

Valneva Reports Annual Results 2014

The company announces a significant improvement to its EBITDA and a strong reduction of its net loss compared to prior-year pro forma result

- Significant progress on building a financially sustainable business, EBITDA improvement of 63.9%, Net loss improvement of 32.5% compared to 2013 on pro forma basis
- 2014 Revenues through marketed products of EUR 28.1 million expected to be substantially increased in 2015 by acquired second commercialized vaccine Dukoral[®]
- Valneva's key phase II and II/III clinical programs are proceeding towards important value inflection points towards the end of 2015
- Active progression on licensing activity for vaccines produced in EB66[®] underpinned by recent announcements

Lyon (France), March 20, 2015 – Valneva SE (“Valneva”), a leading pure-play vaccines biotech company, today published its audited full year financial results for the period ended December 31, 2014 (as reviewed by the Supervisory Board on March 19, 2015), a summary of its operational achievements in 2014 and its 2015 business outlook. The full consolidated financial statements 2014 are available on the Company's website www.valneva.com.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented, “2014 was a successful year for Valneva on its way to further building a leading pure-play vaccines biotech company according to our strategy to seek financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability. We are looking forward to an exciting year 2015 with increased revenues and upcoming important data points in our clinical programs.”

Outlook

- The Company expects its 2015 revenues to be significantly increased to between approximately EUR 75 and 85 million by its recent acquisition of the Dukoral[®] vaccine including a Nordic vaccine sales infrastructure and by revenue growth in its historical activities (revenue includes Dukoral[®] product sales by the seller's group entities under transitional service agreement)
- Revenues of IXIARO[®] product sales are expected to grow to approximately EUR 30 million



- Valneva expects to continue to strive towards break-even following the transitional period of 2015 and the integration of the recently acquired business (2015 results may be significantly impacted by non-cash effects from acquisition accounting)
- Within the next twelve months, Valneva expects important clinical results from its *Pseudomonas aeruginosa* vaccine phase II/III and its *Clostridium difficile* vaccine phase II studies which both have the potential to transform the value of the Company

Key Financial Information

(audited)

EUR in thousands	3 months ended Dec 31,		12 months ended Dec. 31,		
	2014	2013	2014	2013	2013 pro forma
Revenues & Grants	13,113	11,640	42,429	35,991	43,684
Net profit/(loss)	(11,520)	(6,028)	(26,272)	(24,110)	(38,902)
EBITDA	(3,754)	(1,273)	(7,364)	(11,709)	(20,402)
Net operating cash flow	(7,846)	1,130	(14,944)	(20,903)	n/a
Cash, short-term deposits and marketable securities, end of period	29,468	40,167	29,468	40,167	40,167

Financial Review

Note: As a result of the merger between Vivalis SA and Intercell AG, Intercell's business has been included in the Group's consolidated financial statements from the merger closing date May 28, 2013. Therefore, the 2014 and 2013 IFRS results are not fully comparable as the ex-Intercell operations were only included for the period 2013 starting from June 2013. Pro-forma figures including the Intercell business for the 2013 period and excluding one-time effects due to the merger were prepared for illustrative purposes only. For detailed explanation of pro-forma assumptions and reconciliation to IFRS results, please refer to note 32 of the Consolidated Financial Statements 2014 (www.valneva.com).

+ Revenues and grants

Valneva's aggregate revenues and grants increased from EUR 36.0 million in the year 2013 to EUR 42.4 million in the year 2014. Compared to the previous year on a pro forma basis (combining Intercell's revenues and grants in the first five months of 2013 with Valneva's revenues and grants since June) revenues and grants slightly decreased from EUR 43.7 million in 2013 to EUR 42.4 million in 2014. This decrease was mainly due to a decrease in revenues from collaborations and licensing.

IXIARO[®]/JESPECT[®] product sales contributed EUR 28.1 million to revenues in 2014. On a pro-forma basis full year 2013 product sales were EUR 27.2 million representing an increase of 3.4% in 2014 despite the transition in the U.S. military sales responsibility to

Novartis from late 2013 onward which resulted in Valneva now recognizing only two thirds of the total sales revenue to the U.S. military instead of 100% previously.

Revenues from collaborations and licensing increased from EUR 7.2 million in 2013 to EUR 8.8 million in 2014. On pro forma basis revenues from collaborations and licensing decreased from EUR 10.8 million in 2013 to EUR 8.8 million in the full year 2014 due to a decrease in revenues from EB66[®] cell line technology from EUR 3.7 million in the year 2013 to EUR 2.3 million in the year 2014 and a decrease in revenues from the VivalScreen[®] antibody platform from EUR 2.9 million in the year 2013 to EUR 1.7 million in the year 2014.

Grant income amounted to EUR 5.5 million in 2014 and was flat compared to 2013. On a pro forma basis grant income was EUR 5.7 million in the year 2013.

+ Operating result and EBITDA

The operating loss increased from EUR 20.9 million in 2013 to EUR 23.8 million in 2014. On a pro forma basis, the operating loss decreased by EUR 8.7 million, or 26.8%, from EUR 32.5 million in the year 2013 to EUR 23.8 million in the year 2014. This decrease was mainly due to cost synergies and prioritization of R&D activities in connection with the merger, including savings as a result of the disposal of the CMO business in the fourth quarter 2013.

Cost of goods and services increased by EUR 0.6 million from EUR 16.5 million in the year ended 2013 to EUR 17.1 million in the year 2014. The gross margin on the Japanese Encephalitis product improved from 29.0% in 2013 to 44.7% in the full year 2014. On a pro forma basis cost of goods and services decreased by EUR 2.9 million from EUR 20.0 million in the full year 2013 to EUR 17.1 million in the year 2014.

Research and Development expenses ("R&D") increased by EUR 0.8 million from EUR 21.4 million in the year ended 2013 to EUR 22.2 million in the year 2014. On a pro forma basis R&D expenses decreased by EUR 8.5 million. This decrease resulted from R&D pipeline prioritization and cost synergies, implemented as part of the merger integration, as well as timing effects in connection with clinical trial costs and savings as a result of the disposal of the CMO business in the fourth quarter 2013.

General, selling and administrative expenses ("SG&A") decreased slightly from EUR 14.7 million in the year 2013 to EUR 14.1 million in the year 2014. On a pro forma basis SG&A expenses decreased by 32.0% from EUR 20.8 million in the year 2013. The transition of the U.S. military sales responsibility to Novartis contributed significantly to the reduction of selling expenses in 2014 in comparison to 2013.

Amortization and impairment charges increased by EUR 7.0 million from EUR 5.4 million in the year 2013 to EUR 12.3 million in the year 2014. In 2014 an impairment charge of EUR 4.1 million in connection with the antibody business was recognized as the Company decided to change the strategy on the antibody business.

Valneva's EBITDA improved to minus EUR 7.4 million in the year 2014 from minus EUR 11.7 million in year 2013. On a pro-forma basis, the 2014 EBITDA improvement was 63.9% compared minus EUR 20.4 million in the same period of the previous year. EBITDA was calculated by excluding depreciation, amortization and impairment from the operating loss recorded in the condensed consolidated income statement under IFRS.

+ Net result

Valneva's net loss in the year 2014 was EUR 26.3 million compared to EUR 24.1 million for the same period of the previous year. On a pro-forma basis, the net loss decreased by 32.5% to EUR 26.3 million in the year 2014 from EUR 38.9 million in year 2013. The decrease reflects the progress made in both, the merger consolidation and the cost saving projects.

+ Cash flow and liquidity

Net cash used in operating activities decreased by EUR 6.0 million from EUR 20.9 million in the year 2013 to EUR 14.9 million in the year 2014. This decrease reflects the financial progress in cash-flow relevant operating expenses, whereas non-cash expenses such as depreciation, amortization and impairment charges have increased.

The purchases of intangible assets and property, plant and equipment (net of proceeds from sale of such assets) amounted to EUR 2.0 million in the year 2014 and to EUR 0.1 million in the year 2013.

Cash in-flows from financing activities were EUR 5.3 million in the year 2014 and EUR 34.7 million in the year 2013. In the year 2014, net cash generated from financing activities resulted primarily from a capital increase through the Company's equity line, which was partially offset by repayments of borrowings. In the year 2013, net cash generated from financing activities resulted primarily from the net proceeds of a capital increase completed in July 2013.

+ Cash position at year-end

Liquid funds at December 31, 2014 stood at EUR 29.5 million compared to EUR 40.2 million at the end of December 2013 and consisted of EUR 28.9 million cash and EUR 0.6 million restricted cash.

Business Highlights

CORPORATE NEWS

+ Valneva becomes a leading pure-play vaccines biotech company through the Dukoral[®] Vaccine acquisition and the creation of BliNK Biomedical

In February 2015, the Company completed the acquisition of Crucell Sweden AB, including the Nordics vaccine distribution business and all assets, licenses and privileges

related to Dukoral[®], a vaccine against cholera and traveler's diarrhea caused by ETEC. The acquisition included the purchase of a manufacturing site in Solna (Sweden). The acquired business generated revenues of EUR 37.9 million in 2013 and EUR 36.4 million in 2014 from the sales of the Dukoral[®] vaccine and the distribution of several other vaccines for third parties.

In January 2015, Valneva and British company BliNK Therapeutics Ltd created a private company, Blink Biomedical SAS, specialized in the discovery of innovative monoclonal antibodies. Valneva contributed its VIVA|Screen[®] antibody technology to the new business. This step allows Valneva to concentrate on vaccines research, development and commercialization, while continuing to benefit from its VIVA|Screen[®] antibody technology through the new company.

+ GSK becomes Valneva's key strategic partner in vaccines by completing its acquisition of Novartis' vaccine business

On March 2, 2015 GlaxoSmithKline (GSK) and Novartis announced that their three-part transaction which includes the acquisition of Novartis' global vaccines business (excluding influenza vaccines) has been completed. Valneva's partnership with Novartis on the distribution of IXIARO[®], the programs under its Strategic Alliance Agreement with Novartis, including Valneva's late stage Pseudomonas and C. difficile vaccines, and Novartis' shareholding in Valneva of approximately 3.0 million ordinary shares and 2.7 million preferred shares have now transitioned to GSK. The Company has entered into a detailed dialogue with GSK regarding the various aspects of its new strategic relationship.

MARKETED PRODUCT

+ IXIARO[®]/JESPECT[®]

IXIARO[®]/JESPECT[®] product sales were EUR 28.1 million in 2014 compared to EUR 27.2 million pro-forma product sales in 2013, representing a 3.4% year-on-year growth, mainly driven by growth in the travel markets and supplies to the U.S. military. Sales also benefited from favorable currency exchange rates.

After adjusting for the change in revenue recognition resulting from the transition of the U.S. military sales responsibility to Novartis, 2014 product sales represented a 14.0% year-on-year growth compared to 2013 pro-forma product sales. The transition of the U.S. military sales responsibility to Novartis resulted in Valneva now recognizing only two thirds of the total sales revenue to the U.S. military instead of 100% previously.

In April 2014, Valneva granted vaccine manufacturer Adimmune Corporation rights to register and commercialize its JE vaccine under a local trade name in Taiwan. Under the terms of the agreement, Valneva will supply intermediate-stage bulk product while Adimmune will be responsible for final release and commercialization of the product.

In the past year Valneva also recorded the first revenues from royalties on Biological E.'s sales of Japanese encephalitis vaccines (JEV) in India under the trade name JEEV. Valneva expects the royalties on Biological E.'s sales to increase progressively, especially as the vaccine has been prequalified by the World Health Organization (WHO) – a key step for distribution of the vaccine in developing countries.

The Company anticipates its strong disease awareness and promotional efforts to lead to continued double-digit in-market sales growth and revenues to Valneva of approximately EUR 30 million in 2015. Through the new agreement with Adimmune, increasing revenues from royalties on Biological E.'s JEV sales in India, and the changes to the Company's main marketing & distribution agreement, Valneva expects significant improvement in the profitability of its commercial product franchise going forward.

R&D PROGRAMS

+ Pseudomonas aeruginosa: Recruitment of patients for phase II/III continuation progressing according to plan. Preliminary results expected at the end of 2015 early 2016

The enrolment of further patients in the phase II/III pivotal efficacy trial for which the group announced the continuation following an interim analysis at the end of March 2014 is progressing according to plan. In addition to the 394 patients already enrolled in the study, the Company has started the recruitment of another 400 ventilated intensive care patients in 40 different sites. Valneva is also considering the option to extend the study further. Preliminary decisions / results are expected at the end of 2015 / early 2016.

+ Clostridium difficile Vaccine Candidate: Phase II data expected at end of 2015

In December 2014, Valneva initiated the phase II clinical trial of its VLA84 prophylactic vaccine candidate against Clostridium difficile (C. difficile).

The phase II study (VLA84-201) has enrolled 500 healthy subjects aged 50 years and older. This age group represents the target population for a prophylactic C. difficile vaccine as the risk to contract the infection-associated disease increases with age. The randomized, placebo-controlled, observer-blind study is being conducted in Germany as well as in the United States under an Investigational New Drug application (IND).

The phase II study aims to confirm the optimal dose and formulation of the vaccine in two different age groups and to generate sufficient additional clinical data to advance the program into Phase III. Data are expected to be reported by the end of this year.

+ Borrelia (lyme disease): Pre-clinical development completed, decision on next development steps in 2015

Valneva has developed a multivalent, protein subunit based vaccine candidate. This candidate has completed pre-clinical development and is currently in the pre-IND-process including regulatory advice (ongoing) and consultation processes (completed).

In November 2014, the preclinical data of Valneva's novel vaccine candidate for prevention of Lyme borreliosis, were published in PLOS ONE, the largest scientific journal in the world by volume. The publication reveals that Valneva's vaccine candidate, a multivalent, protein subunit based vaccine, has the potential to provide protection against the majority of *Borrelia* species pathogenic for humans. Valneva expects to announce a decision on timing for clinical development entry in 2015.

TECHNOLOGIES & SERVICES

+ EB66[®] cell line

In March 2014, the first ever marketing authorization for a human vaccine produced in EB66[®] cell line was granted to the Chemo-Sero Therapeutic Research Institute (Kaketsuken), a co-development partner to GlaxoSmithKline (GSK). Kaketsuken received the marketing authorization in Japan for a pandemic H5N1 influenza vaccine produced in Valneva's EB66[®] cell line.

In May 2014, Valneva announced the first marketing approval in Europe for a vaccine produced in the EB66[®] cell line. The marketing authorization was granted by the European Medicines Agency (EMA) for the prevention of Muscovy Duck Parvovirus (MDPV).

In September 2014, Valneva joined GlaxoSmithKline (GSK) in celebrating the site dedication of the Texas A&M Pandemic Influenza Vaccine Facility in Texas, which is on track for completion of construction by the end of 2015, to be followed by start-up phase in 2016. This new facility will provide the capabilities to manufacture bulk antigen for GSK's next generation pandemic influenza vaccine, based on Valneva's proprietary EB66[®] cell line, to help protect the United States against global influenza pandemics.

Valneva expects continued momentum in the signing of new EB66[®] license agreements in 2015 as evidenced by the recently announced exclusive license agreement with Chinese company Jianshun Biosciences Ltd to commercialize Valneva's EB66[®] cell line for the manufacturing of human and veterinary vaccines in People's Republic of China as well as the signing of two new veterinary licenses in Europe, with Merial and another undisclosed company.

+ IC31[®] adjuvant

Valneva has granted multiple licenses (to Novartis and Statens Serum Institut – SSI, among others) to evaluate IC31[®] in new vaccine formulations in infectious disease.

In the field of tuberculosis, three clinical vaccine candidates, all formulated with Valneva's IC31[®] adjuvant, are currently being tested in phase I and II clinical trials as part of the Company's agreement with SSI and their partners, including Aeras and Sanofi Pasteur.

In March 2014 Aeras initiated a Phase II randomized clinical trial for their tuberculosis vaccine candidate Aeras-404 using Valneva's IC31[®] proprietary adjuvant.

In December 2014, Valneva announced that the Statens Serum Institut's novel Tuberculosis vaccine candidate H1/IC31[®] formulated with Valneva's proprietary adjuvant IC31[®] showed good safety and immunogenicity in Phase II clinical trial in HIV-infected adults.

At the beginning of 2015, Valneva announced the signing of an exclusive worldwide commercial license agreement with Immune Targeting Systems (ITS) Ltd. The agreement grants ITS the rights to research, develop and commercialize Hepatitis B vaccine candidates in combination with Valneva's IC31[®] adjuvant.

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00pm (CET). Link: <http://edge.media-server.com/m/p/am8qidik>
A replay will be available after the webcast on the Company's website.

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About Valneva SE

Formed in 2013 through the merger of Intercell AG and Vivalis SA, Valneva is a biotechnology company developing, manufacturing and commercializing innovative vaccines with a vision to protect people from infectious diseases. 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[®]) and the second (Dukoral[®]) indicated for the prevention of and protection against traveler's diarrhea caused by ETEC (Enterotoxigenic Escherichia coli) and/or Cholera. 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 operates out of France, Austria, Scotland and Sweden with approximately 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 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.