Valneva Reports Strong Operational Performance for the First Nine Months of 2017

Strong financial performance for first nine months of 2017 and full year outlook leads to upward revision of EBITDA guidance

- Total revenues of €79.8 million in the first nine months 2017 compared to €70.7 million in the first nine months of 2016 benefiting from a 20% year-on-year growth in product sales. Full year revenue expectation confirmed in the previously guided range of €105-115 million.
- EBITDA at €12.3 million in the first nine months of 2017 compared to €3.5 million in the first nine of months 2016. As announced in first half results, following major R&D progress, Valneva expects higher R&D costs in 2017 than initially anticipated of €23-25 million. Despite this, the Company increases its full year EBITDA guidance to €10m - €13 million compared to previous guidance of €5 - €10 million.
- Positive operating cash flow of €18.2 million in the first nine months of 2017 brought cash position to €43.8 million at the end of September 2017.
- As planned, noting the increase in R&D expenditure driven by progression of key R&D programs, under the €25 million loan agreement announced in July 2016 with the European Investment Bank, Valneva expects to draw down a further €5 million prior to the end of this year.

Major R&D Progress – Lyme Phase I study fully recruited; two further programs ready to enter clinical development in the first quarter of 2018

- Phase I study for Valneva's Lyme disease vaccine VLA15 is now fully recruited and the Company expects to announce Phase I data in the first quarter of 2018 followed directly by the launch of Phase II.
- FDA´s fast track designation for VLA15 expected to offer a faster way to market approval through frequent interactions with the FDA.
- Valneva confirms plans to commence Phase I trials of its Chikungunya and Zika vaccine candidates in the first quarter of 2018.
- Valneva decides on a new development and partnering approach for its *Clostridium difficile* vaccine candidate VLA84.

David Lawrence, Valneva's Chief Financial Officer, commented, *"Strong business performance, including sales of our two commercial products and overall business productivity, means that we increase EBITDA guidance for the full year. We are also extremely pleased with the current progression of our R&D portfolio and very much look forward to the further development of these assets, each of which has significant potential. "*

Key Financial Information
(Unaudited)

€ in thousands	9 months ended September 30	
	2017	2016
Revenues & Grants	79,757	70,741
Net profit/(loss)	(7,804)	(46,467)
EBITDA	12,250	3,463
Net operating cash flow	18,250	7,990
Cash, cash equivalents and short-term deposits, end of period	43,797	40,293

Lyon (France), November 9, 2017 – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing and commercialising innovative, life-saving vaccines, reported today its consolidated financial results for the first nine months of the year ended September 30, 2017. The financial report, including the condensed consolidated interim financial results, is available on the Company's website 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: https://edge.media-server.com/m6/p/255tsheb

Commercial vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
Continued sales growth

In the first nine months of 2017, revenues from IXIARO®/JESPECT® product sales reached €45.9 million compared to €40.1 million in the same period last year. The increase was mainly driven by growth in the UK, German and Canadian private markets as well as U.S. military. Earlier this week Valneva also announced the signing of a further contract with the U.S. military worth up to $39.6 million.

Based on nine-month sales, Valneva confirms its expectation to achieve its IXIARO®/JESPECT® full year 2017 revenue guidance of between €58 to €62 million (compared to €53.2 million in 2016) and double-digit growth.

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)
Sales increase 34% in the first nine months of 2017

In the first nine months of 2017, revenues from DUKORAL® sales reached €19.9 million compared to €14.9 million in the same period last year, representing a growth of 34%. In addition to Canada, where more than 50% of DUKORAL® global revenues are generated, the vaccine benefited from strong sales in the UK market.

Based on nine-month sales, Valneva reaffirms its DUKORAL® full year 2017 revenue guidance to approximately €27 million (compared to €24.7 million in 2016).

Clinical vaccine candidates

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE – VLA 84
New development and partnering approach

Valneva´s *Clostridium difficile* vaccine candidate VLA 84 is targeting the primary prevention of healthcare-associated diarrhea, an increasing threat to elderly in a >$1billion expected market potential.
VLA 84 successfully completed Phase II and is Phase III ready. The company confirms that it views its program – based on published immunogenicity & safety data – as not inferior to the other vaccine candidates being developed. In addition, VLA 84 may bring distinct competitive advantages in industrialization and future manufacturing.

At this point, however, potential partners are hesitant about the level of investment required to fund a Phase III clinical trial. Noting this feedback, Valneva has reviewed its development and partnering approach.

Valneva will consider using the first CDI vaccine approval and to conduct a head to head, non-inferiority Phase III based on an immunological correlate that is expected to substantially improve the investment – risk profile of an in-house, or partnered, final development to take the product to market.

Noting the above, the remaining value of the VLA84 intangible assets have been reviewed in the financial statements, as set out in the Financial Review section below.

LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15
Phase I subject enrollment completed, data expected in the first quarter of 2018

Valneva has decided to focus its R&D expertise and resources on the development of a much-needed vaccine against Lyme disease as it is amongst the fastest growing vector-borne infections and there is no other clinical vaccine candidate in development worldwide.

The company has completed subject enrollment for the ongoing Phase I study of its Lyme vaccine candidate VLA 15 and initiated serological testing. Valneva confirms it expects to announce data in the first quarter of 2018 which will be immediately followed by Phase II launch.

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.

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 400,000[1] Americans are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[2].

[1] *As estimated by the CDC based on US reported cases in 2015*
[2] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed*

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 currently estimated at approximately €700 - €800 million annually[3].

CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553
Phase I initiation anticipated at the 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. The Phase I study protocol has now been finalized and the Company expects to initiate Phase I in the U.S. early 2018.

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[4] 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[5].

ZIKA VACCINE CANDIDATE – VLA 1601
Phase I initiation anticipated at the beginning of 2018, Partnered with Emergent BioSolutions

In July 2017, Valneva and US Company Emergent BioSolutions joined forces to accelerate the development of a vaccine against the Zika virus. The Phase I study protocol has now been finalized and the two companies aim to initiate Phase I in the U.S. early 2018, with first Phase I data anticipated in the same year.

Valneva and Emergent BioSolutions 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 and future royalties on annual net sales.

[3] *Company estimate supported by independent market studies*
[4] *PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016)*
[5] *Company estimate supported by independent market studies*

The agreement between the two companies 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.

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[6].

Financial Review

FIRST NINE MONTHS 2017 FINANCIAL REVIEW
(Unaudited)

Financial Reporting Policy
Valneva's revenues and expenses are not distributed equally throughout the year nor across quarters, and this distribution can vary from year to year, thus affecting meaningful quarterly data comparisons. Therefore, the Company has decided to focus on year to date (nine months) data only. However, third-quarter data is included in the IFRS statements in accordance with Austrian Prime Market Rules.

Total Revenues
Valneva's aggregate total revenues in the first nine months of 2017 were €79.8 million compared to €70.7 million in the first nine months of 2016. This represents growth of 12.7%. Most of this growth was driven by increased product sales in the first nine months of 2017, which grew to €67.9 million from €56.6 million in the same period of the previous year representing growth of almost 20%.
Revenues from collaborations and licensing in the first nine months of 2017 were €8.5 million compared to €11.4 million in the first nine months of 2016. Grant income in the first nine months of 2017 increased to €3.4 million from €2.7 million in the first nine months of 2016.

Operating result and EBITDA
Cost of goods and services sold (COGS) were €32.1 million in the first nine months of 2017 representing an overall gross margin of 59.7% compared to 57.6% in the first nine months of 2016.
Research and development expenses in the first nine months of 2017 were €15.1 million compared to €18.7 million in the first nine months of the previous year. This relates to the timing of R&D activities.
Distribution and marketing expenses in the first nine months of 2017 amounted to €12.0 million, compared to €11.3 million in the first nine months of 2016.
General and administrative expenses were €11.1 million compared to €10.4 million in the first nine months of 2016.

[6] *http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en*

Amortization and impairment charges in the first nine months of 2017 were €9.0 million and included one-time, non-cash impairment charges amounting to €3.6 million related to the Clostridium Difficile intangible assets. Amortization and impairment charges of the first nine months of 2016 amounted to €39.5 million (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 as well as driven by lower R&D spend for the year to date, Valneva realized an operating profit of €0.2 million in the first nine months of 2017 compared to an operating loss of €39.1 million in the first nine months of 2016.
During the first nine months of 2017 Valneva reported an EBITDA of €12.3 million compared to an EBITDA of €3.5 million in the first nine months of 2016. First nine months' 2017 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €12.1 million from the operating profit of €0.2 million as recorded in the condensed consolidated income statement under IFRS.

Net result
Valneva's net loss in the first nine months of 2017 was €7.8 million compared to a net loss of €46.5 million in the first nine months of the prior year.
Finance costs and effects amounted to a net finance expense of €7.0 million in the first nine months of both 2017 and 2016. This largely relates to the impact of currency movements amounting to €3.1 million in the first nine months of 2017 compared to €2.5 million during the first nine months of 2016 while interest expenses decreased to €3.9 million from €4.7 million in the comparator period of 2016.

Cash flow and liquidity
Net cash generated by operating activities in the first nine months of 2017 was €18.2 million compared to €8.0 million in the first nine months of 2016. This strong improvement resulted from improved EBITDA and was also supported by positive working capital effects.
Cash outflows from investing activities in the first nine months of 2017 amounted to €3.0 million and resulted primarily from purchase of equipment and software. Cash inflows from investing activities in the first nine months of 2016 amounted to €16.7 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® business.
Cash outflows from financing activities in the first nine months of 2017 amounted to €10.0 million being primarily related to re-payment of borrowings. Cash outflows from financing activities in the first nine months of 2016 amounted to €25.9 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® business), as well as interest payments and re-payments of loans.

Liquid funds on September 30, 2017 stood at €43.8 million compared to €42.2 million on December 31, 2016 and consisted of €40.6 million in cash and cash equivalents and €3.2 million in restricted cash.

Valneva to draw down a second €5 million instalment from the European Investment Bank
As planned, noting the increasing R&D expenditure driven by the progression of key R&D programs, under the €25 million loan agreement concluded in July 2016 with the European Investment Bank (EIB), Valneva expects to draw down a further €5 million prior to the end of 2017. €5 million has already been drawn down in April 2017. Each instalment is repayable five years after the drawdown date.

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 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® cell line and IC31® adjuvant).

Valneva shares are tradable on Euronext-Paris, the Vienna stock exchange and Deutsche Börse's electronic platform Xetra®. 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.

Valneva Investor and Media Contacts

Laetitia Bachelot Fontaine
Global Head of Investor Relations &
Corporate Communications
T +33 (0)2 2807 1419
M +33 (0)6 4516 7099
investors@valneva.com

Nina Waibel
Corporate Communications Specialist
T +43 1206 201 149
M +43 6768 455 6719
Communications@valneva.com

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.