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Valneva Reports Preliminary FY 2013 Revenues of EUR 36.0m and Cash Position of EUR 40.2m at End of 2013

Revenue Ahead of Guidance and Cash Target Met in First year Following Merger

- *Total revenues and grants rose to EUR 36.0 million in FY 2013, exceeding the company's guidance of FY revenues between EUR 30 to 35 million.*
- *IXIARO®/JESPECT® net product sales in FY 2013 reached EUR 27.2 million on a pro-forma basis (combining Intercell's sales in the first five months of 2013 with Valneva's sales since June) – a significant in-market sales growth offsetting a reduction of approximately 30% in distributors' inventory levels in H1.*
- *Valneva's cash position stood at EUR 40.2 million at the end of 2013, in line with the company's expectation*
- *Valneva to announce decision on Pseudomonas clinical development at end of March.*

Outlook:

- *Valneva anticipates continued growth of in-market sales of IXIARO®/JESPECT® and a significant increase in the profitability of its JEV vaccine in 2014.*
- *The company expects 2014 overall IFRS revenue to grow to EUR 40 – 45 million and – together with merger synergies - to contribute to significant reduction of operating loss, while continuing to progress its key development programs.*

Key Financial Information:
(unaudited preliminary numbers)

EUR in thousands	**3 months ended**		**12 months ended**	
	Dec 31, 2013	**Dec 31, 2012**	**Dec 31, 2013**	**Dec 31, 2012**
Product sales	6,542	-	23,239	-
Revenues from collaborations and licensing	2,335	918	7,206	3,431
Grant income	2,763	495	5,546	2,478
Total revenues & grants	**11,640**	**1,413**	**35,991**	**5,909**
Cash, short-term deposits and marketable securities, end of period	40,167	12,057	40,167	12,057

Financial Review:

(unaudited preliminary numbers)

(Note: As a result of the merger, Intercell's business has been included in the Group's consolidated financial statements from the merger closing date May 28, 2013. Therefore, 2012 and 2013 results are not fully comparable. While the results of Vivalis SA (now Valneva SE) were fully included in the income statement of 2012 and of 2013, the results from the ex-Intercell operations were only included for the seven month period starting of June 2013 and are not part of the results for the comparator period of the previous year.)

+ Fourth quarter revenues and grants

Valneva's fourth quarter 2013 revenues and grants were EUR 11.6 million to which IXIARO® product sales contributed EUR 6.5 million. Revenues from collaborations and licensing amounted to EUR 2.3 million, and grant income was EUR 2.8 million. Revenues and grants excluding the ex-Intercell operations were EUR 2.3 million in Q4 2013 and EUR 1.4 million in the fourth quarter 2012.

+ Full year 2013 revenues and grants

Valneva's aggregate full year 2013 revenues and grants increased to EUR 36.0 million compared to EUR 5.9 million in the same period of the previous year. This increase was mainly due to the contribution of ex-Intercell revenues to the business since June 2013 following the closing of the merger of Vivalis and Intercell to form Valneva.

Independently from the significant merger impact on revenues and grants, the group's key revenue sources, IXIARO®/JESPECT®, EB66® and VivaIScreen® all showed revenue growth in 2013. Revenues and grants excluding the ex-Intercell operations increased by 11.8% to EUR 6.6 million in 2013.

IXIARO®/JESPECT® product sales contributed EUR 23.2 million to 2013 revenues since the effective date of the merger. On a pro-forma basis (combining Intercell's sales in the first five months of 2013 with Valneva's product sales since June) full year 2013 product sales were EUR 27.2 million compared to EUR 26.8 million recorded by Intercell in 2012, despite the negative impact of a reduction of approximately 30% in the inventory levels of the company's main distributor in the first half of 2013.

Revenues and grants from the EB66® cell line technology were EUR 3.7 million in 2013, compared to EUR 3.5 million in 2012. Revenues and grants from the VivaIScreen® antibody platform increased to EUR 2.9 million in 2013 from EUR 2.4 million in 2012.

Total revenues from collaboration and licensing increased to EUR 7.2 million in 2013 compared to EUR 3.4 million in the previous year. Grant income was EUR 5.5 million in 2013 and EUR 2.5 million in 2012. Both, fundamental growth and inclusion of the ex-Intercell business contributed to this increase in revenues and grants.

+ Cash position at year-end

Liquid funds at December 31, 2013 stood at EUR 40.2 million compared to EUR 12.1 million at the end of December 2012 and consisted of EUR 36.5 million cash and EUR 3.7 million short-term deposits. In the fourth quarter of 2013, the group's cash position was strengthened by proceeds of the sale of its CMO facility in Nantes and by a USD 30.0 million asset-based loan financing from an investment fund managed by Pharmakon Advisors to the company's Austrian subsidiary, Valneva Austria GmbH.

Business Highlights:

+ **Product:**

  IXIARO®/JESPECT®: Pediatric approval and in-market growth

  Since the first IXIARO® product launch in 2009 and the first full year sales in 2010, the vaccine has convincingly met its initial development objectives in all relevant target populations. Marketing of the vaccine in the traveler´s markets has led to an increased uptake and resulted in a compound annual growth rate (CAGR) of 20% between 2010 and 2013.

  Valneva worked in a collaborative mode with the U.S. Military over the past years, resulting in broadly adopted recommendations for forward deployed troops leading to sales of more than 150,000 doses to the U.S. Military in 2013.
  2013 was also marked by IXIARO®´s pediatric label extension and a subsequent extension of recommendations which - alongside ongoing awareness – built a solid basis for future growth.

  Valneva's Japanese Encephalitis Vaccine (JEV) reached total net product sales of EUR 23.2 million in FY 2013 (which only includes JEV sales since the effective merger date on May 28, 2013). On a pro-forma basis (combining Intercell's sales in the first five months of 2013 with Valneva's sales since June) FY 2013 product sales were EUR 27.2 million compared to EUR 26.8 million in FY 2012 (Intercell).

  IXIARO®/JESPECT® in-market sales have shown significant growth in key travel vaccines markets. However, Valneva´s net product sales were negatively affected by a reduction of approximately 30% in the inventory levels of the company's main distributor in the first half of 2013. This impact was offset by the sales recorded in the second half of the year, which included the largest U.S. military order to date.

  Based on successes and developments in 2013, the company reviewed its future marketing and distribution strategy which resulted in changes to the agreement with its main marketing & distribution partner. These changes are aimed at securing the planned levels of sales and include minimum sales growth targets for the coming years. Valneva also transferred the responsibility of supplying the U.S. military to that partner, resulting in Valneva now recognizing two thirds of the respective total sales revenues (as compared to 100% in the past) which will be offset by lower royalties paid to that partner. The transfer will also allow the company to reduce its own marketing and sales activities for the product in the U.S. Valneva therefore anticipates a significant increase in the profitability of its JEV vaccine in 2014. The Company expects sales of EUR 27-28 million in 2014 – an equivalent of EUR 31-32 million without the changes to the US military revenue recognition.

+ **R&D programs and activities:**

Pseudomonas aeruginosa vaccine candidate – Potential continuation planning still ongoing

Valneva is still in the process of seeking regulatory advices and planning for potential trial execution with its development partner, Novartis. Based on current assumptions, Valneva will be able to announce a decision on the program continuation at the end of March.

At the end of October 2013, a Data Monitoring Committee (DMC) conducted an interim analysis on Valneva's ongoing Phase II/III pivotal efficacy trial for its Pseudomonas aeruginosa vaccine candidate. The DMC observed a clinically meaningful difference on mortality rates between vaccine and placebo groups - the primary efficacy read-out - and had no safety concern with regard to the safety profile of the vaccine candidate - one of the secondary endpoints. Although the difference in mortality rates was not as pronounced as hoped and as reflected in the pre-defined futility criterion, the results confirmed the trend on efficacy observed in the previous Phase II trial. Based on these findings, the development partners have been planning for potential continuation of the development program including modifications of the ongoing clinical trial protocol, taking into account respective regulatory advices.

The Pseudomonas aeruginosa vaccine candidate is part of the Strategic Alliance between Valneva and Novartis, which are co-financing the current Phase II/III study.

Clostridium difficile Vaccine Candidate – Phase II initiation expected in Q4/2014

At the end of August 2013, Valneva announced positive Phase I results for its vaccine candidate to prevent C. difficile infections, the leading cause of nosocomial diarrhea. It showed a favorable safety and tolerability profile in both study populations, elderly subjects and adults, with local tolerability being even better in elderly subjects. The vaccine candidate was also highly immunogenic in elderly subjects and was able to induce immune responses to Clostridium difficile toxins A and B similar to the ones observed in adults.

Based on those findings and including follow-up data and comparison to other vaccine candidates in development, Valneva is currently preparing the initiation of Phase II, expected in the fourth quarter 2014.

Borrelia (lyme disease): Pre-clinical development nearing completion

Valneva has developed a multivalent, protein subunit based Vaccine candidate. This candidate is nearing completion of pre-clinical development and is expected to be ready for clinical entry towards the end of this year. However, a decision on the start of clinical development has not been taken yet.

To date, there is currently no vaccine available to protect humans against Lyme disease. According to the Centers for Disease Control and Prevention (CDC) 300,000 Americans are diagnosed each year with Lyme disease and the disease spread keeps increasing.

+ **Platforms update:**

EB66® Cell Line: **First EB66® human vaccine expected in 2014**

Valneva signed seven new licensing agreements in 2013, the last one being in October when the group announced it had licensed the use of its EB66® cell line to the International AIDS Vaccine Initiative (IAVI) for the evaluation and development of a preventive HIV vaccine candidate in clinical trials. The agreement was a landmark in Valneva's history, as it was the first time the company gave dual rights to a non-profit organization to perform both research and clinical studies using its technology.

Valneva now expects marketing approval for the first human vaccine produced on the EB66® cell line, anticipated for the first half of 2014. This substantial technology validation will be based on the expected approval for a H5N1 pandemic influenza vaccine produced by Kaketsuken, a co-development partner under the exclusive EB66® license for influenza with GlaxoSmithKline (GSK).

VIVA|Screen®:

Valneva has recently initiated a fourth antibody discovery program for Sanofi Pasteur, the vaccine division of Sanofi, on its proprietary screening platform VivaScreen®. As part of the agreement signed with Sanofi Pasteur in June 2010, Sanofi Pasteur will obtain worldwide exclusive development and commercialization rights for the discovered antibodies while Valneva may receive development milestone payments of up to EUR 35 million per infectious disease, as well as royalty payments associated with product sales. In addition, Sanofi Pasteur finances collaborative research activities.

Valneva, which successfully completed antibody discovery work for Sanofi Pasteur in 2013 and delivered respective antibody candidates for three different infectious diseases, is now expecting Sanofi Pasteur´s decision to progress with the first indication towards clinical development, which would trigger a milestone payment.

The company is evaluating the validity and attractiveness of VivaScreen® for indications outside of infectious diseases, including different partnering and collaboration models, to unlock the platform's potential.

IC31® adjuvant / IC31® Tuberculosis Vaccine:

In the field of Tuberculosis, Valneva is collaborating with the Statens Serum Institut (SSI). SSI and Aeras announced the initiation of a Phase I/IIa Clinical Trial for a tuberculosis (TB) vaccine candidate using Valneva's IC31® proprietary adjuvant at the end of 2013.

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.

Data from two of the trials is expected to be published by the fourth quarter of 2014.

Under a strategic alliance agreement signed in 2007, Novartis received a license for the use of IC31® in selected new vaccines. Following investigation of IC31® in influenza vaccines, Novartis is currently clinically investigating the adjuvants in an undisclosed vaccine candidate.

+ **Corporate/Other:**

In December 2013, Valneva announced that it had secured a USD 30 million financing from an investment fund managed by Pharmakon Advisors to the company's Austrian subsidiary Valneva Austria GmbH. The new asset-based financing, which extends over a five year period, followed the repayment in the third quarter of a royalty-related loan of more than EUR 20 million, in connection with the Intercell and Vivalis merger which took place at the end of May 2013. The new loan, secured under improved terms, will be used primarily to support the sales growth of Valneva's Japanese encephalitis vaccine IXIARO®/JESPECT®.

Valneva also confirmed in December the completion of the transaction with Indian biopharmaceutical company Biological E, transferring its Clinical Manufacturing Operations (CMO) in Nantes. This divestment, which is part of Valneva´s announced merger strategy to realize cost synergies of EUR 5 to 6 million annually, is expected to contribute up to EUR 3 million to those savings.

+ **2014 Key Business Milestones:**

2014 will be a significant year in terms of key business milestones. Most importantly the company expects:

- Market approval and launch of EB66® cell-based pandemic influenza vaccine in Japan
- Decision on Phase II/III continuation for the Pseudomonas vaccine candidate
- Sanofi opt-in milestone for the first VIVA|Screen® antibody program
- Second approval of a veterinary product produced in the EB66® cell line
- Phase II trial start for the C. difficile vaccine candidate
- Further IC31® / Tuberculosis data
- Potential initiation of clinical development for the Borrelia vaccine candidate
- First revenues from Biological E sales of JEV vaccine in India

Notice in connection with non GAAP pro forma financial information

On May 28, 2013, the company completed its merger with Intercell AG. As a result of the merger, Intercell's business has been included in the group's full year consolidated financial statements under IFRS from the merger closing date. Therefore, 2012 and 2013 results under IFRS are not fully comparable. Results from the ex-Intercell operations were only included starting from June 2013 and are not part of the results for the comparator period of the previous year.

This press release includes information on non-GAAP pro forma product sales from the company's JEV vaccine as part of the preliminary, unaudited revenue. Management believes that this information is meaningful to assist investors, analysts, and others in understanding our financial results and to better evaluate operating performance for the periods presented. These figures, however, are not a measure of financial performance under IFRS or any other GAAP and should not be considered a substitute for measures determined in accordance with GAAP.

Definitions: For preparing the non-GAAP financial information presented herein, the following changes to the most directly comparable GAAP financial measures under IFRS have been applied. Pro forma product sales from JEV revenue includes in addition to the Valneva SE product sales the ex-Intercell operations for the first five months of 2013 and for the comparator period in 2012.

Pro forma non-GAAP product sales from JEV reconciles as follows to preliminary, unaudited product sales as part of IFRS revenues:

EUR in thousands **(unaudited)**	**Reported preliminary financial information (IFRS)**	**Pro forma adjustments:** **Inclusion of ex-Intercell income**	**Pro forma preliminary financial information (non-GAAP)**
Full year ended December 31, 2012			
Product sales	-	*26,772*	26,772
Full year ended December 31, 2013			
Product sales	23,239	*3,973*	27,212

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About Valneva SE
Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger of Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through in-house programs or in collaboration with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®),commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66®cell line, VIVA|Screen® and IC31®) developed by Valneva that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 300 people in France, Austria, Scotland, the United States, and Japan. The internationally experienced management team has a proven track-record across research, development, manufacturing and commercialization.
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.