

Valneva Announces FY 2015 Results and Confirms Positive Trend towards Strong Revenue Growth and EBITDA Break-even in 2016

Solid financial performance in FY 2015 despite integration of Swedish activities and IXIARO[®] transition

- + Total revenues and grants of €83.3 million in 2015 (vs. €42.4 million in 2014) representing a 96.4% year-on-year increase
- + FY 2015 EBITDA loss of €8.5 million (vs. €7.4 million loss in 2014) driven by R&D spending in new vaccine candidates
- + Profitable Commercial Products and Technology segments generated €13.1 million operating profit before amortization of intangible assets
- + Net loss of €20.6 million in FY2015, an improvement of 21.5% vs. the €26.3 million reported in 2014, driven mainly by acquisition effects
- + €42.6 million cash position at year-end 2015

2016 Outlook

- + Valneva expects 2016 overall IFRS revenues to reach €90 to €100 million with product sales in the expected range of €70 to €80 million, reflecting up to 30% growth over 2015 product sales. More than 60% of the 2016 anticipated product sales are expected to be generated by the Company's own commercial teams.
- + The Company anticipates continued growth of IXIARO[®]/JESPECT[®] sales to approximately €50 million in 2016, up from €30.6 million in 2015.
- + 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 2016 while continuing to invest around €25 million in R&D.

Long-term Strategy

- + Valneva envisions growing its revenues to approximately €250m in 2020 through existing and future products, while generating positive cumulative cash-flows at that time.
- + The Company will continue to build on value growth from R&D and anticipates investing at least 20% of its revenues annually in an innovative R&D pipeline with at least one clinical candidate at the different stages of product development.
- + Valneva expect to execute on this strategy by a combination of organic growth and product development complemented by opportunistic M&A strategies focused on revenue-generating assets.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented, "Since the creation of Valneva in 2013 we have focused on shaping the company according to our strategic vision, by investing in new commercial products, divesting non-core activities, bringing clinical candidates to new inflection points and launching our own commercial network, in order to build a business that would generate strong revenues and be financially sustainable. We are proud to say that we feel we are very close to achieve that goal in 2016 while still investing around €25 million in R&D. This year



will be marked by two very important milestones in our clinical portfolio, namely the Phase II/III results of our Pseudomonas aeruginosa vaccine candidate and a potential partnership agreement for our Clostridium difficile vaccine candidate, which is now ready to enter phase III. We are also looking forward to our Lyme disease vaccine candidate entering clinical development in the second half of the year and are very much excited by our preclinical programs focusing on much-needed vaccines against Zika, Chikungunya, Yellow fever and human Metapneumovirus (hMPV)."

| EUR in thousands | 3 months ended Dec 31, | | 12 months ended Dec 31, | | |
|--|------------------------|----------|-------------------------|----------|-----------------------------------|
| | 2015 | 2014 | 2015 | 2014 | 2015 pro forma ¹ |
| Revenues & grants | 22,652 | 13,113 | 83,335 | 42,429 | 89,235 |
| Net profit / loss | (16,398) | (11,520) | (20,617) | (26,272) | (19,341) |
| EBITDA | (4,185) | (3,754) | (8,492) | (7,364) | - |
| Net operating cashflow | (5,302) | (7,846) | (24,334) | (14,944) | - |
| Cash, short-term deposits and marketable securities, end of period | 42,567 | 29,468 | 42,567 | 29,468 | 42,567 |

Key Financial Information

Lyon (France), March 21, 2016 – Valneva SE ("Valneva" or "the Company"), a leading pure play vaccine company, reported today its audited full year financial results for the period ended December 31, 2015. The full consolidated financial statements 2015 are available on the Company's website www.valneva.com.

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00pm (CET). A replay will be available on the Company's website. Please refer to this link: <u>http://edge.media-server.com/m/p/wodumxcc</u>

FY 2015 Business Highlights

Valneva's business year 2015 was marked by major strategic steps to further build a leading independent vaccine company.

The Company acquired and successfully integrated DUKORAL[®], a vaccine for immunization against Cholera, also indicated in some countries for the prevention of diarrhea caused by LT-ETEC (Enterotoxigenic *Escherichia coli*). With this second and well-established traveler vaccine, Valneva has built the foundation for a portfolio and a critical mass in traveler's vaccines.

In 2015, Valneva also made the important strategic decision to build its own commercial network and to terminate the IXIARO[®]-related marketing & distribution agreement with

¹ including acquired business from Jan 1, 2015 onward



GlaxoSmithKline (GSK). The Company now has its own dedicated sales & marketing organizations with offices in the US, Canada, UK and Sweden. To complement its own commercial sales infrastructure and insure broad geographic availability of its products, Valneva entered into a number of country-specific marketing and distribution agreements with leading local distribution partners including VaxServe, Inc., a Sanofi Pasteur company (US private market) and GSK (Germany / Austria).

Commercialized vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO[®]/JESPECT[®]) Strong in-market sales despite transition – significant growth ahead

In 2015, IXIARO[®]/JESPECT[®] product sales increased to €30.6 million compared to €28.1 million in 2014, representing 8.8% year-on-year growth. IXIARO[®]/JESPECT[®] recent sales performance exceeded the Company's expectations which had been lowered in June 2015 following the decision to establish a new marketing and distribution network for the vaccine. The anticipated temporary reduction in sales due to the transition impact did not materialize owing to a very collaborative and professional collaboration with the previous global distribution partner GSK and substantial in-market sales growth in 2015. Valneva estimates that IXIARO[®]/JESPECT[®] product will grow to approximately €50 million in 2016 as a result of the new commercialization strategy and a continued increase in adoption by travelers. On March 16, 2016, the Company announced the signing of a new \$42 million supply contract with the US Government for its Japanese encephalitis (JE) vaccine IXIARO[®] to protect the almost 360,000 U.S. military and civilian personnel, and their families, working and living in countries where JE is endemic since 2010.

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL[®]) Solid 2015 sales performance

Valneva's 2015 DUKORAL[®] product sales, which were included from the acquisition date on February 10, 2015, reached €21.0 million. The product, which is highly complementary to Valneva's first marketed product, was added through the acquisition of Crucell Sweden AB in February 2015. DUKORAL[®] pro forma 2015 product revenues, for the entire 12 month period, were €26.3 million, representing 2.8% growth over 2014 pro forma sales of €25.6 million under the previous owner. By achieving sales growth, despite the integration and transition impact, DUKORAL[®] confirmed Valneva's expectations in its potential and strategic value. Valneva will continue to invest in growing the DUKORAL[®] vaccine by way of promotional efforts and geographic expansion and to leverage its strategic value for the Group.

An update on the Dukoral[®] product monograph and the associated labeling in Canada resulted in a \in 25 million reduction of the purchase consideration agreed with the seller. \in 15 million of this was used to fully repay an acquisition loan granted by Athyrium Capital Management LLC. Both the purchase price reduction payment and the loan repayment became effective in the first quarter of 2016.



Technologies and services

EB66[®] CELL LINE Additional licensing agreements expected in 2016

Valneva's EB66[®] cell line is a highly efficient platform for vaccine production. It is derived from duck embryonic stem cells and today represents a compelling alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines.

Valneva recently announced the signing of a new R&D collaboration agreement with GSK for the development of EB66[®]-based influenza vaccines. Under the new agreement, Valneva secured additional research fees in addition to the potential milestone payments and royalties that were included in the 2007 agreement signed with GSK, granting the UK company an exclusive license for the development of EB66[®]-based pandemic and seasonal flu vaccines. GSK is developing its EB66[®]-based influenza vaccines in the US in partnership with the Texas A&M University System.

In 2015, Valneva signed 10 new agreements (5 research agreements and 5 commercial agreements) on its EB66[®] platform including an exclusive agreement with Jianshun Biosciences Ltd (JSB) to commercialize the EB66[®] cell line in People's Republic of China. Under the JSB agreement, Valneva received a €2.5 million upfront payment and is entitled to further annual license fees and royalties.

To date, the Company has more than 35 research and commercial agreements with the world's largest pharmaceutical companies (GSK, Sanofi-Pasteur, Zoetis, etc) to license its EB66[®] technology. Valneva expects to announce additional EB66[®] agreements in 2016.

IC31[®] ADJUVANT / IC31[®] TUBERCULOSIS VACCINE New licensing agreements expected in 2016

Valneva's IC31[®] adjuvant is a synthetic vaccine adjuvant targeting antigens to improve immune response. Valneva has granted multiple IC31[®] licenses to leading pharmaceutical companies including GSK, Statens Serum Institut, Aeras or Sanofi Pasteur.

In the field of tuberculosis, three clinical vaccine candidates formulated with Valneva's IC31[®] adjuvant are currently in Phase I and II clinical trials. The Statens Serum Institut's novel tuberculosis vaccine candidate H1/IC31 has shown good safety and immunogenicity in a Phase II clinical trial in HIV-infected adults².

At the beginning of 2015, Valneva announced the signing of an exclusive worldwide commercial license agreement with Immune Targeting Systems, subsequently acquired by Vaxin Inc. (now called Altimmune), granting the Company the rights to develop and commercialize Hepatitis B vaccine candidates in combination with Valneva's IC31[®] adjuvant. In July 2015, Altimmune announced that it had enrolled the first patient into a phase I clinical trial of HepTcell[™], its immunotherapeutic candidate to treat chronic hepatitis B (HBV) infection. The multicenter trial is being conducted at seven sites within the U.K. with the aim of recruiting 72 patients with chronic HBV infection.

Valneva expects to announce new IC31[®] licensing agreements in 2016.

² Reither et al. 2014. PLoS One 9:e114602



Clinical vaccine candidates

PSEUDOMONAS AERUGINOSA VACCINE CANDIDATE- VLA 43 Data from Phase II/III trial expected in the second quarter of 2016

Pseudomonas areuginosa is a highly-resistant bacterium responsible for approximately 51,000³ healthcare-associated infections annually, which carries an economic burden exceeding \$614 million. Currently, there are no approved prophylactic vaccines, and Valneva's Pseudomonas vaccines candidate VLA43 is the only one in clinical development right now. The Company estimates that the total market potential for the product could be significant.

Valneva has completed enrolment of its Phase II/III efficacy trial with 800 ventilated intensive care unit patients recruited across approximately 50 study sites. Valneva expects to release data, including day 180 follow-up time-points, in the second quarter of 2016.

The data will determine potential next clinical development steps and respective routes to first licensure. Based on the program's Phase II data and the interim analysis for the current Phase II/III confirmatory efficacy trial, there are various outcomes that would be considered successful. If the Phase II/III primary endpoint (reduction of all-cause mortality on Day 28) is met, the trial can be used as a pivotal efficacy trial in support of licensure. If the primary endpoint is not met (e.g. not enough conditional power) but a trend towards a clinically meaningful vaccine effect (observed in all prior analysis) is confirmed, the trial will provide a solid basis for a Phase III pivotal efficacy trial, the details of which will be determined upon data discussion and consultation with the authorities.

The development of Valneva's vaccine candidate against *Pseudomonas aeruginosa* is part of the strategic alliance agreement signed between Valneva and Novartis in 2007, which transitioned to GSK in 2015. The current trial is co-financed by GSK.

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE- VLA 84 Licensing agreement expected by end of 2016

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 annually⁴. 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 USD 1 billion annually.

At the end of 2015, Valneva reported positive topline data from its Phase II trial evaluating VLA84 as a prophylactic vaccine for the primary prevention of *Clostridium Difficile* infections (CDI). The key objectives of this Phase II trial have been met, the vaccine candidate generated strong immune responses against *C. difficile* toxins A and B, and the safety and tolerability profile was good. The study met its primary endpoint in terms of identifying the

³ Antibiotics resistance threat in the United States, 2013; <u>http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf</u>

⁴ Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34.

dose/formulation with the highest seroconversion rates against both Toxin A and B on Day 56, the 200 µg without Alum dose, in both age groups.

Immune response and safety parameters in this trial will be monitored until Day 210 and final study close-out is expected mid-2016. The study design was agreed with regulators in Europe and the U.S. with the aim of potentially supporting a subsequent progression into Phase III. Therefore, Valneva considers this program to be Phase III ready.

GSK has opt-in rights to the program following Phase II completion which can be exercised following the study close-out. Valneva is holding discussions with other potential partners for the Phase III financing in case GSK chooses not to pursue the program.

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 humans⁵.

Valneva expects to commence a Phase I trial in 2016. The single-blind, partially randomized, dose escalation Phase I study trial will be conducted in the U.S. 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.

Pre-clinical vaccine candidates

Beyond its clinical stage product candidates, Valneva is also working on a range of preclinical development stage vaccine candidates as well as early stage vaccine research programs.

Valneva has prioritized pre-clinical candidates which are technologically and scientifically complementary to the company's strong viral vaccines development competence gathered through the bench-to market development of the Japanese Encephalitis Vaccine (JEV) as well as its commercial traveler's vaccines portfolio. Earlier stage research candidates target different areas of high medical need including human Metapneumovirus (hMPV) or, as most recently announced, Zika.

Valneva's most advanced pre-clinical project focuses on chikungunya. The virus (CHIKV) reemerged from East Africa in 2014 to cause devastating epidemics of debilitating and often chronic arthralgia that have affected millions of people in the Indian Ocean Basin and Asia. There is currently no antiviral treatment for CHIKV infection and no licensed vaccine to prevent the disease. Valneva is working on a live attenuated vaccine candidate and expects to enter Phase I clinical development in 2017.

⁵ http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294



Valneva's research teams are also working on the development of a second-generation vaccine candidate against yellow fever. Although a live attenuated vaccine has been used to prevent yellow fever for more than 70 years, frequent supply problems and potential adverse reactions underline the necessity of a new, modern and well tolerated yellow fever vaccine.

Valneva recently announced that it is evaluating the development of a Zika vaccine and has already launched a pre-clinical proof of concept program. The Zika virus is related to the Japanese encephalitis virus, also an arthropod-borne flavivirus transmitted through mosquito bites, against which Valneva has already successfully developed a vaccine (IXIARO[®]/JESPECT[®]), using a technology platform that could accelerate the quest for a Zika vaccine. The World Health Organization (WHO) has declared Zika an international health emergency and estimates that as many as 4 million people could be affected by the virus as it spreads from Latin America and the Caribbean to North America in the coming months. There is no specific treatment or vaccine currently available against the disease. Valneva has already initiated discussions with WHO, BARDA and WRAIR to potentially join forces in the acceleration of the development of a Zika vaccine.

Besides much-needed new travel vaccine candidates, Valneva is also targeting one of the most significant and common human viral infections, Human metapneumovirus (HMPV). Although the virus was primarily known as causative agent of respiratory tract infections in children, HMPV has become an important cause of respiratory infections in adults as well. To date, no vaccine is available and treatment is supportive.

Valneva expects that its research programs will lead to the development of novel vaccine candidates and form part of its clinical portfolio in the coming years.

Financial Review

FULL YEAR 2015 FINANCIAL REVIEW

Revenues and grants

Valneva's aggregate revenues and grants increased to €83.3 million in the full year 2015 from €42.4 million in the year 2014. This increase was mainly a result of the acquisition of the Crucell Sweden's business whose overall revenue contribution amounted to €36.4 million. IXIARO[®]/JESPECT[®] product sales contributed €30.6 million to revenues in 2015, representing an 8.8% increase over the 2014 product sales of €28.1 million. This increase was recorded despite the transition towards a newly established global marketing and distribution network following Valneva's termination of the marketing and distribution partnership with GSK in June 2015. DUKORAL[®] product sales contributed €21.0 million and third party product distribution contributed €9.9 million to the full year 2015 product sales.

Revenues from collaborations and licensing increased to €16.8 million in 2015 from €8.8 million in 2014. Acquisition effects from the Crucell Sweden business amounted to €5.5 million, primarily related to R&D services provided to Johnson & Johnson. Excluding acquired revenues, revenues from collaborations and licenses grew to €11.3 million in 2015 from €8.8 million in 2014. They mainly benefited from additional licensing agreements and milestone payments received for the EB66[®] platform as well as co-development revenues for the Pseudomonas project from partner GSK.



Grant income amounted to \in 5.0 million in 2015 representing a reduction of \in 0.5 million compared to 2014.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €47.0 million in 2015 of which €16.4 million related to IXIARO[®] sales, yielding a product gross margin of 46.4%. €18.2 million of COGS related to DUKORAL[®] sales, yielding a gross margin for the acquired DUKORAL[®] business of 13.3%, which was negatively impacted by idle capacity costs during a manufacturing transition period in 2015 and by acquisition accounting effects (cost of sales of acquired product inventory recorded at fair market value as opposed to the lower historical manufacturing cost). Of the remaining 2015 COGS, €7.3 million related to the Third Party product distribution business and €5.0 million related to cost of services. In the comparable period of 2014, COGS were €17.1 million, of which €15.6 million related to IXIARO[®] and €1.6 million to cost of services.

Research and development (R&D) expenses in 2015 reached €25.4 million compared to €22.2 million in the previous year. This increase was mainly due to clinical study costs, especially for the phase II study of Valneva's Clostridium difficile vaccine candidate and for the phase II/III study of Valneva's Pseudomonas vaccine candidate.

Distribution and marketing expenses in 2015 amounted to €9.1 million, compared to €2.1 million in 2014. The newly acquired ex-Crucell business contributed an additional €6.3 million of distribution and marketing expenses in 2015. Furthermore distribution and marketing costs increased as a result of the transition towards Valneva's own sales and marketing organization after termination of the global distribution partnership with GSK in June 2015.

General and administrative (G&A) expenses in 2015 amounted to €14.4 million, compared to €12.1 million in 2014. This increase was due to €2.9 million additional G&A costs from the newly acquired ex-Crucell business, which were partly offset by lower G&A expenses of the original business.

Amortization and impairment expenses for intangible assets decreased to €7.3 million in 2015 from €12.3 million in 2014, which included €4.1 million impairment for the VivalScreen[®] technology.

Valneva's operating loss decreased by \in 3.9 million, or by 16.3%, to \in 19.9 million in 2015 compared to \in 23.8 million in 2014.

Valneva's EBITDA loss was €8.5 million in 2015, compared to a €7.4 million loss in 2014. EBITDA for 2015 was calculated by excluding depreciation, amortization and impairment amounting to €11.4 million from the operating loss amounting to €19.9 million as recorded in the condensed consolidated income statement under IFRS.

Segment overview

The Commercialized Vaccines segment showed an operating profit of \in 1.7 million in 2015, compared to an operating profit of \in 1.1 million in 2014. Excluding amortization expenses for acquired intangible assets, the profit of that segment was \in 8.4 million in 2015 and \in 7.8 million in 2014.



The Technologies and Services segment showed an operating profit of \notin 4.1 million in 2015 compared to \notin 7.3 million operating loss in 2014. Excluding amortization and impairment, the profit of the Technologies and Services segment amounted to an operating profit of \notin 4.6 million in 2015 and recorded an operating loss of \notin 1.6 million in 2014.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €11.2 million in 2015 compared to €5.2 million in 2014.

Net result

Valneva's net loss in 2015 was €20.6 million compared to a net of €26.3 million in the prior year, an improvement of €5.7 million, or 21.5%. Net finance expenses were €4.6 million in 2015 and €2.1 million in 2014. The increase in net finance expenses mainly resulted from an increase in interest expenses due to a higher level of debt. The 2015 net result also includes a loss from investments in affiliates of €9.0 million related to Valneva's 48.2% shareholding in BliNK Biomedical SAS. The investment in this spin-off company, which mainly consisted in the contribution of Valneva's antibody technology, was fully impaired at the end of 2015.

The 2015 net result was positively impacted by a \in 13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of the ex-Crucell business including DUKORAL[®] and the vaccine distribution business in the Nordics. The gain resulted from an adjustment to the initial purchase accounting in December 2015 after Health Canada had requested changes to the DUKORAL[®] product monograph. In order to reflect the business changes resulting from the DUKORAL[®] label change in Canada, Valneva and the seller agreed on amendments to the purchase agreement which led to a \in 25 million reduction of the purchase consideration, bringing it from originally \in 45 million down to \in 20 million. Following a re-assessment of the valuation of the acquired assets, their fair value exceeded the total net purchase consideration by the amount of \in 13.2 million ("negative goodwill") which was retrospectively recognized in the first quarter of 2015 as gain on bargain purchase.

An unaudited quarterly breakdown of the audited full year 2015 financial results (as will be used for prior year comparators in 2016 interim financial reports) is available on the Company's website www.valneva.com. These quarterly results differ from previously released results due to the retrospective adjustments to the purchase accounting for the ex-Crucell acquisition in the first quarter of 2015.

Cash flow and liquidity

Net cash used in operating activities in 2015 amounted to €24.3 million (compared to €14.9 million in 2014) and resulted primarily from the operating loss in connection with the Group's R&D activities, from an increase in working capital and from an increase in interest payments.

Cash out-flows from investing activities amounted to €26.6 million in 2015 and resulted primarily from the acquisition of Crucell Sweden AB and all assets, licenses and privileges related to DUKORAL[®] as well as a vaccine distribution business in the Nordics, net of cash, and from investments in associated companies.

Cash inflows from financing activities in 2015 amounted to €64.2 million and primarily included net proceeds from a capital increase of €42.0 million (after deduction of transaction



costs of €3.3 million) in February 2015 and net proceeds of new borrowings amounting to €26.5 million.

Liquid funds stood at \in 42.6 million on December 31, 2015, compared to \in 29.5 million on December 31, 2014 and consisted of \in 38.2 million in cash and cash equivalents, \in 3.7 million in short-term bank deposits and \in 0.7 million in restricted cash.

FOURTH QUARTER 2015 FINANCIAL REVIEW (non-audited)

Revenues and grants

Valneva's fourth-quarter 2015 revenues and grants increased by $\in 9.5$ million to $\in 22.7$ million compared to $\in 13.1$ million in the same period of the previous year. The increase was mainly driven by a $\in 13.2$ million contribution in revenues by the acquired ex-Crucell operations. Acquired revenues offset a decrease in IXIARO[®] fourth quarter product sales which was due to temporary effects from the transition to Valneva's new commercialization structure and is expected to be fully offset in 2016.

Fourth quarter 2015 product sales amounted to \in 17.4 million compared to \in 8.8 million in the same quarter of 2014. IXIARO[®]/JESPECT[®] revenues in the fourth quarter of 2015 were \in 5.9 million, representing a decrease by \in 3.0 million compared to the same period last year. DUKORAL[®] product sales were \in 8.7 million and product sales of third party products contributed \in 2.8 million to fourth quarter sales of 2015.

Revenues from collaborations, licensing and services increased to \in 3.6 million in the fourth quarter of 2015 from \in 2.7 million in the fourth quarter of 2014. Service fees generated by the ex-Crucell business contributed \in 1.7 million to this increase. Grant income slightly increased to \in 1.7 million in the fourth quarter of 2015 from \in 1.6 million in the fourth quarter of 2014.

Operating result and EBITDA

Cost of goods and services sold in the fourth quarter of 2015 amounted to €13.3 million, of which €12.0 million were related to cost of goods and €1.3 million to cost of services. In the fourth quarter of 2014, cost of goods and services were €7.0 million (€6.7 million related to cost of goods and €0.3 million to cost of services).

Research and development expenses in the fourth quarter of 2015 were \in 6.6 million compared to \in 7.0 million in the fourth quarter of 2014.

Distribution and marketing expenses in the fourth quarter of 2015 were \in 3.3 million compared to \in 0.6 million for the same period of 2014. The increase was mainly a result of the integration of the ex-Crucell business adding \in 2.2 million of distribution and marketing expenses in the fourth quarter of 2015.

General and Administrative (G&A) expenses in the fourth quarter of 2015 were \in 4.2 million compared to \in 3.4 million in the fourth quarter of 2014.

Non-cash amortization and impairment expenses for intangible assets were \in 1.8 million in the fourth quarter of 2015 compared to \in 4.9 million in the fourth quarter of 2014, which included \in 2.8 million impairment for the VivalScreen[®] technology.



Valneva's operating loss in the fourth quarter of 2015 was €7.1 million, compared with a €9.9 million loss in the fourth quarter of 2014. Of the operating loss in the fourth quarter, €2.3 million related to the acquired DUKORAL[®] and the Nordics Third Party vaccine distribution business. In the fourth quarter of 2015, Valneva showed a negative EBITDA of €4.2 million compared to a negative EBITDA of €3.8 million in the fourth quarter of 2014.

Net result

Valneva's net loss in the fourth quarter of 2015 was \in 16.4 million compared to \in 11.5 million for the same period of the previous year. The net result of the fourth quarter of 2015 included \in 8.4 million non-cash charges related to Valneva's 48.2% shareholding in BliNK which was fully impaired during the reporting period.

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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: one for the prevention of Japanese Encephalitis (IXIARO[®]/JESPECT[®]) and the second (DUKORAL[®]) indicated for the prevention of Cholera and, in some countries, prevention of diarrhea caused by LT-ETEC (Enterotoxigenic Escherichia coli). The Company has proprietary vaccines in development including candidates against *Pseudomonas aeruginosa, 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 approximately 400 employees. More information is available at <u>www.valneva.com</u>.

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 forwardlooking 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 forwardlooking 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.