

Q3 2016

**QUARTERLY REPORT
VALNEVA SE**

November 9, 2016

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 **valneva**

Valneva Reports Strong Business Performance in First Nine Months Company Increases Financial Guidance for Full Year 2016

Nine Months financial performance ahead of initial expectations:

- + Total revenues and grants grew to €70.7 million in the first nine months of 2016 (vs. €60.7 million in the same period of 2015) benefiting from a more than 60% increase of IXIARO®/JESPECT® revenues to €40.1 million.
- + Valneva reported a positive EBITDA of €3.5 million in the first nine months of 2016 (vs. an EBITDA loss of €4.3 million in the same period of 2015) despite a slightly negative EBITDA of minus €1.2 million in the third quarter of 2016 (vs. €1.0 million positive EBITDA in the same period of 2015).
- + Nine months 2016 net loss was impacted by a non-cash impairment charge on acquired intangible assets following the discontinuation of the Pseudomonas program in Q2.
- + Positive operating cash flow of €8.0 million in the first nine months of 2016 brought cash position to €40.3 million as of September 30, 2016 (vs. €37.3 million as of September 30, 2015).
- + Strong nine months performance was driven by revenue and EBITDA growth in the first two quarters of 2016, while third quarter 2016 revenues and grants slightly decreased to €19.4 million (vs. €21.5 million in the third quarter of 2015) due to usual quarterly fluctuations.

2016 Outlook

Based on the Company's strong year to date financial performance, Valneva raises its FY 2016 operating guidance:

- + The Company now expects EBITDA profit of €1-5 million in FY 2016 compared to its previous guidance of less than €5 million of EBITDA loss, while still investing around €25 million in R&D.
- + Valneva narrows its revenue guidance to the upper end of the previously communicated range and now expects FY 2016 IFRS revenues to reach between €95 and €100 million with product sales of between €75 and €80 million and a gross margin on product sales higher than 50%.

Key upcoming clinical milestones

- + Following successful completion of Phase II and comparison of its data with the only more advanced vaccine program targeting primary prevention of *Clostridium difficile* Infections, Valneva continues to seek a partner and is in discussion with several potential partners. The Company has therefore revised its expected timelines for entering into a partnering deal to 2017.
- + Valneva confirms it will initiate a Phase I clinical trial of its Lyme borreliosis vaccine candidate before the end of 2016. The Company will hold a Key Opinion Leader conference and live webcast for investors on Lyme in New York on December 12, 2016.
- + Valneva expects to launch a second clinical program in 2017 from its promising pre-clinical portfolio which includes vaccine candidates against Chikungunya and Zika.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented, *“We are excited that our financial performance clearly confirms the Company’s transition towards financial self-sustainability while maintaining significant investments in promising R&D programs including much-needed vaccines such as our Lyme disease vaccine candidate. Besides further anticipated growth of our product sales, the ongoing R&D partnership discussions, including those on our C. difficile vaccine candidate, may provide additional upside going forward.”*

Key Financial Information

(unaudited)

€ in thousand	3 months ended September 30,		9 months ended September 30,	
	2016	2015	2016	2015
Revenues & grants	19,354	21,468	70,741	60,682
Net profit/(loss)	(7,007)	(5,164)	(46,467)	(4,218)
EBITDA ¹	(1,209)	1,039	3,463	(4,307)
Net operating cash flow	4,155	(6,054)	7,990	(19,032)
Cash, short-term deposits and marketable securities, end of period	40,293	37,258	40,293	37,258

Lyon (France), November 9, 2016 – Valneva SE (“Valneva” or “the Company”), a leading independent pure play vaccine company, reported today its consolidated financial results for the first nine months and third quarter of the year ending September 30, 2016. The financial report, including the condensed consolidated interim financial 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/jv2idge8>

Commercialized vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

Nine months 2016 revenues increased by more than 60% compared to same period in 2015

In the first nine months of 2016, Ixiaro®/Jespect® revenues grew 61.2% to €40.1 million (including €39.9 million of product sales and €0.2 million of royalties) compared to €24.8 million in the first nine months of 2015. Nine months 2016 revenues benefited mostly from additional revenue margins under the Company’s new sales and distribution network. In the third quarter of 2016, Ixiaro®/Jespect® product sales were €9.8 million compared to €9.7 million in the

¹ EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets as well as gains from bargain purchase (“negative goodwill”) from the operating loss.

third quarter of 2015. The 2016 third quarter sales were lower than the two previous quarters as a result of usual quarterly sales fluctuations driven by order patterns of major clients such as the US government and key distributors. Based on the strong nine months IXIARO[®]/JESPECT[®] revenues, Valneva expects its full-year 2016 IXIARO[®]/JESPECT[®] revenues to exceed €50 million.

CHOLERA/ ETEC- DIARRHEA VACCINE (DUKORAL[®])

A strong third quarter

DUKORAL[®] revenues in the first nine months of 2016 grew to €14.9 million compared to €12.6 million reported by Valneva in the first nine months of 2015. The revenue increase was recorded despite the fact that Valneva largely suspended promotional efforts during the first part of 2016 to include the product monograph updates agreed with Health Canada. In the third quarter of 2016, DUKORAL[®] revenues rose to €5.1 million (including €5.0 million of product sales and €0.1 million of royalties) compared to €4.4 million in the third quarter of 2015 as Valneva resumed active promotion of the product in its main market in Canada.

Valneva confirms its expectation to meet 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

GE Healthcare and Valneva Collaboration Delivers Optimized Cell Culture Medium for Vaccine Production in EB66[®] cell-line

New Research agreement with IDT Biologika

GE Healthcare and Valneva recently announced the launch a new cell culture medium, CDM4Avian, to optimize virus productivity in Valneva's proprietary EB66[®] cell-line. The new medium is chemically defined, fully characterized and animal derived component free , offering efficient cell growth and virus replication. GE Healthcare and Valneva believe that this state-of the art medium will further ease the regulatory processes for new products developed in EB66[®] cells.

Valneva also welcomes the European Medical Agency's decision to issue new guidelines to allow the production of live attenuated vaccines in immortal cell-lines such as EB66[®] allowing Valneva's partners to now utilize the EB66[®] cell line to develop and manufacture vaccines including Modified Vaccinia Ankara-based vaccines, measles and oncolytic vaccines. Until now, only inactivated vaccines could be developed in EB66[®] cells in Europe. Valneva expects these new guidelines to open new, untapped markets for the EB66 cell line.

Valneva continues to license its technology for the manufacturing of human and veterinary vaccines. In the third quarter of 2016, the Company signed a new research agreement with German animal health firm IDT Biologika GmbH allowing IDT to use the EB66[®] cell line to research new veterinary vaccines. This new agreement with IDT follows the recent signing of a commercial agreement with IDT's subsidiary Gallant Custom Laboratories Inc. to develop, manufacture and commercialize vaccines for the prevention of influenza virus in poultries and fowl adenovirus using the EB66[®] cell line.

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 before the end of 2016.

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE – VLA 84

Phase II, including more recent follow-up data until Day 210, reconfirms our competitive Phase III ready asset – Company expects partnering deal to occur in 2017

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 annually². Currently, no vaccine against *C. difficile* is commercially available 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.

Valneva previously 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.

The Phase II study design had been agreed in advance with regulators with the aim of supporting a subsequent progression into Phase III. The program's Phase III readiness was confirmed through an independent Scientific Advisory Board (SAB).

The comparison with published Phase II data³ from the only more advanced vaccine program targeting primary prevention of *Clostridium Difficile Infections* (CDI) indicates that Valneva's VLA84 provides a comparable immunological profile. Supported by the competitive data comparison, Valneva continues to seek a partner and is in discussion with several potential partners. The company has therefore revised its expected timelines for entering into a partnering deal to 2017.

LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15

Phase I clinical trial expected to commence by the end of 2016

Valneva to hold a Lyme disease KOL event in New York on December 12, 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 humans⁴.

Valneva expects to commence a Phase I trial before the end of 2016. The single-blind, partially randomized, dose escalation Phase I study trial will be conducted in the US and Europe. The primary objective will be to evaluate safety and tolerability. Immunogenicity, measured by

² Lessa et al, Burden of *Clostridium difficile* Infection in the United States. N Engl J Med 2015;372:825-34.

³ G. de Bruyn et al. Vaccine 34 (2016) 2170-2178

⁴ <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294>

observing IgG antibodies specific against six OspA serotypes, will also be monitored for different dose groups and formulations at different time-points.

Considering the strong interest shown on the disease by investors, shareholders and the general public, Valneva has planned a conference on Lyme borreliosis in New York on December 12, 2016 to provide more detailed information on the disease and the opportunity to develop a vaccine. The conference will be co-presented by Prof. Stanley A. Plotkin, Emeritus Professor, University of Pennsylvania, and Valneva's Lyme R&D experts led by CEO Thomas Lingelbach.

Financial Review⁵

THIRD QUARTER 2016 FINANCIAL REVIEW (unaudited)

Revenues and grants

Valneva's aggregate third quarter 2016 revenues and grants were €19.4 million compared to €21.5 million in the third quarter of 2015.

Product sales in the third quarter of 2016 decreased to €15.7 million from €16.7 million in the same period of the previous year. The overall decrease in product sales was due to the lower number of third party products that are currently marketed by Valneva than in 2015, which led to a reduction of third party product sales to €0.9 million in the past quarter compared to €2.7 million in the third quarter of 2015. Product sales from Valneva's two proprietary vaccines again increased in the past quarter. IXIARO[®]/JESPECT[®] product sales contributed €9.8 million to revenues in the third quarter of 2016 slightly increasing from €9.7 million in the third quarter of 2015. DUKORAL[®] sales contributed €5.0 million to the third quarter 2016 product sales, growing by 18.7% from €4.2 million in the third quarter of 2015.

Revenues from collaborations and licensing in the third quarter of 2016 decreased to €2.7 million compared to €3.5 million in the third quarter of 2015. Grant income in the third quarter of 2016 decreased to €1.0 million from €1.3 million in the third quarter of 2015.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €8.3 million in the third quarter of 2016 of which €4.3 million related to IXIARO[®]/JESPECT[®] sales, yielding a product gross margin of 56.0%, and €2.3 million related to DUKORAL[®] sales, yielding a product gross margin of 53.6%. Of the remaining COGS for the third quarter of 2016, €0.5 million related to the Third Party product distribution business and €1.1 million related to cost of services. In the comparator period of 2015, COGS were €10.0 million, of which €8.8 million related to cost of goods and €1.3 million to cost of services.

Research and development expenses in the third quarter of 2016 reached €6.3 million and were almost flat compared to €6.2 million in the third quarter of the previous year.

Distribution and marketing expenses in the third quarter of 2016 amounted to €3.9 million, compared to €2.3 million in the third quarter of 2015. Distribution and marketing costs increased

⁵Note: 9M 2016 and 9M 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 are only included 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.

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 expenses amounted to €3.1 million in both the third quarter of 2016 and the comparator quarter of 2015.

Amortization and impairment charges in the third quarter of 2016 were also flat to the third quarter of 2015 at €1.8 million.

As a result of the lower revenues and increased distribution and marketing expenses, Valneva's operating loss for the third quarter 2016 increased to €4.0 million compared to an operating loss of €1.8 million reported for the third quarter of 2015.

Valneva's third quarter 2016 showed an EBITDA loss of €1.2 million which compares to an EBITDA profit of €1.0 million in the third quarter of 2015. Q3 2016 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €2.8 million from the operating loss of €4.0 million as recorded in the condensed consolidated income statement under IFRS.

Segment overview

The Commercialized Vaccines segment showed an operating profit of €2.2 million in the third quarter of 2016, which compares to €3.3 million in the third quarter of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €3.9 million in the third quarter of 2016 and €5.0 million in the third quarter of 2015.

The Technologies and Services segment showed an operating profit of €0.4 million in the third quarter of 2016 compared to €0.3 million in the third quarter of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €0.6 million in the third quarter of 2016 compared to €0.5 million in the third quarter of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €3.4 million in the third quarter of 2016 compared to a €2.5 million loss in the third quarter of 2015.

Net result

Valneva's net loss in the third quarter of 2016 was €7.0 million compared to a net loss of €5.2 million in the third quarter of the prior year. Finance-expenses slightly decreased to €2.9 million in the third quarter of 2016 from €3.1 million in the third quarter of 2015.

Cash flow

Net cash generated by operating activities in the third quarter of 2016 amounted to €4.2 million compared to a net operating cash outflow of €6.1 million in the third quarter of 2015, and mainly resulted from the collection of receivables following the strong revenues of the previous quarter.

Cash outflows from investing activities in the third quarter of 2016 amounted to €0.7 million and resulted primarily from purchase of equipment.

Cash out-flows from financing activities in the third quarter of 2016 amounted to €1.6 million and primarily consisted of interest payments and re-payments of loans.

FIRST NINE MONTHS 2016 FINANCIAL REVIEW

Revenues and grants

Valneva's aggregate revenues and grants in the first nine months of 2016 increased to €70.7 million from €60.7 million in the first nine months of 2015. This increase was mainly a result of strong growth of IXIARO[®]/JESPECT[®] product sales.

Product sales increased to €56.6 million in the first nine months of 2016 from €44.2 million in the first nine months of 2015. IXIARO[®]/JESPECT[®] product sales contributed €39.9 million to revenues in the first nine months of 2016 compared to €24.7 million in the first nine months of 2015 representing 61.3% growth. The strong increase was driven by the capturing of additional revenue margins under the new sales and distribution network and also benefited from strong demand from the US military and from private markets in Germany and the UK. DUKORAL[®] sales contributed €14.9 million to the first nine months 2016 product sales representing growth of €2.5 million, or 20.5% compared to the first nine months of 2015. Third Party product sales in the first nine months of 2016 decreased to €1.9 million from €6.8 million in the first nine months of 2015 due to the fact that several GSK vaccines are no longer marketed by Valneva.

Revenues from collaborations and licensing decreased from €13.2 million in the first nine months of 2015 to €11.4 million in the first nine months of 2016.

Grant income decreased to €2.7 million in the first nine months of 2016 compared to €3.3 million in the first nine months of 2015.

Operating result and EBITDA

Cost of goods and services sold (COGS) in the first nine months of 2016 were €30.0 million of which €14.8 million related to IXIARO[®]/JESPECT[®] sales, yielding a product gross margin of 63.1%, and €9.2 million related to DUKORAL[®] sales, yielding a product gross margin of 38.6%. Of the remaining COGS for the first nine months of 2016, €1.4 million related to the Third Party product distribution business and €4.6 million related to cost of services. In the comparator period of 2015, COGS were €33.6 million, of which €14.0 million related to IXIARO[®]/JESPECT[®], €10.9 million to DUKORAL[®], €5.0 million to Third Party products, and €3.7 million to cost of services.

Research and development expenses in the first nine months of 2016 reached €18.7 million and remained flat compared to the first nine months of 2015.

Distribution and marketing expenses in the first nine months of 2016 amounted to €11.3 million compared to €5.8 million in the first nine months 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 expenses slightly increased in the first nine months of 2016 and amounted to €10.4 million compared to €10.2 million in the first nine months of 2015.

Amortization and impairment charges for the first nine months of 2016 amounted to €39.5 million and included €34.1 million of non-cash impairment charges which were recognized in the second quarter following negative Phase II/III study results for the *Pseudomonas* vaccine candidate and discontinuation of the program.

Valneva's operating loss for the first nine months of 2016 was also impacted by the impairment charges relating to the *Pseudomonas* project and amounted to €39.1 million. Excluding the one-time impairment charges Valneva's operating loss in the first nine months of 2016 was

€5.0 million compared to an operating gain of €0.4 million reported for the first nine months of 2015. The first nine months of 2015 included a €13.2 million gain on bargain purchase (“negative goodwill”) related to the acquisition of the Crucell Sweden AB business. Without taking into account the positive one-time effect, Valneva’s operating loss in the first nine months of 2015 amounted to €12.8 million.

Valneva’s first nine months 2016 EBITDA showed a strong improvement and amounted to an EBITDA profit of €3.5 million, compared to an EBITDA loss of €4.3 million in the first nine months of 2015. First nine months 2016 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €42.5 million from the operating loss of €39.1 million as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase in the calculation for the comparator period of the previous year.

Segment overview

The Commercialized Vaccines segment showed an operating profit of €12.2 million in the first nine months of 2016 compared to an operating profit of €2.2 million in the first nine months of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €17.3 million in the first nine months of 2016 and €7.2 million in the first nine months of 2015.

The Technologies and Services segment showed an operating profit for the first nine months of 2016 of €2.3 million compared to €3.4 million in the first nine months of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €2.6 million in the first nine months of 2016 compared to €3.9 million in the first nine months of 2015.

The Vaccine Candidates segment currently represents the Company’s main area of investment and showed an operating loss of €8.8 million in the first nine months of 2016 (excluding one-time impairment charges of €34.1 million related to the *Pseudomonas* project) compared to €8.3 million in the first nine months of 2015.

Net result

Valneva’s net loss in the first nine months of 2016 was €46.5 million. Excluding the one-time impairment charges related to the *Pseudomonas* project, Valneva’s net loss amounted to €12.4 million compared to a net loss of €4.2 million in the first nine months of the prior year. The first nine months of 2015 included a €13.2 million gain on bargain purchase (“negative goodwill”) related to the acquisition of the Crucell Sweden AB business. Without taking into account the one-time effects in both periods, the net loss significantly improved to €12.4 million in the first nine months of 2016 compared to €17.4 million in the first nine months of 2015. The finance result amounted to minus €7.0 million in the first nine months of 2016 compared to minus €3.6 million in the first nine months of 2015. This increase in net finance expenses was mainly due to negative exchange rate effects in the current year as opposed to positive effects in the previous year.

Cash flow and liquidity

Net cash generated by operating activities in the first nine months of 2016 amounted to €8.0 million, compared to net cash used in operating activities of €19.0 million in the first nine months of 2015. This strong improvement resulted from the positive EBITDA development and was also helped by working capital effects.

Cash inflows from investing activities in the first nine months of 2016 amounted to €16.7 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 the first nine months of 2016 amounted to €25.9 million and included the re-payment of borrowings to Athyrium LLC as well as interest payments and re-payments of loans.

Liquid funds on September 30, 2016 stood at €40.3 million, compared to €37.3 million on September 30, 2015 and consisted of €39.7 million in cash and cash equivalents and €0.6 million in restricted cash.

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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, UK, Sweden, Canada and the US 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.

**VALNEVA SE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT
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CONDENSED CONSOLIDATED INTERIM INCOME STATEMENT

€ in thousand (except per share amounts)	Three months ended September 30,		Nine months ended September 30,	
	2016	2015 ¹	2016	2015 ¹
Product sales	15,740	16,672	56,648	44,169
Revenues from collaboration, licensing and services	2,655	3,533	11,384	13,241
Revenues	18,395	20,205	68,032	57,410
Grant income	959	1,263	2,709	3,272
Revenues and grants	19,354	21,468	70,741	60,682
Cost of goods and services	(8,291)	(9,988)	(29,981)	(33,646)
Research and development expenses	(6,262)	(6,241)	(18,719)	(18,730)
Distribution and marketing expenses	(3,929)	(2,293)	(11,285)	(5,784)
General and administrative expenses	(3,080)	(3,122)	(10,403)	(10,205)
Other income and expenses, net	(20)	163	23	309
Amortization and impairment of fixed assets/intangibles	(1,795)	(1,818)	(39,453)	(5,456)
Gain on bargain purchase	-	-	-	13,183
OPERATING PROFIT/LOSS	(4,023)	(1,831)	(39,077)	352
Finance income	11	16	200	1,307
Finance expenses	(2,891)	(3,071)	(7,160)	(4,912)
Result from investments in affiliates	-	(303)	-	(567)
PROFIT/LOSS BEFORE INCOME TAX	(6,903)	(5,189)	(46,038)	(3,820)
Income tax	(104)	25	(429)	(398)
PROFIT/LOSS FOR THE PERIOD	(7,007)	(5,164)	(46,467)	(4,218)
Profit/losses per share				
for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share				
- basic	(0.09)	(0.07)	(0.62)	(0.04)
- diluted	(0.09)	(0.07)	(0.62)	(0.04)

¹ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10), as well as the presentation of the gain on bargain purchase within the operating result.

CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE INCOME

€ in thousand	Three months ended September 30,		Nine months ended September 30,	
	2016	2015 ²	2016	2015 ²
Profit/Loss for the period	(7,007)	(5,164)	(46,467)	(4,218)
Other comprehensive income/(loss)				
Items that are or may be reclassified subsequently to profit or loss				
Currency translation differences	(119)	(300)	(1,239)	(1,876)
Total items that are or may be reclassified subsequently to profit or loss	(119)	(300)	(1,239)	(1,876)
Other comprehensive income/(loss) for the period, net of tax	(119)	(300)	(1,239)	(1,876)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY	(7,125)	(5,465)	(47,706)	(6,095)

² The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).

CONDENSED CONSOLIDATED INTERIM BALANCE SHEET

€ in thousand	September 30, 2016	December 31, 2015
ASSETS		
Non-current assets	115,908	158,804
Intangible assets and goodwill	59,177	98,567
Property, plant and equipment	39,682	42,439
Other non-current assets	17,049	17,797
Current assets	87,055	116,383
Inventories	24,754	26,687
Trade receivables	12,946	15,754
Other current assets	9,062	31,374
Cash, cash equivalents, short-term deposits and current financial assets	40,293	42,567
TOTAL ASSETS	202,962	275,187
EQUITY		
Capital and reserves attributable to the Company's equity holders	97,577	144,335
Share capital	11,205	11,205
Share premium and other regulated reserves	245,965	245,965
Retained earnings and other reserves	(113,127)	(92,219)
Net result for the period	(46,467)	(20,617)
LIABILITIES		
Non-current liabilities	69,510	84,489
Borrowings	62,865	76,568
Deferred tax liability	89	112
Other non-current liabilities and provisions	6,556	7,810
Current liabilities	35,876	46,363
Borrowings	17,338	25,687
Trade payables and accruals	10,341	10,698
Current tax liability	417	425
Tax and employee-related liabilities	5,962	6,889
Other current liabilities and provisions	1,819	2,664
TOTAL LIABILITIES	105,386	130,852
TOTAL EQUITY AND LIABILITIES	202,962	275,187

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENT

€ in thousand	Nine months ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Profit/Loss for the period	(46,467)	(4,218) ³
Depreciation and amortization	8,431	8,524
Impairment	34,109	-
Share-based payments	1,048	445
Income tax	430	410
Other adjustments for reconciliation to cash used in operations	6,533	(7,461)
Changes in working capital	4,362	(13,318)
Cash generated from/(used in) operations	8,447	(15,618)
Income tax paid	(457)	(147)
Net cash generated from/(used in) operating activities⁴	7,990	(15,765)
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of other businesses, net of acquired cash	15,279	(22,181)
Purchases of property, plant and equipment	(1,448)	(1,474)
Proceeds from sale of property, plant and equipment	1	173
Purchases of intangible assets	(336)	(542)
Investments in associated companies	-	(1,999)
Interest received	3,200	69
Net cash generated from/(used in) investing activities	16,697	(25,954)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of costs of equity transactions	-	42,010
Disposal/(Purchase) of treasury shares	(101)	(2)
Proceeds from borrowings, net of transaction costs	1,481	14,719
Repayment of borrowings	(20,857)	(3,805)
Interest paid ⁴	(6,420)	(3,267)
Net cash generated from/(used in) financing activities	(25,897)	49,656
Net change in cash and cash equivalents	(1,210)	7,937
Cash at beginning of the period	41,907	28,857
Exchange gains/(losses) on cash	(1,048)	(178)
Cash at end of the period	39,649	36,617
Cash, cash equivalents, short-term deposits and financial assets at end of the period	40,293	37,258

³ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).

⁴ Presentation revised – see note 1

CONDENSED CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY

€ in thousand	Share capital	Share premium and other regulated reserves	Retained earnings and other reserves	Net result	Total equity
Balance as of January 1, 2015	8,453	206,707	(64,444)	(26,272)	124,444
Total comprehensive loss	-	-	(1,876)	(4,218) ⁵	(6,095)
Income appropriation	-	-	(26,272)	26,272	-
Employee share option plan					
- value of employee services	-	-	445	-	445
- exercise of share options	17	299	-	-	317
Treasury shares	-	-	(2)	-	(2)
Issuance of common stock, February 2015	2,735	42,297	-	-	45,032
Cost of equity transactions, net of tax	-	(3,338)	-	-	(3,338)
	2,752	39,258	(27,705)	22,053	36,359
Balance as of September 30, 2015	11,205	245,965	(92,149)	(4,218)	160,803
Balance as of January 1, 2016	11,205	245,965	(92,219)	(20,617)	144,335
Total comprehensive loss	-	-	(1,239)	(46,467)	(47,706)
Income appropriation	-	-	(20,617)	20,617	-
Employee share option plan					
- value of employee services	-	-	1,049	-	1,049
- exercise of share options	-	-	-	-	-
Treasury shares	-	-	(101)	-	(101)
Cost of equity transactions, net of tax	-	-	-	-	-
	-	-	(20,908)	(25,850)	(46,758)
Balance as of September 30, 2016	11,205	245,965	(113,127)	(46,467)	97,577

⁵ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).

SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT

1. Basis of preparation

This condensed consolidated interim financial report of Valneva SE (hereafter referred to as the “Group” or “Company”) for the first nine months ended September 30, 2016 has been prepared in accordance with International Financial Reporting Standards as adopted by the EU applicable to interim financial reporting (IAS 34) authorizing the presentation of selected explanatory notes. In consequence, these condensed consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2015 available in French and in English at the company’s website: www.valneva.com.

In this interim financial reporting the same accounting policies and methods of computation as in the most recent annual financial statements for the year ended December 31, 2015, have been applied.

No standards or interpretations were early adopted, if they are not mandatorily applicable in 2016.

The following standards may in future have an effect on the Groups financial statements, but are not yet applicable or adopted by the European Union:

- IFRS 9 “Financial Instruments” applicable as of January 1, 2018
- IFRS 15 “Revenue from Contracts with Customers” applicable as of January 1, 2018
- IFRS 16 “Leases” applicable as of January 1, 2019

Standards and amendments to standards published and effective as of January 1, 2016 have no effect on the financial statements of the Group.

Taking into consideration the increased importance of the group’s financing structure on the cash flow statement in the first nine months of 2016 and going forward, and to provide more relevant information, interest payments are being presented within the cash flow from financing activities instead of the cash flow from operating activities in the condensed consolidated interim cash flow statement for the first nine months of the financial year 2016. The previous year comparative period was adjusted accordingly.

The 2015 income statement amounts differ from previously released interim results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 11). Furthermore, upon the request of the French Financial Market Authority (“AMF”), the Company changed the presentation of the “gain on bargain purchase” compared to the consolidated annual financial statements for the year ended December 31, 2015 and presents such gain within “operating profit/loss”.

EBITDA, as calculated by the Company, has been removed from the face of the income statement and a detailed reconciliation of EBITDA to operating profit/(loss) is presented in note 6.

For presentation clarity, figures herein have been rounded and, where indicated, are presented in thousands of euros. However, calculations are based on exact figures. For this reason, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

The “Brexit” vote had no significant impact other than the FX rate implications on our financial statements as of September 30, 2016. Future events following the vote and their implications on our business are monitored by the management.

This interim report of Valneva SE has not been audited or reviewed.

2. Group structure

List of direct or indirect interests:

Name	Country of incorporation	Consolidation method	September 30, 2016	December 31, 2015
BliNK Biomedical SAS	FR	at equity	43.29%	48.22%
Intercell USA, Inc.	US	full	100%	100%
Vaccines Holdings Sweden AB	SE	full	100%	100%
Valneva Austria GmbH	AT	full	100%	100%
Valneva Canada Inc.	CA	full	100%	100%
Valneva Scotland Ltd.	UK	full	100%	100%
Valneva Sweden AB	SE	full	100%	100%
Valneva Toyama Japan KK	JP	full	100%	100%
Valneva UK Ltd.	UK	full	100%	100%

3. Revenues

Revenues comprise grant income, revenues from collaborations and licensing and product sales. The main part relates to product sales from commercialized vaccines as broken down in the following table:

€ in thousand	Nine months ended September 30,	
	2016	2015
JEV	39,899	25,002
DUKORAL	14,879	12,347
Third-party products	1,870	6,820
Product sales	56,648	44,169

In general, revenues have fluctuated in the past and the Company expects that they will continue to do so over different reporting periods in the future.

4. Segment reporting

The segments consist of the following:

- + “Commercialized vaccines” (marketed vaccines, currently the Group’s vaccines IXIARO[®]/JESPECT[®], DUKORAL[®], as well as Third-party products)
- + “Vaccine candidates” (proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies)
- + “Technologies and services” (services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements, including EB66[®] and IC31[®])

Income statement aggregates by segment for the nine months ended September 30, 2016:

€ in thousand	Commer- cialized vaccines	Vaccine candi- dates	Techno- logies and services	Un- allocated	Total
Revenues and grants	56,836	5,355	8,550	-	70,741
Cost of goods and services	(25,341)	-	(4,640)	-	(29,981)
Research and development expenses	(3,508)	(14,142)	(786)	(284)	(18,719)
Distribution and marketing expenses	(10,731)	-	(523)	(30)	(11,285)
General and administrative expenses	(1)	-	-	(10,402)	(10,403)
Other income and expenses, net	-	-	-	23	23
Amortization and impairment of fixed assets/intangibles	(5,012)	(34,132)	(331)	23	(39,453)
Operating profit/(loss)	12,243	(42,920)	2,270	(10,670)	(39,077)
Finance income/loss, result from investments in affiliates, and income tax	-	-	-	(7,389)	(7,389)
Income/(Loss) for the period	12,243	(42,920)	2,270	(18,059)	(46,467)

Income statement aggregates by segment for the nine months ended September 30, 2015:

€ in thousand	Commer- cialized vaccines	Vaccine candi- dates	Techno- logies and services	Un- allocated	Total
Revenues and grants	44,745	6,112	9,824	-	60,682
Cost of goods and services	(29,949)	-	(3,697)	-	(33,646)
Research and development expenses	(2,377)	(14,373)	(1,757)	(223)	(18,730)
Distribution and marketing expenses	(5,235)	(33)	(510)	(7)	(5,784)
General and administrative expenses	-	-	-	(10,205)	(10,205)
Other income and expenses, net	-	-	-	309	309
Amortization and impairment of fixed assets/intangibles	(5,029)	-	(426)	-	(5,456)
Gain on bargain purchase	-	-	-	13,183	13,183
Operating profit/(loss)	2,155	(8,294)	3,434	3,057	352
Finance income/loss, result from investments in affiliates, and income tax	-	-	-	(4,570)	(4,570)
Income/(Loss) for the period	2,155	(8,294)	3,434	(1,513)	(4,218)

5. Intangible Assets

Impairment testing

In case of triggering events, the book values of capitalized in-process research & development projects have been assessed for impairment testing purposes using the risk-adjusted discounted cash flow method. Management reviews the business performance based on in-process Research & Development projects. The recoverable amounts of these projects are determined based on value-in-use calculations.

The calculations use post tax risk-adjusted cash flow projections based on the Group's long-range business model including the Management's best estimate on probability of success of the respective projects (risk-adjustment) and a discount rate.

Triggering events have been identified for two development projects in 2016:

1) *Pseudomonas aeruginosa*

During the second quarter of the 2016, Valneva announced that the Phase II/III trial results of its *Pseudomonas aeruginosa* vaccine candidate did not confirm the all-cause mortality reduction observed in previous studies. While the trial confirmed good immunogenicity and an acceptable safety profile, all-cause mortality (primary endpoint) and overall survival (secondary endpoint) did not differ between the VLA43 treatment group and the placebo group. The Company has now discontinued the program.

Consequently the book-value of the intangible asset amounting to €34.1 million was fully impaired in June 2016 as it is highly unlikely that the asset will generate any future cash flows.

2) *Clostridium difficile*

In May 2016 GSK communicated its decision to Valneva to not exercise the opt-in rights granted to GSK through the Strategic Alliance Agreement signed in 2007. Valneva has started to identify alternative partners to finance the upcoming Phase III-studies and final market approval steps necessary to bring the asset to the market.

The existing business model has been revised resulting in a reduction of future cash-flows, however, the value-in-use still significantly exceeds the current book value of the intangible asset and therefore no adjustment has been made in our financial statements related to *C.difficile*.

The result of the acquired research & development projects is inherently uncertain and the Group may experience delays or failures in clinical trials. A failure to demonstrate safety and efficacy in clinical product development of one of the acquired research & development projects would result in an impairment loss. The net present value calculation uses a probability of success rate of 10% to 50% for acquired products in the stage of Research & Development. Applying the Industry standard for the likelihood of successfully passing clinical Phase II, Phase III or final filing stages, results in no additional impairment. Assumptions used were a 10% likelihood of failure to gain regulatory approval following a positive Phase II result (2.5% weighted risk), a 50% chance to fail in Phase III after having successfully passed Phase II (22.5% weighted risk) and a risk of 50% for failing in Phase II after successful finalization of Phase I (50% weighted risk).

The discount rate of 11.22% per annum is based on 0.49% risk-free rate, 7.00% market risk premium, 1.10% country risk premium, 0.47% currency risk, a beta of 1.49, and a peer group related equity-capital ratio.

The long range business model covers a period of 20 years and therefore accounts for all project related cash flows from the development stage over the market entry until the market phase-out (project life cycle) of the relevant projects.

Sensitivity to changes in assumptions (*C.difficile* only)

The net present value calculations are most sensitive to changes in the following assumptions:

- Discount rate
- Probability of project success
- Reduction in expected revenues / royalties

The net present value calculation uses a discount rate of 11.22%. An increase in the discount rate of 22.23% points to 33.45% would trigger an impairment loss. Furthermore, an increase in the discount rate of one percentage point would result in no additional impairment loss.

The net present value calculations are based upon assumptions regarding market size, expected sales volumes resulting in sales value expectations, or expected royalty income. A reduction in revenues or royalty income of 10% would result in no additional impairment loss. A reduction of expected revenues / royalties of 95.43% would trigger an impairment loss.

6. EBITDA

EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets as well as gains from bargain purchase ("negative goodwill") from the operating loss.

€ in thousand	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Operating profit/(loss)	(4,023)	(1,831)	(39,077)	352
Depreciation	964	1,148	3,279	3,280
Amortization	1,850	1,722	5,153	5,244
Impairment on intangibles and fixed assets	-	-	34,109	-
Gains from bargain purchase ("negative goodwill")	-	-	-	(13,183)
EBITDA	(1,209)	1,039	3,463	(4,307)

7. Financial instruments

The Company's only derivatives measured at fair market value are interest rate SWAPs with a negative fair market value of €3 thousand as of September 30, 2016.

Other financial assets and financial liabilities accounted at their carrying amount which corresponds to their approximate fair value.

8. Cash, cash equivalents and short-term deposits

Cash, cash equivalents and short-term deposits include the following:

€ in thousand	September 30, 2016	December 31, 2015
Cash at bank and in hand	39,293	38,841
Other short-term deposits	1,000	3,726
Cash, cash equivalents and short-term deposits	40,293	42,567

As of September 30, 2016, cash and cash equivalents include €644 thousand (December 31, 2015: €660 thousand) with restrictions on remittances.

9. Contingencies

In July 2016 a claim for additional payment was raised, and litigation was threatened, in connection with the 2009 acquisition of Humalys SAS (“Humalys”), by which Vivalis (now Valneva) had acquired a technology which was later combined with other antibody discovery technologies and spun off to Blink Biomedical in early 2015. Former shareholders of Humalys claimed additional consideration as a result of the spin-off transaction. Valneva believes that this claim is unsubstantiated and not likely to succeed in case of litigation. Detailed information on the potential specific financial consequences which might result from a successful claim could adversely affect Valneva’s ability to defend its interests in this case, and therefore is not provided, in accordance with IAS 37.92.

10. Business combination

On February 9, 2015, the Group completed the acquisition of Crucell Sweden AB, (subsequently renamed Valneva Sweden AB), and all assets, licenses and privileges related to DUKORAL[®], a vaccine against cholera and diarrhea caused by LT-EPEC (including a manufacturing site in Solna, Sweden) as well as a vaccine distribution business in the Nordic countries (together “Crucell Sweden”). After completion of the acquisition, Valneva holds 100% of the voting rights of the acquired company.

The acquisition was financed through a combination of debt and equity. The latter was raised through a public rights issue with final gross proceeds of €45.0 million. The debt part of the acquisition financing was raised through a loan facility put in place with Athyrium in an amount of €15.0 million, which was repaid in January 2016.

The comparative results of the 2015 income statement in this document differ from previously released quarterly results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business.

In December 2015 changes to the Canadian DUKORAL[®] product monograph that Health Canada had requested became effective. The updated product monograph and subsequent labelling may negatively impact DUKORAL[®] sales in Canada going forward. In order to reflect these business changes Valneva and the seller agreed on amendments to the purchase agreement which led to a €25 million reduction of the purchase consideration, bringing it from originally €45 million down to €20 million.

Therefore, the Company adjusted the preliminary purchase price accounting retrospectively in December 2015 in accordance with IFRS 3.45. The purchase price, intangible assets, fixed assets, inventories, and deferred taxes were adjusted accordingly. The resulting €13.2 million gain on bargain purchase related to the acquisition was retrospectively included in the income statement of Q1 2015. Adjustments to asset values also led to changes in the income statements of the subsequent quarters, in particular affecting costs of goods sold through changes in depreciation and amortization relating to the re-valued assets.

The final allocation of the purchase price was presented in the consolidated annual financial statements for the year ended December 31, 2015.

The cash consideration paid, net of cash acquired through the acquisition includes the final payment from J&J of €15 million in January 2016 due to the label-change in Canada and is as follows:

€ in thousand	
Cash consideration paid	35,000
Cash and cash equivalents in acquired business	(2,795)
Payments received from J&J (WC adjustment, label-change Canada, other liabilities)	(25,303)
Cash outflow through acquisition	6,902

11. Events after the reporting period

No events that are expected to have a material effect on the financial statements occurred after the reporting period until November 9, 2016.

Translation disclaimer: This is a free translation into English of the original French language version of the interim financial report provided solely for the convenience of English speaking. While all possible care has been taken to ensure that this translation is an accurate representation of the original French document, this English version has not been audited by the company's statutory auditors and in all matters of interpretation of information, views or opinions expressed therein, only the original language version of the document in French is legally binding. As such, the translation may not be relied upon to sustain any legal claim, nor be used as the basis of any legal opinion and the VALNEVA expressly disclaims all liability for any inaccuracy herein.