

Valneva Announces H1 2013 Business Results and Provides Outlook

First combined financial results since formation of Valneva through the merger of Vivalis and Intercell:

- + *Significant revenues added by the merger, bringing revenues and grants to EUR 9.7m in H1 2013 (H1 2012: EUR 2.7m)*
- + *Moderate increase of net loss by 8% to EUR 8.1m in H1 as a result of the merger*
- + *IXIARO[®]/JESPECT[®] becomes main revenue source showing H1 pro forma product sales of EUR 9.3m, ahead of highest expected product sales since product launch in Q3 2013*
- + *IXIARO[®] gets FDA and EMA Pediatric Approval*
- + *NDA filed for production of the first human vaccine in EB66[®] cell line*
- + *Proprietary development programs on track towards next value inflection points*
- + *Cash position strengthened after balance sheet date through success of recent capital increase*
- + *Company on track to execute on its integration including cost synergies*

Outlook:

- + Valneva expects FY 2013 revenues and grants of EUR 30 to 35 million driven by its IXIARO[®]/JESPECT[®] sales.
- + The group expects IXIARO[®]/JESPECT[®] third quarter sales to record their highest performance since the launch of the product.
- + The group expects a net loss between EUR 20 to 25 million in 2013.
- + Valneva estimates its cash position should stand above EUR 40 million at the end of 2013.
- + The group confirms its guidance for profitability in the mid-term.



Key Financial results*:

(EUR in thousands)

6 months ended June 30	2013	2012
Revenues and grants	9,671	2,746
Net (loss)	(8,114)	(7,502)
Net operating cash flow	(7,105)	(7,605)
Liquid funds, end of period	23,801	17,974

**AS THE MERGER BETWEEN VIVALIS AND INTERCELL BECAME EFFECTIVE AT THE END OF MAY, TO COMPLY WITH LEGAL REQUIREMENTS, VALNEVA 1H RESULTS INCLUDE 1 MONTH OF VALNEVA AND 5 MONTH OF VIVALIS.*

- + Revenues and grants in the first six months of 2013 reached EUR 9.7m, in large part resulting from the inclusion of IXIARO[®]/JESPECT[®] sales.
- + Valneva's net loss amounted to EUR 8.1m in H1 2013, compared to a net loss of EUR 7.5m in H1 2012, due to the inclusion of the ex-Intercell business' loss in June.
- + The group's cash position at the end of H1 2013 stood at EUR 23.1m. It will be strengthened in H2 by a recent EUR 40.2 million capital increase with a subscription rate of 146%.

Business Highlights:

- + **Merger between Vivalis SA and Intercell AG to create VALNEVA SE closed on May 28, 2013**

H1 2013 was marked by the merger of Vivalis and Intercell to create Valneva, combining the strengths of the two companies in antibody discovery and vaccine development and commercialization. Valneva communicated a clear growth strategy to build a sustainable business by growing revenues through marketed product(s) as well as through existing and future partnerships, and to invest in proprietary vaccines development and antibody discovery for licensing.

- + **Successful completion of a EUR 40.2m capital Increase, oversubscribed by 146%.**

In June, Valneva launched a capital increase, which was successfully completed with a subscription rate of 146%. The proceeds of the capital increase of EUR 40.2 million, will allow the Company to strengthen its financial profile and implement its strategy (increased IXIARO[®] marketing, development of a second commercial vaccine, increased clinical research on vaccines and antibodies). Upon completion of the capital increase, Groupe Grimaud as Valneva's single largest shareholder held 21.7% of the

ordinary shares of the Company and the FSI, now transformed into Bpifrance Participations SA, held 10.1%.

+ **Integration on track to deliver strong cost synergies**

Following the merger effective date, key integration activities across the two previous operations have been progressing.

In addition to the alignment and consolidation of key business processes and structures, Management has focused on delivering against its synergy target of EUR 5-6m annual operating cost savings.

On August 20, 2013, following the signing of a binding term sheet in June, Valneva signed a preliminary sales agreement with Biological E, a leading Indian biopharmaceutical company, for its Clinical Manufacturing Operations (CMO) in Nantes. The divestment of the CMO activity is expected to contribute up to EUR 3 million cost savings to the annual merger synergies. In addition, Valneva will receive an undisclosed purchase price, exceeding the current book value of the facility.

+ **Passing of Management Board Member, Chief Scientific Officer Majid Mehtali**

With deep regret and profound sadness Valneva had to announce that its Management Board member, Dr Majid Mehtali, Chief Scientific Officer, passed away on August 10, 2013, at the age of 51. Majid Mehtali joined Vivalis in 2003 and co-managed the company, both as Chief Scientific Officer and Managing Director for ten years. He was a well-recognized and respected leading scientist in the life-science industry and played a major role in developing and encouraging many of his colleagues who had worked with him. His passing away is a great loss for Valneva. However, the strong research team built by Majid will continue his work according to plan, and Valneva's Boards will ensure a smooth succession in due course.

Product(s):

+ **IXIARO®/JESPECT® :**

Since May 2013, IXIARO® is also approved by the FDA and the EMA for use in children from the age of 2 months and hence a licensed vaccine will now be available to vaccinate against JE traveling children and those children of forward deployed military personal in Asia.

Since the merger effective date on May 28, 2013, sales of the JE vaccine contributed EUR 5.3m to Valneva's revenues.

Total IXIARO®/JESPECT® net product sales (by Intercell AG and Valneva) decreased by 37% to EUR 9.3m in H1 2013 compared to EUR 14.7m in H1 2012 despite growing in-market sales (+8% Novartis, +11% U.S. Military). Sales were negatively impacted by stock level and timing effects.

Valneva expects to offset this decrease by recording strong IXIARO® sales in the third quarter, which should be the company's best quarter since the launch of the product, based on current order status from the U.S. military and the group's distribution partners.

Valneva has also initiated a process to assess the commercialization efforts by its marketing & distribution partners with the aim of finding mutually acceptable solutions to foster marketing & sales activities resulting in increased penetration in current markets and approved countries where no or very low sales levels are seen today.

The Company reiterates its intent to achieve total net sales of approx. EUR 50m in the mid-term, supporting its financial self-sustainability strategy.

Platforms revenues and update:

+ EB66[®] Cell Line:

In H1 2013, revenues and grants generated through EB66[®] rose 23.1% to EUR 1.6m, up from EUR 1.3 m in H1 2012. The EB66[®] cell line achieved significant newsflow in H1 2013, with 4 new licensing agreements and the first New Drug application (NDA) submission for a human vaccine.

- In March, Valneva distributed a press release issued by GSK detailing its continued efforts, along with the Texas A&M University System (TAMUS), to develop an EB66[®] cell culture based influenza vaccine funded by the U.S. Department of Health and Human Services (HHS). Under this program, the HHS approved the development of a USD 91 million influenza vaccine manufacturing facility to be located in Bryant-College Station, Texas.
- In April 2013, Valneva announced that Kaketsuken, a co-development partner with GlaxoSmithKline (GSK) Vaccines, submitted a new drug application (NDA) to the Ministry of Health, Labour and Welfare (MHLW) in Japan for an H5N1 adjuvanted pandemic influenza vaccine produced in Valneva's EB66[®] cell line. The vaccine, which will be the first human vaccine produced in the EB66[®] line, is expected to get marketing approval in 2014.
- Valneva also signed an EB66[®] cell line research services and license option agreement with GlaxoSmithKline ("GSK") to establish the feasibility of producing a new viral vaccine against an important viral disease using EB66[®]. This is the second EB66[®] cell line agreement signed with GSK following a first agreement in 2007 on the development of influenza vaccines.
- The company also announced the signing of additional research licenses in human and veterinarian vaccines field, with Italian animal health vaccine company FATRO, with a North American animal health vaccine and one of the world's largest human vaccine developers, whose names were not disclosed.

+ VIVA|Screen[®]:

In H1 2013 revenues and grants generated through VIVA|Screen[®] rose 21.4% to EUR 1.7m, up from EUR 1.4m in H1 2012.

During the first half, Valneva successfully completed antibody discovery work under the licensing agreement it signed with Sanofi-Pasteur in 2010, and delivered antibody candidates in 3 indications to Sanofi-Pasteur for further evaluations.

Valneva expects Sanofi Pasteur's decision to progress with the first indication towards development by the end of 2013 / early 2014 which would trigger a first milestone.

In addition, a fourth antibody discovery program is expected to be launched at the end of 2013. Valneva also evaluates the validity and attractiveness of its platform for indications and respective antibody product candidates outside of infectious diseases to unlock additional partnering and licensing potential.

+ **IC31[®] adjuvant**

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 initiated in 2011, a Phase I clinical trial, combining an additional undisclosed vaccine candidate with the IC31[®] adjuvant.

The potential of respective licenses and collaborations to date reaches approximately. EUR 100m in milestones and future potential mid-digit royalties on sales

Proprietary development programs on track towards next value inflection points:

The Company's current proprietary pipeline includes the vaccine candidates against Pseudomonas (Phase II/III with Novartis) and C. difficile (Phase I) and a pre-IND stage program against Lyme / Borreliosis

Valneva's adjuvants IC31[®] is part of different Tuberculosis vaccine candidates (most advanced: Phase II with Statens Serum Institut, Sanofi and AERAS).

+ **Pseudomonas aeruginosa vaccine candidate – a leading cause of nosocomial infections**

In March 2012, Intercell started a pivotal Phase II/III efficacy trial with its investigational Pseudomonas aeruginosa vaccine to treat nosocomial infections, which mostly occur during hospitalization for other conditions. The trial follows an exploratory Phase II study in which lower all-cause mortality rates were observed in the vaccine groups as compared to the control group.

The Phase II/III trial is sufficiently powered to show a clinically meaningful reduction in all-cause mortality with statistical significance between the vaccine and control group.

The study enrollment for approx. 400 patients has been completed, enabling the futility analysis to be conducted by an independent drug monitoring board (DMC). Its respective recommendations for this program as part of the strategic alliance between Novartis and Intercell are expected in Q4 2013.

- + **Clostridium difficile vaccine candidate – leading cause of nosocomial diarrhea**
Valneva's vaccine candidate IC84 to prevent C. difficile infection is currently in Phase I clinical trial (Phase Ib). Data from the first half of the study (Phase Ia) in a population of healthy adults aged 18-65 years showed good safety and immunogenicity of the vaccine candidate, and indicated functionality of induced antibodies in this study population. The second half of the study (Phase Ib), enrolling 80 healthy elderly subjects above 65 years of age - representing the main target population for a C. difficile vaccine, was initiated in March 2012. This second part of the study (Phase Ib) aims to confirm besides safety and immunogenicity, the dosing and potential adjuvantation. Data release is still expected in Q3 2013.

- + **IC31[®] Tuberculosis Vaccine:**
In the field of Tuberculosis, Valneva is collaborating with the Statens Serum Institut (SSI). Previous Phase I clinical trials in Europe and Africa demonstrated that SSI and Valneva's collaborative novel investigational TB vaccine is safe and highly immunogenic in different populations.
Three clinical vaccine candidates, all formulated with Valneva's IC31[®] adjuvant, are tested in clinical trials.
Two trials are currently conducted and expected to deliver first data by Q4 2014.
A third candidate, partnered with Sanofi Pasteur and Aeras, is currently being tested in a phase I/II clinical trials (with the support of Aeras and Impaact).

- + **Lyme disease:**
Valneva has developed a multivalent, protein subunit based Vaccine candidate. This candidate undergoes pre-clinical development at the moment, aiming for clinical trial initiation in H2 2014. Currently no vaccine is available in Europe to protect humans against Lyme disease. While antibiotic therapies can treat an existing infection, a prophylactic vaccine could prevent it

H1 2013 Financial Review:

- + **Revenues:**
Revenues and grants in the first six months of 2013 reached EUR 9.7m, including a EUR 6.4m contribution by the ex-Intercell operations, mostly coming from IXIARO[®]/JESPECT[®] product sales. Revenues and grants excluding the ex-Intercell operations increased by 21.0% to EUR 3.3m in H1 2013 from EUR 2.7m in H1 2012.

- + **Operating results:**
Cost of goods sold amounted to EUR 3.6m in H1 2013 and was exclusively related to sales of IXIARO[®]/JESPECT[®] in June 2013.
Research and development costs in H1 2013 reached EUR 7.0m compared to EUR 6.2m in H1 2012, including a EUR 1.5m contribution by the ex-Intercell operations.

Selling, general, and administrative expenses (SG&A) increased from EUR 2.7m in H1 2012 to EUR 5.1m. The ex-Intercell business contributed EUR 2.0m to the increase. Without giving effect to the ex-Intercell contribution, the year-on-year increase in SG&A costs was 14.8% and was due to EUR 1.1m of merger-related costs.

Amortization expenses for intangible assets increased to EUR 1.4m in H1 2013 from EUR 0.5m in H1 2012. Out of the total amortization expenses, EUR 0.5m was related to intangibles assets, which were acquired through the merger and recorded at their fair value as of the merger's effective date.

Valneva's operating loss increased by 12.6% to EUR 7.7m in H1 2013 from EUR 6.8m in H1 2012. Ex-Intercell operations contributed for EUR 1.4m to the operating loss.

+ **Net result**

Valneva's net loss in H1 2013 reached EUR 8.1m, compared to EUR 7.5m at the same period last year. The 8.2% increase reflects recognition for June of a EUR 1.6m loss coming from the ex-Intercell business. Excluding this amount, the Group's net loss would have decreased by 13.6% to EUR 6.5m in H1 2013 from EUR 7.5m in H1 2012.

+ **Cash flow and liquidity**

Net cash used in operating activities in H1 2013 amounted to EUR 7.1m and resulted primarily from the operating loss in connection with the Group's R&D activities.

Cash in-flows from investing activities reached EUR 18.1m in H1 2013, of which EUR 13.6m were acquired through the stock-for-stock merger with Intercell AG.

Cash flows from financing activities amounted to EUR 4.9m, resulting primarily from the monetization of the Company's CIR (Research Tax Credit - Crédit Impôt Recherche) for the years 2010 to 2012 through a EUR 6.3m credit line, repayable upon collection of the respective tax credits. This cash inflow from borrowings was partly offset by the repayment of borrowings and purchase of treasury shares.

Liquid funds at the end of June 2013, stood at EUR 23.1m compared to EUR 12.1m at the end of December 2012, including EUR 15.6m in cash and short-term deposits and EUR 7.5m in financial assets.

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About Valneva SE

Valneva is a new European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger between 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 both 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 350 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 their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.