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Valneva Delivers Strong 2017 Financial Results and Advances Key R&D Programs

The Company expects continued double digit product sales growth in 2018 and to invest further in R&D, notably the Lyme and Chikungunya programs

Strong sales and EBITDA performance in 2017

- Total revenues and grants of €109.8 million in 2017 (vs. €97.9 million in 2016)
- Product sales of €92.6 million representing 15% year on year growth
- EBITDA of €10.8 million in 2017 (vs. €2.8 million in 2016)
- Improved gross margin of 58% (vs. 56% in 2016)
- Positive operating cash flow of €12.8 million in 2017 brought cash position to €38.1 million at the end of 2017

Double-digit product sales growth to continue in 2018

- The Company projects that product sales this year will grow to over €100 million.
    - Other revenues (including R&D tax credits, grants, service revenue, royalties), which tend to fluctuate from year to year, are expected to bring the company's overall revenue to between €110 million and €120 million for the year.
- Valneva will maintain positive EBITDA in the range of €5 million - €10 million in 2018 with higher R&D investment of €30 million - €35 million, compared to €23.4 million in 2017, driven by the clinical development progression of its Lyme and Chikungunya vaccine candidates.

Key R&D Progress

- Valneva recently announced positive Phase I interim results for its Lyme disease vaccine candidate VLA15[1]. Phase II planning and preparation activities have been initiated for this promising FDA fast-tracked vaccine candidate and the study is expected to commence in the second half of 2018.
- The Company also recently announced Phase I study initiations for its Chikungunya (VLA1553)[2] and Zika (VLA1601)[3] vaccine candidates.

David Lawrence, Valneva's Chief Financial Officer, commented, "In 2017, we executed on our key business goals and continued to improve our financial performance, giving us the flexibility to invest for future portfolio growth. Achieving product sales of over €100 million will be a major milestone for the Company this coming year. With multiple value catalysts in 2018, we believe we are poised for a pivotal year."

[1] *http://www.valneva.com/download.php?dir=News_2018&file=2018_03_19_VLA15_Phase_I_Results_PR_ENG.pdf*
[2] *http://www.valneva.com/download.php?dir=News_2018&file=2018_03_13_Chikungunya_Phase_I_initiation_EN.pdf*
[3] *http://www.valneva.com/download.php?dir=News_2018&file=2018_02_26_Phase_1_Initiation_VLA1601_EN.pdf*

Key Financial Information

€ in million	12 months ending December 31	
	2017	2016
Revenues & grants	109.8	97.9
Net profit/(loss)	(11.5)	(49.2)
EBITDA[4]	10.8	2.8
Net operating cash flow	12.8	6.5
Cash, short-term deposits and marketable securities, end of period	38.1	42.2

Lyon (France), March 22, 2018 – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, reported today its full year financial results ending December 31, 2017. The annual financial report, including the consolidated financial statements 2017, 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/7d3fjx9c

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
Continued sales growth supported by market penetration

In 2017, IXIARO®/JESPECT® sales reached €60.0 million compared to €53.0 million in 2016, representing 13% year-on-year growth. This increase was largely driven by growth in the UK, German and Canadian private markets where continued marketing and sales efforts resulted in increased product adoption by travelers. Sales to the US military also contributed to the growth and a new $39.6 million contract was signed with the US government in November 2017 to supply IXIARO® to the US Department of Defense, over a one year period.
Valneva expects continued double digit growth in IXIARO®/JESPECT® revenues through increased market penetration and the development of its commercial network, including in the US private market where the Company took direct control of sales and marketing in late 2017.

[4] *EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets.*

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)
Double-digit sales growth in 2017

In 2017, DUKORAL® sales reached €28.5 million, compared to €24.6 million in 2016, representing year-on-year growth of 16%. In addition to Canada, where more than 50% of DUKORAL® global revenues are generated, the vaccine benefited from strong sales in the UK market. Valneva expects DUKORAL® revenues to continue to grow healthily in 2018 through continued market penetration.

Clinical vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA 15
Positive Phase I interim results reported

The Company is focusing its R&D expertise and resources to a large extend on the development of a much-needed vaccine against Lyme disease, the most common and one of the fastest growing vector-borne illnesses in the Northern Hemisphere for which there is no other clinical vaccine candidate in development worldwide.

Valneva recently reported positive Phase I interim data for its Lyme disease vaccine candidate VLA15. The study met its primary endpoint. The vaccine candidate is overall safe and was well tolerated with very few severe, related Adverse Events (AEs) in all treatment groups and no associated safety concerns. The safety profile of all tested doses and formulations is considered comparable to other licensed lipidated recombinant vaccines or lipid-containing vaccine formulations, and supports further clinical development.

VLA15 was immunogenic in all doses and formulations tested. OspA-specific IgG antibody responses were induced in all treatment groups and against all OspA serotypes, with significant dose responses seen between the lowest and the higher dose groups. For all six OspA serotypes, IgG levels were highest after three immunizations (Day 84) and Seroconversion Rates (SCR) for the highest, adjuvanted dose group, which is considered preferred for further development, ranged from 71.4% to 96.4% for the different OspA serotypes.

Valneva's Phase I study VLA15-101 is an observer-blind, partially randomized, dose escalation trial that aims to evaluate the safety, tolerability and immunogenicity of its Lyme vaccine candidate VLA15. The study enrolled 179 healthy adults under 40 years of age in Europe and the U.S. who were not previously infected with Borrelia burgdorferi. Subjects were randomized into six treatment groups to receive one of three dose levels either in an alum adjuvanted formulation or without adjuvant. Study subjects were vaccinated at three occasions one month apart (Day 0-28-56). The interim analysis for the primary and secondary endpoints included safety and immunogenicity data up to Day 84 (Month 3). Final safety and immunogenicity data including one year follow-up are expected early 2019.

The Company is committed to advance its Lyme vaccine candidate as quickly as possible into Phase II which is currently expected to commence in the second half of 2018, subject to regulatory clearances.
The next clinical phase is intended to be conducted in Lyme-endemic regions and will include people previously infected with Borrelia burgdorferi, the bacteria that cause Lyme disease. Further dose optimization will be considered.

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected Ixodes ticks. According to the Centers for Disease Control and Prevention (CDC), approximately 400,000[5] Americans are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[6]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called Erythema migrans or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system.

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 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.
Vaccination with OspA was already proven to work in the 1990s and VLA15 pre-clinical data showed that the vaccine has the potential to provide protection against the majority of the Borrelia species pathogenic for humans[7].

The global market for a vaccine against Lyme disease is currently estimated at approximately €700 - €800 million annually[8].

CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553
Phase I in the U.S. ongoing (VLA1553-101)

Valneva's Phase I study VLA1553-101 is a randomized, observer-blinded, dose-escalation, multi-centre study investigating three different dose levels of VLA1553 in approximately 120 healthy adults vaccinated with a single-shot immunization.
The trial design includes the investigation of antibody persistence and an additional vaccination with the highest dose at 6 or 12 months of the live-attenuated vaccine candidate. This re-vaccination serves as intrinsic human viral challenge demonstrating that subjects are protected from vaccine-induced viremia and thereby potentially indicating efficacy of VLA1553 early in clinical development.

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[5] *As estimated by the CDC based on US reported cases in 2015*
[6] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*
[7] *New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017*
https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/
[8] *Company estimate supported by independent market studies*

Chikungunya is a mosquito-borne viral disease caused by the Chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash potentially developing into long-term, serious health impairments[9]. Chikungunya outbreaks were reported in Asia, Africa, the Americas and recently (2017) in Europe. Until 2017, there were more than 1 million reported cases in the Americas[10] and the economic impact can be considered significant (e.g. Columbia outbreak 2014: USD 73.6m)[11]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to further spread geographically. 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 for protection against various Chikungunya virus outbreak phylogroups and strains aiming for a long-lasting protection conferred by neutralizing antibodies in adults and children[12]. The target populations are travelers, military personnel or individuals at risk who live in endemic regions.

In pre-clinical development a single-vaccine shot was highly immunogenic with a strong, long lasting neutralizing antibody response and vaccinated Non-Human Primates (NHP) (cynomolgus macaques) showed no signs of viremia after challenge[13].

First data from the Phase I trial are expected to be available by early 2019.

The global market for vaccines against Chikungunya is estimated at up to €500 million annually[8].

ZIKA VACCINE CANDIDATE – VLA 1601
Phase I in the U.S. ongoing (VLA1601-101)[3], Partnered with Emergent BioSolutions

In July 2017, Valneva and US company Emergent BioSolutions joined forces to accelerate the development of a vaccine against Zika.

After finalizing the Phase I study protocol at the end of 2017, the two companies initiated Phase I in the US in February 2018. The Phase I study of VLA1601-101 is a randomized, observer-blinded, placebo-controlled, single center study investigating two dose levels with two different vaccination schedules in approximately 65 healthy adults.

Valneva and Emergent BioSolutions are sharing all costs until Phase I completion. Valneva is responsible for the program's execution until completion of Phase I and Emergent will have the option to continue the development arrangement with Valneva for a milestone payment of €5 million, upon availability of Phase I data. The agreement also provides Valneva potential

[9] *WHO, PAHO*
[10] *PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[11] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[12] *Hallengärd et al. 2013 J. Virology 88: 2858-2866*
[13] *Roques et al. 2017JCI Insight 2 (6): e83527*

additional milestone payments of up to €44 million related to product development, approval, commercialization and product sales, as well as future royalties on annual net sales[14].

Zika is a mosquito-borne viral disease caused by the Zika Virus (ZIKV), a flavivirus transmitted by Aedes mosquitoes[15]. Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, in 2015, in the Americas. According to the World Health Organization, there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome[16]. Between 2015 and the end of July 2017, 1 million cases of Zika infection and many cases of the congenital syndrome associated with the ZIKV had been reported by countries and territories in the Americas, according to the World Health Organization[17]. Today there is 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®.

First data from the Phase I trial are expected to be available in late 2018 or early 2019.

[14] http://www.valneva.com/download.php?dir=News_2017&file=2017_07_26_VLA_Emergent_ZIKA_PR_EN.pdf
[15] https://www.cdc.gov/zika/transmission/index.html
[16] http://www.who.int/mediacentre/factsheets/zika/en/
[17] http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en

Full Year 2017 Financial Review

Revenues and grants

Valneva's aggregate revenues and grants in the full year 2017 increased to €109.8 million from €97.9 million in 2016. This increase was largely as a result of strong growth of IXIARO®/JESPECT® and DUKORAL® product sales.

Total product sales increased to €92.6 million in the full year 2017, up from €80.4 million in 2016. IXIARO®/JESPECT® product sales contributed €60.0 million to revenues in 2017, compared to €53.0 million in 2016 (representing 13% growth). The strong increase was driven by growth in the UK, German and Canadian private markets. US Military sales continue to contribute significantly to overall IXIARO® sales.

DUKORAL® product sales contributed €28.5 million to 2017 product sales representing growth of €4.0 million, or 16% compared to 2016. Third party product sales for the year 2017 increased to €4.0 million from €2.9 million in the year 2016.

Revenues from collaborations and licensing decreased slightly to €12.7 million in 2017 from €13.6 million in the year 2016.

Grant income increased to €4.5 million in 2017 compared to €3.8 million in 2016.

Operating result and EBITDA

Cost of goods and services ("COGS") in 2017 were €46.0 million, leading to an overall gross margin of 58%. €21.7 million in COGS related to IXIARO®/JESPECT® sales, yielding a product gross margin of 64%, and €15.2 million related to DUKORAL® sales, yielding a product gross margin of 46%. Of the remaining COGS for full year 2017, €2.8 million related to the third party product distribution business and €6.3 million related to cost of services. In the comparative period in 2016, COGS were €43.1 million, of which €21.1 million related to IXIARO®/JESPECT®, €13.5 million to DUKORAL®, €2.3 million to third party products, and €6.2 million to cost of services.

Research and development expenses for the year 2017 reached €23.4 million, representing a slight decrease compared to 2016 R&D expenses of €24.6 million.

Marketing and distribution expenses in 2017 amounted to €17.9 million compared to €16.6 million in 2016.

General and administrative expenses in 2017 amounted to €15.5 million compared to €14.4 million in 2016. This increase is in line with additional marketing and sales activities that are driving product sales growth.

Amortization and impairment charges for full year 2017 amounted to €10.7 million, and included €3.6 million of non-cash impairment charges, which were recognized in the third quarter, related to the *Clostridium difficile* vaccine candidate.

Valneva's operating loss for the year 2017 was €4.0 million, compared to an operating loss of €42.6 million reported for the year 2016, which included a one-time impairment charge amounting to €34.1 million related to the discontinued Pseudomonas vaccine candidate.

Valneva's full year 2017 EBITDA showed continued strong improvement and amounted to an EBITDA of €10.8 million, compared to an EBITDA of €2.8 million in the year 2016. 2017 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €14.7 million from the operating loss of €4.0 million as recorded in the condensed consolidated income statement under IFRS.

Net result

Valneva's net loss for the year 2017 was €11.5 million. Excluding the one-time impairment charges related to the *Clostridium difficile* project, Valneva's net loss amounted to €7.9 million for the year 2017, compared to a net loss of €15.1 million for the year 2016 (excluding the one-time impairment charges related to the Pseudomonas project).

The net finance result amounted to minus €8.6 million for the year 2017, compared to minus €6.3 million in the year 2016. This increase in net finance expenses was mainly due to adverse exchange rate effects in 2017.

Cash flow and liquidity

Net cash generated by operating activities in 2017 was €12.8 million compared to €6.5 million in 2016. This improvement resulted from the positive EBITDA development and was also helped by working capital effects.

Cash outflows from investing activities in the year 2017 amounted to €4.1 million and were related to purchases of equipment and software. Cash inflows from investing activities in the year 2016 was €14.9 million and resulted primarily from a 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 out-flows from financing activities in 2017 amounted to €10.4 million and were primarily related to re-payment of borrowings and interest and were partly offset by drawings from an available loan facility with the European Investment Bank (EIB). Cash-outflows from financing activities in 2016 amounted to €26.8 million and included the re-payment of borrowings to Athyrium LLC, as well as interest payments and re-payments of loans.

Cash on December 31, 2017 stood at €38.1 million, compared to €42.2 million on December 31, 2016, and consisted of €33.5 million in cash and cash equivalents and €4.5 million in restricted cash.

Listing strategy review

Valneva is currently reviewing its listing strategy and specifically its secondary listing. The Company plans to complete this process within two months and expects to announce any decision in the second quarter of this year.

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 unique vaccines against Lyme disease and Chikungunya. 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.

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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.