €100 million, nine-month product sales revenues of €71.1 million (10% year on year growth at CER<sup>1</sup>, 5% AER growth).
- FY revenues and grants of €110 million - €120 million confirmed.
- FY EBITDA expected in the range of €5 million - €10 million. Nine-month EBITDA at €6.1 million.
- FY R&D investment now estimated to be at €25 million - €30 million. Nine-month R&D investments at €18.2 million.

**David Lawrence, Valneva's Chief Financial Officer**, commented, "The important milestones that we have achieved during the year reflect the continued execution against our business and R&D objectives. The €50 million financing is a notable achievement to strengthen our shareholder base as we plan our capital needs for future R&D investments, notably the upcoming Lyme Phase 3. Our achievements in the year to date also give us confidence to confirm that we will meet both our business and R&D objectives for the year."

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<sup>1</sup> CER growth: In order to illustrate underlying performance, Valneva has decided to include information on its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Euros had remained unchanged from those used in the comparative period. CER% represents growth at constant exchange rates. AER% represents growth at actual exchange rates.

## Key Financial Information

(Unaudited)

€ in million	9 months ending September 30,	
	2018	2017
Product Sales	71.1	67.9
Total Revenues	78.3	76.3 <sup>2</sup>
Net profit/(loss)	(3.3)	(7.8)
EBITDA	6.1	12.3
Cash	33.0	43.8

**Saint Herblain (France), November 8, 2018** – 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 nine months of the year ended September 30, 2018. The condensed consolidated interim financial results are available on the Company’s website [www.valneva.com](http://www.valneva.com).

A webcast for the financial community and media will be held today at 2:00 pm (CET). A replay will be available on the Company’s website. Please refer to this link: <https://edge.media-server.com/m6/p/4awwekgc>

## Commercial Vaccines

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

In the first nine months of 2018, revenues from Ixiaro®/Jespect® product sales reached €50.0 million, compared to €45.7 million in the first nine months of 2017. The increase was largely driven by demand in the US, including in the private market where Valneva has taken direct control of sales and marketing. There was also a strong increase in Ixiaro® sales in Canada in the nine-month period in 2018 compared to the same period in 2017.

Last month, Valneva announced that the U.S. Food and Drug Administration (“FDA”) approved an accelerated Ixiaro® vaccination schedule of two doses administered seven days apart. This new schedule is an alternate to the existing 28 day schedule providing travelers and healthcare professionals with commensurate flexibility.

Based on nine-month sales and anticipated fourth-quarter supplies, Valneva reaffirms its double-digit growth expectations for Ixiaro®/Jespect® sales in 2018 compared to 2017.

<sup>2</sup> For greater clarity, reporting of grants has been re-classified and will, as of 2018, be included in the Company’s Other Income / Expense line. The comparator period of 2017 was adjusted accordingly.

Valneva expects to enter into a new supply contract with the US DoD by the end of 2018.

### **CHOLERA / ETEC<sup>3</sup>-DIARRHEA VACCINE (DUKORAL<sup>®</sup>)**

In the first nine months of 2018, revenues from DUKORAL<sup>®</sup> sales reached €18.6 million, compared to €19.9 million in the first nine months of 2017. The strong sales volume performance in Canada in the first nine months of the year was eroded by a combination of adverse exchange rate movements (mainly between the Canadian dollar and the Euro) and supply constraints.

Noting that seasonality of demand will drive strong fourth quarter sales, Valneva is confident that it will report increased DUKORAL<sup>®</sup> sales in the second half of 2018 compared to the first half of 2018 and that full-year 2018 sales will meet 2017 levels.

## **Research and Development**

Valneva's Clinical Stage R&D programs are progressing well with key value inflection milestones according to market guidance. R&D investments amounted to €18.2 million in the first nine months of the year and the Company now expects that the investment level for R&D in the full year will be in the range of €25 million - €30 million compared to €30 million - €35 million previously. This reflects the phasing of costs relating to external CRO and CMO partners as well as a more efficient and focused use of R&D resources.

### **Clinical Stage Vaccine Candidates**

#### **LYME DISEASE VACCINE CANDIDATE – VLA15 Progression into Phase 2 at end 2018**

Valneva is finalizing its Phase 2 preparations and re-confirms its expectation to initiate Phase 2 clinical development at the end of 2018.

It is planned that the Phase 2 studies will include approximately 800 subjects across more than 10 study sites in the U.S. and Europe.

The studies are planned to include both participants that have previously been exposed to Lyme as well as participants that have not previously experienced Lyme infection.

Phase 2 will evaluate further dosages and schedules in addition to those evaluated in Phase 1. The final dose and schedule for Phase 3 will be determined based on the immunogenicity and safety data generated in the Phase 2 studies.

The Phase 2 duration is expected to be approximately two years.

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<sup>3</sup> 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.

The Company recently announced that the European Medicines Agency (EMA) provided positive feedback on the Company's general development approach for its Lyme disease vaccine candidate, VLA15. This EMA's comprehensive scientific advice is largely aligned with previous discussions with the US FDA.

Lyme disease is the most common vector-borne illness in the northern hemisphere for which there is no other clinical vaccine candidate in development worldwide. According to the US Centers for Disease Control and Prevention (CDC), approximately 300,000<sup>4</sup> Americans are infected with Lyme disease annually with at least a further 200,000 cases in Europe<sup>5</sup>.

Valneva's vaccine candidate VLA15, under Fast Track Designation by the FDA, is a multivalent, protein subunit vaccine that targets the outer surface protein A (OspA) of *Borrelia* and is intended to protect against the majority of human pathogenic *Borrelia* species. VLA15 is designed to confer protection by raising antibodies that prevent *Borrelia* from migrating from ticks to humans after a bite.

The global market for a vaccine for Lyme disease is currently estimated at approximately €700 - €800 million annually<sup>6</sup>.

### **CHIKUNGUNYA VACCINE CANDIDATE – VLA1553**

#### **Primary endpoint data expected by end of the year**

Valneva expects to release the primary endpoint data (safety data at day 28) and secondary endpoint data (immunogenicity at day 28, dosage) by the end of the year.

As recently announced, the Company has now commenced the second stage of its Phase 1 study. A first group of study participants is now being re-vaccinated with the highest vaccine dose. This re-vaccination is intended to provide an intrinsic human challenge early in the VLA1553 clinical development, with the goal of demonstrating that subjects are protected from vaccine-induced viremia.

The Phase 1 study VLA1553-101 is a randomized, observer-blinded, dose-escalation, multicenter study. It is investigating three different dose levels of VLA1553 in approximately 120 healthy adults, initially vaccinated with a single-shot immunization.

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by *Aedes* mosquitoes. As of 2017, there have been more than one million reported cases in the Americas<sup>7</sup> and the economic impact is considered significant (e.g. Colombia outbreak 2014: \$73.6 million)<sup>8</sup>. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically.

<sup>4</sup> As estimated by the CDC [https://wwwnc.cdc.gov/eid/article/21/9/15-0417\\_article](https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article)

<sup>5</sup> As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.

<sup>6</sup> Company estimate supported by independent market studies

<sup>7</sup> PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)

<sup>8</sup> Cardona-Ospina et al., Trans R Soc Trop Med Hyg 2015

There are no preventive vaccines or effective treatments available and as such, Chikungunya can be considered a major public health threat.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate aiming for protection against various Chikungunya virus outbreak phylogroups and strains designed for long-lasting protection conferred by neutralizing antibodies in adults and children<sup>9</sup>. In pre-clinical development, a single-vaccine shot was highly immunogenic, eliciting a strong, long lasting neutralizing antibody response. Vaccinated non-human primates (NHP) (*cynomolgus* macaques) showed no signs of viremia after challenge<sup>10</sup>.

The target populations for vaccines against Chikungunya are travelers, military personnel or individuals at risk who live in endemic regions. The global market is estimated to be worth up to €500 million annually<sup>6</sup>.

### **ZIKA VACCINE CANDIDATE – VLA1601**

#### **Phase 1 study fully enrolled, Partnered with Emergent BioSolutions**

Valneva is currently in the data analysis phase for its Phase 1 Zika vaccine candidate VLA1601, partnered with Emergent BioSolutions and expects to release data (safety and immunogenicity at day 56) in the next few weeks.

The Phase 1 study VLA1601-101 is a randomized, observer-blinded, placebo-controlled, single center study investigating two dose levels with two different vaccination schedules in 67 healthy adults.

Zika Virus infection is a mosquito-borne viral disease caused by the Zika Virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes<sup>11</sup>. Disease outbreaks have been reported in tropical Africa, South-East Asia, the Pacific Islands, and, since 2015, in the Americas. According to the World Health Organization (WHO), there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome<sup>12</sup>. Between 2015 and early January 2018, over 500,000 cases of suspected Zika infection and many cases of the congenital syndrome associated with the ZIKV were reported by countries and territories in the Americas, according to the WHO<sup>13</sup>. There is currently no specific treatment available.

VLA1601 is a highly purified inactivated whole virus vaccine candidate developed using Valneva's proven and licensed inactivated JE vaccine platform. In pre-clinical development, VLA1601 demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to IXIARO®.

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<sup>9</sup> Hallengård et al. 2013 *J. Virology* 88: 2858-2866

<sup>10</sup> Roques et al. 2017 *JCI Insight* 2 (6): e83527

<sup>11</sup> <https://www.cdc.gov/zika/transmission/index.html>

<sup>12</sup> <http://www.who.int/mediacentre/factsheets/zika/en/>

<sup>13</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)

## First nine months 2018 Financial Review

(Unaudited)

### Revenues

Valneva's total revenues in the first nine months of 2018 were €78.3 million compared to €76.3 million in the first nine months of 2017.

Product sales revenues (on an AER basis) in the first nine months of 2018 increased to €71.1 million from €67.9 million in the same period of the previous year.

Revenues from collaborations and licensing amounted to €7.2 million in the first nine months of 2018 compared to €8.5 million in the first nine months of 2017. Reporting of grants has been re-classified and included in Other income and expenses, net as of January 2018. The comparator period of 2017 has been adjusted accordingly.

### Operating result and EBITDA

Costs of goods and services sold (COGS) were €32.3 million in the first nine months of 2018, representing an overall gross margin of 58.8% compared to 57.9% for the same period in 2017. €18.4 million of COGS related to IXIARO®/JESPECT® sales, yielding a product gross margin of 63.4%. €8.7 million of COGS related to DUKORAL® sales, yielding a product gross margin of 53.4%. Of the remaining COGS for the first nine months of 2018, €1.6 million related to the Third Party product distribution business and €3.6 million was related to cost of services. In the comparative period of 2017, COGS were €32.1 million, of which €27.6 million related to cost of goods and €4.6 million related to cost of services.

Research and development expenses in the first nine months of 2018 increased to €18.2 million from €15.1 million in the first nine months of the previous year. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates, notably Lyme. Marketing and distribution expenses in the first nine months of 2018 amounted to €15.0 million, compared to €12.0 million in the first nine months of 2017. This increase was mainly a result of investment in the US Travel market combined with higher spending in other markets. In the first nine months of 2018, general and administrative expenses amounted to €12.6 million compared to €11.1 million in the comparator period of 2017. Amortization and impairment charges in the first nine months of 2018 amounted to €2.4 million compared to €9.0 million in the first nine months of 2017. The reduction resulted from re-assessment of the lifetime of IXIARO®/JESPECT® related intangible assets, driven by patent extensions in both Europe and the US (lifetime extended from 15 to 23.75 years). Furthermore, the first nine months of 2017 included a one-time non-cash impairment charge amounting to €3.6 million related to Valneva's Phase 3 ready Clostridium difficile vaccine candidate.

In the first nine months of 2018, Valneva realized an operating profit of €0.9 million compared to an operating profit of €0.2 million in the first nine months of 2017. EBITDA in the first nine months of 2018 was €6.1 million, compared to an EBITDA of €12.3 million in the first nine months of 2017. The reduction in EBITDA was driven by the increased investments into Research & Development and Marketing & Distribution as outlined above.



### **Net result**

In the first nine months of 2018, Valneva's net loss was €3.3 million compared to a net loss of €7.8 million in the first nine months of the prior year.

Finance costs and currency effects for the first nine months of 2018 resulted in a net finance expense of €3.1 million, compared to a net finance expense of €7.0 million in the first nine months of 2017. The reduced net finance expense year over year compared to the prior year was partly the result of lower interest expenses from continued loan re-payments and foreign currency related losses incurred during the first nine months of 2017.

### **Cash flow and liquidity**

Net cash generated by operating activities in the nine months of 2018 amounted to €11.7 million compared to €18.3 million in the first nine months of 2017.

Cash outflows from investing activities in the first nine months of 2018 amounted to €1.5 million and resulted primarily from the purchase of equipment. Cash outflows from investing activities amounted to €3.0 million in the first nine months of 2017.

Cash outflows from financing activities amounted to €12.8 million in the first nine months of 2018 and were mainly related to re-payment of borrowings and interest payments. Cash outflows from financing activities amounted to €10.0 million in the first nine months of 2017.

Liquid funds on September 30, 2018 stood at €33.0 million compared to €38.1 million on December 31, 2017 and consisted of €30.1 million in cash and cash equivalents and €3.0 million in restricted cash. These figures exclude the proceeds resulting from the recent €50.0 million fundraising that completed in early October.

### **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®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 450 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.