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Valneva Reports Strong Q1 2015 Financial Results and Provides Operational Update

- Total Revenues and Grants of EUR 19.5 million in Q1 2015 compared to EUR 7.1 million in Q1 2014
- Revenue growth mainly driven by IXIARO®'s strong Q1 sales (EUR 9.7 million) and product sales from the newly acquired DUKORAL® and Nordics vaccine distribution business (EUR 5.4 million)
- Resulting EBITDA improvement of 7.0% and net loss improvement of 29.4% compared to Q1 2014
- Integration of acquired DUKORAL® and Nordics vaccine distribution business progressing well
- Valneva´s clinical stage programs Pseudomonas (Ph II/III) and C. difficile (Ph II) proceeding according to plan: data and/or future development decisions expected by year end 2015/ early 2016
- Strong newsflow for Valneva's vaccine technologies EB66® and IC31® with the signing of new collaborations and agreements
- Valneva re-confirms its 2015 revenue expectation of approximately EUR 75 to 85 million, compared to EUR 42.4 million in 2014

Lyon (France), May 12, 2015 – Valneva SE ("Valneva"), a leading pure-play vaccines biotech company, today reports its consolidated financial results for the first quarter ended March 31, 2015 and provides an operational update. The condensed consolidated interim financial report is available on the Company's website www.valneva.com. It includes the preliminary first-time consolidation of Crucell Sweden AB (now Valneva Sweden AB) and acquired assets related to DUKORAL® and the Nordics vaccine distribution business.

Key Financial Information (unaudited)

EUR in thousands	**3 months ended March 31,**	
	2015	**2014**
Revenues & Grants	19,501	7,095
Net profit/(loss)	(5,019)	(7,112)
EBITDA	(3,063)	(3,293)
Net operating cash flow	(10,947)	(10,037)
Cash, short-term deposits and marketable securities, end of period	38,979	28,706

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented, "We are pleased to present a quarter showing our operational business, including the integration of the newly acquired DUKORAL® and Nordics vaccine distribution business, performed to our expectations. We will remain focused on executing our strategy to build a leading, financially self-sustainable pure-play vaccine company balancing growth from commercial product contributions and investments in promising R&D vaccine programs."

FIRST QUARTER 2014 FINANCIAL REVIEW: (unaudited)

Note: As a result of 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, the acquired business has been included in the Group's consolidated financial statements from the acquisition closing date February 9, 2015. Therefore, first quarter 2015 and first quarter 2014 IFRS results are not fully comparable because the ex-Crucell operations are not part of the results for the comparator period of 2014. In the initial accounting for the acquisition, the net purchase consideration and the fair values assigned to the identifiable acquired assets and liabilities were determined on a provisional basis. Adjustments to those provisional values as a result of completing the initial accounting are possible and may lead to subsequent adjustments of the first quarter 2015 results. Such adjustments may be recognized within twelve months of the acquisition date.

+ Revenues and grants

Valneva's aggregate first quarter 2015 revenues and grants increased by EUR 12.4 million to EUR 19.5 million compared to EUR 7.1 million in the same period of the previous year.

IXIARO® product sales contributed EUR 9.7 million to Valneva's first quarter 2015 revenues, DUKORAL® product sales accounted for EUR 4.5 million and the Nordics trade business contributed EUR 0.9 million in the period from Feb 10, 2015 to March 31, 2015.

Revenues from collaborations, licensing and services amounted to EUR 3.5 million in the first quarter 2015 and EUR 2.5 million in the first quarter 2014. This increase was mainly due to revenues from services generated by the acquired business, which contributed EUR 0.9 million in the period starting Feb 10, 2015.

Grant income increased slightly and amounted to EUR 0.9 million in the first quarter 2015 and to EUR 0.8 million in the comparable period of 2014.

+ Operating Result and EBITDA

Cost of goods and services sold in the first quarter 2015 amounted to EUR 14.3 million of which EUR 6.7 million related to sales of IXIARO® (yielding a product gross margin of 31.2%) and EUR 6.8 million related to the acquired business. The gross margin for the acquired business was negatively impacted, and will continue to be so in the coming quarters, due to the fact that sales where mainly generated from acquired product inventory valued at fair market value as opposed to its lower historical manufacturing cost.

Research and development expenses in the first quarter 2015 reached EUR 5.5 million compared to EUR 5.8 million in the first quarter 2014. The decrease reflected the spin-off of the antibody business in January 2015. Selling, general and administrative expenses amounted to EUR 4.0 million in the first quarter 2015, compared to EUR 3.2 million in the first quarter 2014. The increase was due to EUR 0.2 million of acquisition costs and an additional EUR 1.3 million of SG&A expenses contributed by the acquired business since acquisition closing. The main part of these additional expenses consisted of selling expenses resulting from the acquired vaccines sales infrastructure in the Nordic countries.

Valneva's operating loss decreased by EUR 0.5 million to minus EUR 6.0 million in the first quarter 2015 compared to minus EUR 6.4 million in the first quarter 2014.

Valneva's EBITDA was minus EUR 3.1 million in the first quarter 2015 compared to minus EUR 3.3 million in the first quarter 2014. The acquired business contributed EBITDA of minus EUR 1.3 million.

+ Net Result
Valneva's net loss in the first quarter 2015 was minus EUR 5.0 million compared to minus EUR 7.1 million in the same period of the previous year.

Financial income, net of expenses in the first quarter 2015 amounted to EUR 0.7 million, whereas financial expense, net of income amounted to EUR 0.7 million in the comparable period of the previous year. In the first quarter financial income included a gain from exchange rate fluctuations of EUR 2.1 million.

Result from investment of affiliates amounted to a loss of EUR 0.1 million for the first quarter 2015, which represented Valneva's portion of the net loss reported by BLiNK Biomedical SAS. Valneva's investment in BLiNK Biomedical SAS is consolidated at equity.

+ Cash flow and Liquidity
Net cash used in operating activities in the first quarter 2015 amounted to EUR 10.9 million and resulted primarily from the operating loss in connection with the Group's R&D activities and from an increase in working capital due to a significant reduction of trade payables.

Cash outflows from investing activities of EUR 34.9 million in the first quarter 2015 resulted mainly from the acquisition of the Crucell Sweden AB and all assets, licenses and privileges related to DUKORAL® as well as a vaccine distribution business in the Nordics.

Cash inflows from financing activities amounted to EUR 55.8 million and resulted primarily from EUR 41.8 million net proceeds from a capital increase and EUR 14.7

million net inflows from new borrowings in connection with the financing of the above mentioned acquisition.

Liquid funds at March 31, 2015, stood at EUR 39.0 million compared to EUR 28.7million at March 31, 2014. Liquid funds at March 31, 2015 consisted of EUR 38.3 million cash, and EUR 0.7 million restricted cash.

Business Highlights

CORPORATE NEWS

+ Integration of acquired vaccine DUKORAL® and Nordic vaccine distribution progressing well

In February 2015, Valneva 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 Travelers' Diarrhea caused by ETEC. 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.

The integration of the acquired company renamed Valneva Sweden AB, is progressing well. Valneva is already leading manufacturing, supply and sales activities while it continues to integrate transitional services, processes and systems from the seller. The Nordics vaccine distribution business is now operated by Valneva under the traditional brand "SBL Vaccines", and the Company is progressing initiatives to further grow this business segment.

+ 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 by GSK of Novartis' global vaccines business (excluding influenza vaccines) has been completed. The transaction also included Valneva's partnership with Novartis regarding the marketing & distribution agreement for IXIARO®, the R&D programs under the Strategic Alliance Agreement, including Valneva's late stage Pseudomonas aeruginosa and Clostridium difficile vaccine candidates, as well as Novartis' shareholding in Valneva (approximately 3 million ordinary shares and 2.7 million preferred shares).

GSK is already an important strategic partner for Valneva´s EB66® cell line technology and the Company has entered into a detailed dialogue with GSK regarding the various aspects of its new strategic relationships.

COMMERCIALIZED VACCINES

+ IXIARO®/JESPECT®

Highest first quarter product sales since launch
IXIARO®/JESPECT® product sales were EUR 9.7 million in the first quarter of 2015 compared to EUR 3.8 million product sales in the first quarter of 2014, positively impacted by the timing of deliveries to Valneva's marketing & distribution partners and favorable foreign exchange effects, but also showing continued growth of product sales in the market. The Company re-confirms 2015 guidance for IXIARO®/JESPECT® revenues of approximately EUR 30 million. Market growth should continue to be driven through promotional efforts including further collaboration with the U.S. Military in order to support enhanced vaccination recommendations and policies for their staff at risk of exposure.

In April 2015, Valneva received a positive recommendation from CHMP for the European approval of an alternative, rapid IXIARO® vaccination schedule for adults. This accelerated alternative vaccination schedule will allow adult travelers (18-65 years) to receive full immunization within one week compared to almost four weeks under the conventional vaccination schedule (second dose 28 days after first dose).

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. An application for licensure of final product was submitted to TFDA (Taiwan Food and Drug Administration) in June 2014. Under this collaboration and assuming respective tenders, Valneva may expect first revenues from supplies as early as H2/ 2016.

+ DUKORAL®

Valneva's recently acquired a second commercialized vaccine indicated for active immunization against Cholera and, in some countries, prevention of Travelers' Diarrhea caused by ETEC (Enterotoxigenic Escherichia coli).

First quarter product sales included EUR 4.5 million sales of DUKORAL® in the period from February 10, 2015 (acquisition completion date) through to quarter end.

DUKORAL® sales during the full first calendar quarter (including sales by the seller until acquisition closing) were EUR approximately EUR 9.8 million.

Through the acquisition, Valneva gained an experienced marketing and sales team in the Nordics and is currently complementing this team by building its own sales and marketing force in key markets like Canada with the objective to directly control DUKORAL®´s commercialization.

+ Nordic sales of third party products
The acquired Nordics vaccine distribution business generated revenues of EUR 0.9 million from the sale of third party vaccines including Vivotif®, Rabipur®, Encepur® and Menveo® from the acquisition date to the end of the first quarter of 2015.

The Nordics vaccine distribution business is now operated by Valneva under the traditional brand of "SBL Vaccines", and the Company has commenced initiatives to further leverage and grow this business segment based on its long-standing heritage in vaccines.

R&D PROGRAMS

+ Pseudomonas aeruginosa: Recruitment of patients in current phase II/III progressing according to plan. Results / development decisions expected at the end of 2015 or early 2016
The enrolment of patients in the second part of the current phase II/III pivotal efficacy trial post interim analysis is progressing according to plan. To date more than 700 ventilated intensive care patients (of 800 planned) have been enrolled in the trial. As previously announced the company and its development partner GSK are also considering extending the number of patients in this trial. New data are expected at the end of 2015/ early 2016.

Valneva estimates that up to one million intensive care unit patients on mechanical ventilation in the U.S. and Europe annually could represent a potential target population for this vaccine candidate. According to Valneva's assumptions, the total market potential may be as significant as USD 1 billion annually.

+ Clostridium difficile vaccine candidate: phase II enrolment completed, data expected in Q4 2015
Valneva's second most advanced prophylactic vaccine candidate against Clostridium difficile (C. difficile) is currently being investigated in a phase II clinical trial.

The enrolment for this randomized, placebo-controlled, observer-blinded phase II study in 500 healthy patients 50 and older has recently been completed. This age group represents the overall target population for a prophylactic C. difficile vaccine as the risk of contracting the infection-associated disease increases with age. The current trial is being conducted in Germany and the United States under an Investigational New Drug application (IND) and aims to confirm the optimal dose and formulation of the vaccine in two different age groups (first group: 50 to 64 years and second group: 65+) to enable advancing the program into phase III. Data are expected in Q4 2015.

According to Valneva's assumptions, the total market potential for prophylactic C. difficile vaccines may significantly exceed USD 1 billion annually.

+ Borrelia (lyme disease): pre-clinical development completed, clinical entry planned for 2016
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 and consultation processes (both of which have been completed). Valneva expects to initiate a phase I clinical study in 2016.

+ Other pre-clinical activities
Valneva is conducting pre-clinical vaccine research for new vaccine candidates. Lead projects are focused in the area of travel vaccines but also include other vaccine indications in areas of high, unmet medical need.

TECHNOLOGIES & SERVICES

+ EB66® cell line
During the first quarter 2015, Valneva's cell line technology business showed good momentum with four additional license agreements on EB66®. The quarter was marked by the execution of an exclusive license agreement with Jianshun Biosciences Ltd to commercialize the EB66® cell line for the manufacturing of human and veterinary vaccines in the People's Republic of China. As part of the agreement, Valneva is entitled to receive an upfront payment of EUR 2.5 million (expected to be recognized as revenue in the second quarter 2015) and is entitled to further annual license fees and royalties.

The EB66® technology is increasingly seen as an alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines and two additional European laboratories have entered into partnership with Valneva during the first quarter to develop and commercialize veterinary vaccines based on the EB66® cell line.

Valneva's historical partner Merial has also renewed its commitment to the EB66® technology by signing a new research license agreement for the development of new veterinary vaccines.

Valneva is confident that it will meet its target of seven to eight new license agreements on the EB66® cell line in 2015.

+ 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 January, 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.

OTHER NEWS

Valneva was chosen to receive the Tech 40 label, which recognizes innovative listed European small and medium enterprises launched by EnterNext. EnterNext is a subsidiary of Euronext dedicated to promoting and growing the market for small and medium enterprises. Although the 40 companies are not expected to vary significantly from year to year, Tech 40 will allow each year 40 top-performing European companies to benefit from premium services. It is one of a series of measures adopted by EnterNext since 2014 to boost the visibility of tech companies on financial markets and provide them with special assistance.

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00 pm (CET). Link: http://edge.media-server.com/m/p/cf54ip2w
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 specialized in the development, manufacture and commercialization of innovative vaccines with a mission 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 active immunization against Cholera and, in some countries, prevention of Travelers' Diarrhea caused by 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 has its registered seat in Lyon, France, is 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.