Valneva Reports Strong Revenue Growth and Positive EBITDA in H1 Confirming the Company's Trend towards EBITDA Break-even

Financial performance of commercial products continued to improve in the second quarter while non-cash impairment charges on acquired R&D assets drove a substantial overall net loss

- Total revenues and grants grew to €51.4 million in H1 2016 (vs €39.2 million in H1 2015) as IXIARO®/JESPECT® sales doubled to €30.1 million following the successful establishment of the Company's new marketing and distribution network
- DUKORAL® sales grew to €9.8 million in H1 2016 (vs €8.1 million from the vaccine acquisition date in H1 2015);
- The Company recorded the first royalties from the sales of a human vaccine produced on the EB66® technology in H1 2016
- EBITDA improved to €4.7 million in H1 2016 (vs. a €5.3 million EBITDA loss in H1 2015);
- As expected, high net loss in H1 2016 was driven by non-cash impairment charges on acquired intangible assets following the Pseudomonas clinical results in Q2
- Positive operating cash flow in the second quarter brought cash position to €38.7 million at the end of June 2016 (vs. €33.4 million at the end of Q1 2016)

New Agreements

- Valneva announces the signing of a commercial license agreement for the use of its EB66® technology with Gallant, a subsidiary of German animal health firm IDT Biologika GmbH, and several new research license agreements
- Valneva just recently signed a Marketing & Distribution Agreement for Seqirus' (formerly BioCSL) flu vaccines Sandovac® and Fluad® in Austria

Recent R&D newsflow

- At the end of July, Valneva announced the successful completion of the Phase II study for its *Clostridium difficile* vaccine candidate and is currently in partnering discussions for financing the Phase III trial
- Valneva also announced in July that the Company signed a €25 million loan agreement with the European Investment Bank to support its R&D activity including the research and development of its Lyme Borreliosis and Zika vaccine candidates.
  - The Company confirms it expects to launch the Phase I clinical trial of its Lyme Borreliosis vaccine candidate by the end of 2016
  - Valneva recently announced the successful generation of a highly-purified Zika vaccine candidate and is now looking for a co-development partner to start the clinical trials

2016 Outlook

Valneva re-affirms its FY 2016 financial outlook:

- 2016 IFRS revenues expected to reach €90 to €100 million, with product sales between €70 and €80 million - reflecting up to 30% growth over 2015 product sales;
- Improved revenues due to Valneva´s new global marketing & distribution network are expected to lead to a gross margin on product sales of approximately 50% in 2016;

+ Valneva will continue to strive towards financial self-sustainability and expects to reduce its EBITDA loss to less than €5 million in FY 2016 while continuing to invest around €25 million in R&D this year.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented, *"Valneva achieved a strong financial performance in H1. We doubled our JE vaccine revenues, continued to improve our EBITDA and posted a positive cash flow in the second quarter. The Company will continue to maximize the value of its own commercial products and potential third-party products while at the same time reinforce the value of its R&D pipeline by progressing its vaccine candidates towards new inflection points."*

Key Financial Information

€ in thousands	3 months ended June 30,		6 months ended June 30,	
	2016	2015	2016	2015
Revenues & Grants	26,700	19,713	51,387	39,214
Net profit/(loss)	(34,422)	(8,846)	(39,460)	946
EBITDA	4,658	(4,384)	4,672	(5,346)
Net operating cash flow	10,475	(1,029)	3,888	(10,886)
Cash, short-term deposits and marketable securities, end of period	38,657	43,673	38,657	43,673

Lyon (France), August 31, 2016 – Valneva SE ("Valneva" or "the Company"), a leading independent pure play vaccine company, reported today its consolidated financial results for the first half ended June 30, 2016. 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

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/wp4kodbe

Commercialized vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
H1 2016 sales doubled compared to H1 2015

In the first half of 2016, revenues from IXIARO®/JESPECT® product sales doubled to €30.1 million compared to €15.3 million in the first half of 2015. The increase was strongly driven by the capturing of additional revenue margins under the new sales and distribution network, notably in the US, German, UK and Canadian private markets, and from shipments to the US military related to the 2 year supply contract awarded in the first quarter.

In March 2016, Valneva announced the signing of a $42 million contract with the US Government's Department of Defense to supply IXIARO® doses to the US military over a two-year period to protect the nearly 360,000 US military and civilian personnel and their families working and living in endemic countries.

Based on first-half sales, the observed demand pattern in the travel markets and anticipated further supplies to the US military, Valneva re-affirms its FY 2016 guidance of IXIARO®/JESPECT® product sales reaching approximately €50 million.

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)
Good potential for further growth

DUKORAL® sales in the first half of 2016 grew to €9.8 million compared to €8.1 million reported by Valneva in the first half of 2015, despite the negative transitional impact of the change in the product monograph in Canada and the fact that Valneva largely suspended promotional efforts during the fourth quarter of 2015 and the first quarter of 2016 to include the updates in the indication and labeling.

Valneva confirms its expectation to achieve its DUKORAL® full year 2016 revenue goal of approximately €23 million (compared to €26.3 million on a pro-forma basis in 2015). The Company will continue to invest in growing the DUKORAL® vaccine by way of promotional efforts and geographic expansion.

Technologies and services

EB66® CELL LINE
New licensing agreements signed in H1 and additional ones expected in H2

Valneva's EB66® cell line, which is derived from duck embryonic stem cells, is a highly efficient platform for vaccine production and today represents a compelling alternative to chicken eggs for large scale manufacturing of human and veterinary vaccines. Valneva's EB66® cell-line has become increasingly profitable and the Company expects growing cash-contributions from this technology.

In the second quarter of 2016, Valneva recorded its first royalties from the sale of EB66®-based pandemic influenza vaccines under its partnership with GSK.

During the first six months of 2016, Valneva also signed several new agreements for its EB66® cell line including a commercial license agreement with Gallant Custom Laboratories Inc., a Canadian subsidiary of the German animal health firm IDT Biologika GmbH.

Valneva expects to sign additional EB66® license agreements in the second part of 2016.

Clinical vaccine candidates

Valneva's current proprietary clinical pipeline includes vaccine candidates against *Clostridium difficile* (Phase II completed), and *Lyme borreliosis* which is expected to enter Phase I in the later part of 2016.
During the second quarter of the year, Valneva announced that the Phase II/III trial results for its *Pseudomonas aeruginosa* vaccine candidate (VLA43) did not confirm prior Phase II and

interim analysis findings which had shown a clinically meaningful vaccine effect of all-cause mortality reduction. As a result, the Company decided to discontinue the program.

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE – VLA 84
Phase II successfully completed – Company expects to find a partner for Phase III

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[1]. Currently, no vaccine against *C. difficile* exists and antibiotic treatment of the established disease has significant limitations with recurrence in ~20% of cases. Valneva estimates that the total market potential for prophylactic C. difficile products may exceed US$1 billion annually.

At the end of July 2016, Valneva announced that it successfully completed Phase II development of its *C. difficile* vaccine candidate and that the final results confirmed the previously announced positive topline data that it presented at the American Society of Microbiology's annual meeting, ASM Microbe 2016, on June 17, 2016 in Boston.

VLA84 was immunogenic at all doses and formulations tested, in that Immunoglobulin G (IgG) and functional (neutralizing) antibody responses were seen. The study met its primary endpoint in terms of identifying the dose/formulation with the highest seroconversion rate against both toxins A and B and confirmed the favorable safety profile observed in Phase I. Final Phase II results included the follow-up on the 500 study participants out to Day 210.

The Phase II study design had been agreed in advance with regulators with the aim of supporting a subsequent progression into Phase III. Valneva has confirmed Phase III readiness through an independent Scientific Advisory Board (SAB) and is now ready to support an end-of Phase II meeting (EOP2 meeting) once the final Phase III design is agreed with a potential partner. The Company reaffirms its expectation to find a partner for its *C. difficile* program by the end of year.

LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15
Phase I clinical trial expected to commence in 2016

Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection that is increasingly common in the US and Europe.

Valneva has developed a multivalent vaccine candidate which addresses OspA, one of the most dominant proteins expressed by the bacteria when present in a tick. Pre-clinical data showed that this vaccine candidate can provide protection against the majority of Borrelia species pathogenic for humans[2].

Valneva expects to commence a Phase I trial towards the end of 2016. The single-blind, partially randomized, dose escalation Phase I study trial will be conducted in the US and Europe. Besides its primary objective of evaluating safety and tolerability, immunogenicity, measured by observing IgG antibodies specific against six OspA serotypes, will also be monitored for different dose groups and formulations at different time-points.

[1] Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34.
[2] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294

Pre-clinical vaccine candidates

Beyond its clinical product candidates, Valneva is working on a range of pre-clinical candidates, some of which are now ready for clinical testing. Valneva has prioritized pre-clinical candidates which are technologically and scientifically complementary to the Company´s strong viral vaccines development competence.

ZIKA VACCINE CANDIDATE – VLA 1601

Valneva recently announced successful generation of a highly-purified vaccine candidate using the same manufacturing platform as its Japanese encephalitis vaccine, a vaccine which has already been approved by the American (FDA, Health Canada), European (EMA) and other regulatory agencies. By working on a vaccine technology that is familiar to the regulatory agencies and which has been previously used in approved commercial vaccines, Valneva believes that regulatory risk can be minimized, resulting in the most efficient path to market. The Zika vaccine candidate, generated on the IXIARO® (JESPECT®) platform, has demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to the commercially produced JE vaccine. The Company has already received a positive feedback from the European Medicines Agency (EMA) and is now seeking a partner to support advancement into clinical testing.

Other pre-clinical stage projects include vaccines against diseases such as Chikungunya (CHIKV), yellow-fever (YF) and human metapneumovirus (hMPV).

Financial Review[3]

SECOND QUARTER 2016 FINANCIAL REVIEW

Revenues and grants

Valneva's aggregate second quarter 2016 revenues and grants increased to €26.7 million from €19.7 million in the second quarter of 2015. This increase resulted mainly from the strong growth of IXIARO®/JESPECT® product sales.

Product sales increased to €20.5 million in the second quarter of 2016 from €12.4 million in the second quarter of 2015. Revenues from collaborations and licensing decreased from €6.2 million in the second quarter of 2015 to €5.4 million in the second quarter of 2016. Grant income decreased from €1.1 million in the second quarter of 2015 to €0.8 million in the second quarter of 2016.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €8.8 million in the second quarter of 2016 and €11.5 million in the comparator period of 2015.

Research and development (R&D) expenses in the second quarter of 2016 reached €6.7 million compared to €7.0 million in the second quarter of the previous year. Distribution

[3] *Note: HY 2016 and HY 2015 IFRS results are not fully comparable because of the acquisition of the Crucell Sweden AB business in February, 2015. As a result of the acquisition, which included all assets, licenses and privileges related to DUKORAL® as well as a vaccine distribution business in the Nordics, the comparator period of 2015 includes specific acquisition-related transaction effects and the results of the acquired business only from the acquisition closing date on February 9, 2015. Furthermore, the Company amended the presentation of its income and cash flow statements compared to the consolidated annual financial statements for the year ended December 31, 2015 with respect to "gain on bargain purchase" (now presented within "operating profit/loss") and "interest paid" (now presented within the "cash flow from financing activities"). The previous year comparative period was adjusted accordingly.*

and marketing expenses in the second quarter of 2016 amounted to €4.1 million compared to €2.3 million in the second quarter of 2015. Distribution and marketing costs increased as a result of the establishment of the Company's own sales and marketing organization following the termination of its global distribution partnership with GSK in June 2015.
General and administrative (G&A) expenses in the second quarter of 2016 amounted to €3.6 million, compared to €4.3 million in the second quarter of 2015.
Amortization and impairment charges for the second quarter of 2016 amounted to €35.9 million and included €34.1 million in non-cash impairment charges related to the *Pseudomonas aeruginosa* project. The final Phase II/III study results for the Pseudomas vaccine candidate published during the second quarter of 2016 did not confirm a positive vaccine effect resulting in discontinuation of the program and full impairment of the related intangible assets. Excluding this one-time effect amortization and impairment, charges remained unchanged compared to the second quarter of 2015 and amounted to €1.8 million.
Valneva's operating profit for the second quarter 2016 was also impacted by the €34.1 million impairment charges of *Pseudomonas aeruginosa* related intangible assets and amounted to a loss of €32.3 million. Excluding the one-time impairment charges, Valneva achieved considerably improved profitability and delivered an operating profit amounting to €1.8 million compared to an operating loss of €7.3 million reported for the second quarter of 2015.
Valneva's second quarter 2016 EBITDA continued showing strong improvements and amounted to an EBITDA profit of €4.7 million compared to an EBITDA loss of €4.4 million in the second quarter of 2015. EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €37.0 million from the operating loss of €32.3 million as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase.

Segment overview
The Commercialized Vaccines segment showed an operating profit of €7.0 million in the second quarter of 2016, compared to an operating loss of €1.9 million in the second quarter of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €8.6 million in the second quarter of 2016 and an operating loss of €0.2 million in the second quarter of 2015.
The Technologies and Services segment showed an operating profit of €1.3 million in the second quarter of 2016 compared to €2.4 million operating profit in the second quarter of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €1.4 million in the second quarter of 2016 compared to €2.5 million in the second quarter of 2015.
The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €2.8 million in the second quarter of 2016 (excluding one-time impairment charges of intangible fixed assets of €34.1 million related to the Pseudomonas project) compared to €3.4 million in the second quarter of 2015.

Net result
Valneva's net loss in the second quarter of 2016 was €34.4 million compared to a net loss of €8.8 million in the second quarter of the prior year. Excluding the one-time impairment charges related to the Pseudomonas project, Valneva's net loss significantly improved to €0.3 million driven by increased product sales and improved operating results. Financial expenses increased to €1.9 million in the second quarter of 2016 from €1.4 million in the second quarter of 2015, mainly due to negative exchange rate effects on financial assets held in British Pounds (£). Going forward, the Company's operating expenses, in particular cost of goods for the JE vaccine manufactured in Scotland, are expected to benefit from the weakness of the British Pound versus the Euro.

HALF YEAR 2016 FINANCIAL REVIEW

Revenues and grants

Valneva's aggregate first half 2016 revenues and grants increased to €51.4 million from €39.2 million in the first half of 2015. This increase was mainly a result of strong growth of IXIARO®/JESPECT® product sales.

Product sales increased to €40.9 million in the first half of 2016 from €27.5 million in the first half of 2015. IXIARO®/JESPECT® product sales contributed €30.1 million to revenues in the first half of 2016 compared to €15.3 million in the first half of 2015 representing 97% growth. The strong increase was primarily driven by shipments to the US military related to the recently awarded 2 year supply contract announced in March 2016. DUKORAL® sales contributed €9.8 million to the first half 2016 product sales representing growth of €1.7 million compared to the first half of 2015. Third Party product sales decreased to €0.9 million in the first half of 2016 from €4.0 million in the first half of 2015.

Revenues from collaborations and licensing decreased from €9.7 million in the first half of 2015 to €8.7 million in the first half of 2016.

Grant income slightly decreased from €2.0 million in the first half of 2015 to €1.8 million in the first half of 2016.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €21.7 million in the first half of 2016 of which €10.5 million related to IXIARO®/JESPECT® sales, yielding a product gross margin of 65.4%. €6.8 million of COGS related to DUKORAL® sales, yielding a gross margin of 30.9%. Of the remaining COGS for the first half of 2016, €0.9 million related to the Third Party product distribution business and €3.5 million related to cost of services. In the comparator period of 2015, COGS were €23.7 million.

Research and development (R&D) expenses in the first half of 2016 reached €12.5 million and remained flat compared to the first half of 2015.

Distribution and marketing expenses for the first half of 2016 amounted to €7.4 million, compared to €3.5 million in the first half of 2015. Distribution and marketing costs increased as a result of the establishment of the Company's own sales and marketing organization following the termination of its global distribution partnership with GSK in June 2015.

General and administrative (G&A) expenses slightly increased in the first half of 2016 and amounted to €7.3 million compared to €7.1 million in the first half of 2015.

Amortization and impairment charges for the first half of 2016 amounted to €37.7 million and included the €34.1 million non-cash impairment charges related to the *Pseudomonas aeruginosa* project.

Valneva's operating loss in the first half of 2016 was also impacted by the €34.1 million impairment charges of *Pseudomonas aeruginosa* related intangible assets and amounted to a loss of €35.1 million. Excluding the one-time impairment charges, Valneva's operating performance amounted to a loss of €0.9 million compared to an operating gain of €2.2 million reported for the first half of 2015. The first half of 2015 included a €13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of the Crucell Sweden AB business.

Valneva's first half 2016 EBITDA continued to show strong improvements and amounted to an EBITDA profit of €4.7 million, compared to an EBITDA loss of €5.3 million in the first half of 2015. EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €39.7 million from the operating loss of €35.1 million as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase.

Segment overview

The Commercialized Vaccines segment showed an operating profit of €10.1 million in the first half of 2016 compared to an operating loss of €1.2 million in the first half of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €13.4 million in the first half of 2016 and an operating profit of €2.1 million in the first half of 2015.

The Technologies and Services segment showed an operating profit of €1.8 million in the first half of 2016 compared to €3.1 million operating profit in the first half of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €2.1 million in the first half of 2016 compared to €3.4 million in the first 6 months of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €5.4 million in the first half of 2016 (excluding one-time impairment charges of intangible fixed assets of €34.1 million related to the Pseudomonas project) compared to €5.8 million in the first half of 2015.

Net result

Valneva's net loss in the first half of 2016 was €39.5 million. Excluding the one-time impairment charges related to the Pseudomonas project, Valneva's net loss amounted to €5.3 million compared to a net profit of €0.9 million in the first half of the prior year. Finance expenses slightly increased to €4.3 million in the first half of 2016 from €2.7 million in the first half of 2015 mainly due to exchange rate effects.

Cash flow and liquidity

Net cash generated by operating activities in the first half of 2016 amounted to €3.9 million compared to net cash used in operating activities of €10.9 million in the first half of 2015 and resulted primarily from the positive EBITDA development and was also helped by working capital effects.

Cash inflows from investing activities in the first half of 2016 amounted to €17.4 million and resulted primarily from a payment received from Johnson & Johnson in connection with the adjustment of the purchase consideration for the Crucell Sweden AB business and the DUKORAL® vaccine.

Cash out-flows from financing activities in the first half of 2016 amounted to €24.3 million and primarily included the re-payment of borrowings to Athyrium LLC.

Liquid funds stood at €38.7 million on June 30, 2016 compared to €43.7 million on June 30, 2015 and consisted of €34.0 million in cash and cash equivalents, €4.0 million in short-term bank deposits and €0.6 million in restricted cash.

Contacts Valneva SE

Laetitia Bachelot Fontaine
Head of Investor Relations & Corporate Communications
T +02-28-07-14-19
M +33 (0)6 4516 7099
investors@valneva.com

Teresa Pinzolits
Corporate Communications Specialist
T +43-1-206 20-1116
M +43-676-84 55 67 357
Communications@valneva.com

About Valneva SE

Valneva is a fully integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.

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®/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 (*Enterotoxigenic Escherichia coli*). 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® vaccine production cell line, IC31® adjuvant).
Valneva is headquartered in Lyon, France, listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland and Sweden with over 400 employees. More information is available at www.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.