Q3 2013

# QUARTERLY REPORT VALNEVA SE

VALNEVA SE

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Valneva SE announces Q3 2013 financial results and provides operational update





# Valneva Records Highest IXIARO®/JESPECT® Sales in Q3 2013, Confirms Full Year Outlook, and Provides R&D update for Pseudomonas Vaccine Candidate

- + IXIARO®/JESPECT® posts highest quarterly sales since product launch at EUR 11.4m driven by supply of largest U.S. military order to date
- + Revenues and grants were EUR 14.7m in Q3 2013 (Q3 2012: EUR 1.8m), benefiting from the merger
- + Net loss was EUR 10.0m in Q3 as a result of the merger
- + Merger cost synergies to be implemented faster than expected
- + Encouraging Data from Phase II/III interim analysis on Pseudomonas Vaccine
- + Positive Phase I Results for Valneva's Clostridium Difficile Vaccine Candidate
- + Two new EB66® cell line agreements signed in Q3

#### **OUTLOOK:**

- + Valneva confirms its expectation for FY 2013 revenues and grants of EUR 30 to 35 million, driven by its IXIARO®/JESPECT® sales.
- + The group expects a net loss at the high end of its previous net loss guidance of EUR 20 to 25 million for FY 2013.
- + Valneva estimates that its cash position should stand above EUR 40 million at the end of 2013, and confirms it is on track to secure new debt financing following a loan repayment of more than EUR 20 million in Q3.

#### **KEY FINANCIAL INFORMATION:**

| EUR IN THOUSANDS  | 3 MONTHS ENDED |               | 9 MONTHS ENDED |               |
|---|----------------|---------------|----------------|---------------|
|   | Sept 30, 2013  | Sept 30, 2012 | Sept 30, 2013  | Sept 30, 2012 |
| Revenues & Grants   | 14,680         | 1,750         | 24,351         | 4,496         |
| Net profit/(loss)   | (9,968)        | (2,428)       | (18,082)       | (9,931)       |
| Net operating cash flow                                     | (14,928)       | (1,175)       | (22,033)       | (8,780)       |
| Cash, short-term deposits and marketable securities, end of | 10 170         | 1F F00        | 10 170         | 15 500        |
| period  | 18,179         | 15,589        | 18,179         | 15,589        |





- + Revenues and grants increased by EUR 12.9m in the third quarter to EUR 14.7m, strongly benefiting from the merger and the inclusion of the IXIARO®/JESPECT® sales, which recorded their highest grossing quarter since the launch of product.
- + Valneva's net loss amounted to EUR 10.0m in the third quarter 2013, compared to a net loss of EUR 2.4m in the third quarter 2012, due to the inclusion of the ex-Intercell business' loss.
- + The group's cash position at the end of September 2013 stood at EUR 18.2m, following the repayment of a royalty-related loan in connection with the merger. Valneva is currently in advanced negotiations to secure the re-financing through a new loan under improved terms. In addition, the company expects to strengthen its cash position through the proceeds of the sale of its CMO facility in Nantes, (closing is imminent) and the collection of trade receivables, which were at a high level of EUR 12.3m at the end of Q3 and have since been largely collected.

#### **OPERATIONAL BUSINESS & STRATEGY REVIEW:**

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

  In July, Valneva announced it successfully completed a EUR 40.2m capital increase, with a 146% subscription rate. The proceeds 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 Company's ordinary shares and the FSI, now transformed into Bpifrance Participations SA, held 10.1%.
- + Integration on track implementation of expected cost synergies largely completed by end 2013
  The alignment and consolidation of key business activities, processes and structures, across the two previous operations (Intercell and Vivalis) continued to progress in the third quarter. The closing of the sale of the Nantes Clinical Manufacturing Operations (CMO), including transfer of the facility and 25 Valneva employees, to Indian biopharmaceutical company Biological E is scheduled for the first half of November. The divestment is expected to contribute up to EUR 3m cost savings to the annual merger synergies.

  In the third quarter, Management also continued to focus on delivering against its synergy target of EUR 5-6m annual operating cost savings. The Company confirms that implementation measures to achieve the expected cost synergies will be largely completed by end 2013 and thus be already fully effective for the fiscal year 2014.

#### **PRODUCT:**

+ IXIARO \*/JESPECT\*: Best quarterly sales since product launch

Revenues from IXIARO®/JESPECT® product sales were EUR 11.4m in the third quarter 2013, making it the best sales quarter since the launch of the product in 2009.

Net product sales in the first nine months of 2013 (combining Intercell's sales in the first five months of 2013 with Valneva's sales since June) increased by 13.7% to EUR 20.7m compared to EUR 18.2m in the first nine months of 2012. Since the merger effective date on May 28, 2013, JE vaccine sales contributed EUR 16.7m to Valneva's revenues. Sales in Q3 2013 benefited from a significant supply order by the U.S. military which represents the largest to date.

The order followed the FDA and EMA's pediatric approvals for IXIARO® in May 2013 and the extension in June of the ACIP recommendation to include travelling children aged 2 months and





above, such as family members of military personnel residing in endemic countries in Asia. Valneva also continues 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.

#### **R&D PROGRAMS AND ACTIVITIES PROGRESSING TO NEXT DEVELOPMENT STAGES:**

#### + Pseudomonas aeruginosa vaccine candidate

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 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 DMC forwarded its recommendations to the study sponsor (Valneva) who is now in a position to decide with its development partner on trial continuation including possible modifications of the clinical trial protocol. The Pseudomonas aeruginosa vaccine candidate is part of the Strategic Alliance between Valneva and Novartis, who are co-financing the current Phase II/III study, and thus have initiated discussions on trial continuation, in line with the DMC findings and recommendations. Possible protocol modifications for trial continuation as early as Q1 2014, will be discussed with the DMC, if needed.

#### + Clostridium difficile Vaccine Candidate - Positive Phase I Results

At the end of August, Valneva announced positive Phase I results for its vaccine candidate IC84 to prevent C. difficile infections, the leading cause of nosocomial diarrhea. IC84 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 similar immune responses to Clostridium difficile toxins A and B as the ones observed in adults.

The analysis of long-term safety and immunogenicity data is still ongoing and is expected to be available in the fourth quarter of 2013.

Next development steps will be decided after final study close-out and in agreement with Valneva's strategic alliance partner, Novartis.

#### + 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).





#### + Borrelia (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 to protect humans against Lyme disease. While antibiotic therapies can treat an existing infection, a prophylactic vaccine could prevent it.

#### **PLATFORMS UPDATE:**

#### + EB66® Cell Line:

Valneva signed two new EB66® cell line agreements in the third quarter:

In September, Valneva announced a new agreement with German biopharmaceutical company Delta-Vir GmbH for the production of Newcastle Disease Virus, a component of Delta-Vir's novel cancer therapy vaccine. The cell therapy has already been used in human patients and Delta-Vir expects to file a Clinical Trial Application (CTA) in Europe for a confirmatory clinical trial in the second half of 2014. Financial terms of the agreement, which also includes a commercial option, were not disclosed but do include upfront and annual maintenance payments.

• In July, Valneva announced a new research license agreement with German pharmaceutical company Boehringer Ingelheim for the development of animal health vaccines. This non-exclusive agreement also includes a commercial option for future marketed products. Terms of the deal were not disclosed.

To date, Valneva, has signed seven new EB66® agreements in 2013, including the one signed with International Aids Vaccine Initiative (IAVI) in October, and is planning to sign an additional one by the end of the year.

The company expects marketing approval for the first human vaccine produced in the EB66® line, which should be granted in the first quarter of 2014. This first product is an H5N1 pandemic influenza vaccine for which a new drug application (NDA) has been filed with the Japanese Ministry of Health, Labour and Welfare (MHLW) in April 2013 by Kaketsuken, a co-development partner of GlaxoSmithKline (GSK) Vaccines. GSK holds an exclusive EB66® license from Valneva in the field of influenza vaccines.

#### VIVA/Screen®:

Following successful completion of antibody discovery work for Sanofi-Pasteur in the first half and the delivery of 3 antibody candidates, 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 a Phase I trial in 2011, combining an additional undisclosed vaccine candidate with the IC31® adjuvant. Current IC31® licenses and collaborations represent a potential of approximately EUR 100m in milestones and future potential mid-digit royalties on sales.





## Financial Review

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 28th, 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 for the first nine months of 2012 and of 2013, the results from the ex-Intercell operations were only included for the four month period starting of June 2013 and are not part of the results for the comparator period of the previous year.

#### THIRD QUARTER 2013 FINANCIAL REVIEW

#### + Revenues and grants

Valneva's third-quarter 2013 revenues and grants were EUR 14.7m, mostly resulting from IXIARO® product sales of EUR 11.4m. Revenues and grants excluding the ex-Intercell operations were EUR 1.0m in Q3 2013 and EUR 1.8m in Q3 2012.

#### + Operating Result

Cost of goods sold - exclusively related to sales of IXIARO® - amounted to EUR 6.6m in Q3 2013, yielding a product gross margin of 41.7%.

Research and development costs in Q3 2013 reached EUR 7.8m compared to EUR 2.6m in Q3 2012. In Q3 2013, R&D expenses included a EUR 5.3m contribution by the ex-Intercell operations. Selling, general, and administrative expenses (SG&A) were EUR 7.0m in Q3 2013, to which the ex-Intercell business contributed EUR 5.7m. Amortization expenses for intangible assets increased to EUR 2.0m in Q3 2013 from EUR 0.7m in Q3 2012. EUR 1.6m of the total amortization expenses in Q3 2013 were related to intangible.

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 EUR 7.2m to EUR 9.6m in Q3 2013 compared to EUR 2.4m in Q3 2012. Ex-Intercell operations contributed for EUR 6.4m to the operating loss in Q3 2013.

#### + Net Result

Valneva's net loss in Q3 2013 reached EUR 10.0m, compared to EUR 2.4m at the same period last year. The EUR 7.5m increase reflects recognition of a EUR 6.7m loss coming from the ex-Intercell business. Excluding this amount, the Group's net loss in Q3 2013 would have increased by EUR 0.8m, or by 32.8%.

#### **NINE MONTHS 2013 FINANCIAL REVIEW**

#### + Revenues and grants

Valneva's aggregate revenues and grants in the first nine months of 2013 increased to EUR 24.4m compared to EUR 4.5m in the same period of the previous year. This increase was due to the contribution of ex-Intercell revenues to the business since June 2013. Revenues and grants excluding the ex-Intercell operations decreased by 3.0% to EUR 4.4m in in the first nine months





of 2013.

#### + Operating Result

Cost of goods sold in the first nine months of 2013 amounted to EUR 10.2m and was exclusively related to sales of IXIARO®/JESPECT®.

Research and development costs in the first nine months of 2013 were EUR 14.8m and included EUR 6.8m contribution by the ex-Intercell operations. Without giving effect to the ex-Intercell contribution, R&D costs in the first nine months of 2013 were EUR 8.0m which compare to EUR 8.8m in the 2012 comparator period. Selling, general, and administrative expenses (SG&A) in the first nine months of 2013 were EUR 12.1m compared to EUR 3.4m in the first nine months of 2012. The ex-Intercell business contributed EUR 7.7m to the increase. Without giving effect to the ex-Intercell contribution, the year-on-year increase in SG&A costs was 32.4% and was due to EUR 1.1m of merger-related costs.

Amortization expenses for intangible assets increased to EUR 3.3m in the first nine months of 2013 from EUR 1.3m in the same period of the previous year. EUR 2.1m of this increase was related to intangible 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 EUR 8.1m to EUR 17.3m for the first nine months of 2013 from EUR 9.3m in the 2012 comparator period. Ex- Intercell operations contributed for EUR 7.8m to the operating loss in the first nine months of 2013.

#### + Net Result

Valneva's net loss in the first nine months of 2013 reached EUR 18.1m, compared to EUR 9.9m at the same period last year. The increase reflects recognition of EUR 8.4m of net loss coming from the ex-Intercell business during the four months since closing of the merger. Excluding this amount, the Group's net loss would have decreased by 2.3% to EUR 9.7m in the first nine months of 2013 from EUR 9.9m in the first nine months of 2012.

#### + Cash flow and Liquidity

Net cash used in operating activities in the first nine months of 2013 amounted to EUR 22.0m 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 amount of trade receivables of EUR 12.3m at quarter-end. The increase in trade receivables resulted primarily from the substantial increase in IXIARO® sales in Q3 2013, and most of the respective amounts have already been collected after the balance sheet date. Cash in-flows from investing activities reached EUR 19.8m in the first nine months of 2013, of which EUR 13.6m were acquired through the stock-for-stock merger with Intercell AG and the remaining in-flow was mainly due to the sale of financial assets. Cash flows from financing activities amounted to EUR 15.8m, resulting primarily from the net proceeds of EUR 38.8m of a capital increase completed in July 2013 and 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 of EUR 28.6m, mainly in connection with the merger and by purchase of treasury shares of EUR 0.6m in connection with the exercise of exit rights of former Intercell shareholders in connection with the merger. Liquid funds at the end of September 2013, stood at EUR 18.2m compared to EUR 12.1m at the end of December 2012 and consisted of cash and short-term deposits. The company expects to strengthen its cash position by re-financing the Q3 loan-repayments, for which it is in advanced negotiations, and with the proceeds of the sale of its CMO facility in Nantes, which should close in the first half of November and by the collection of trade receivables in Q4. Valneva therefore expects to hold liquid funds of more than EUR 40.0 million by year-end.





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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.

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#### 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 requlatory 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.





# Condensed Consolidated Interim Financial Report as of September 30, 2013

### **TABLE OF CONTENTS**

| + | CONDENSED CONSOLIDATED INTERIM INCOME STATEMENT (UNAUDITED)                  | 10 |
|---|--|----|
|   | CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED) | 11 |
| + | CONDENSED CONSOLIDATED INTERIM BALANCE SHEET (UNAUDITED)                     | 12 |
| + | CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENT (UNAUDITED)               | 13 |
|   | CONDENSED CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)    | 14 |
|   | SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL               | 15 |





# CONDENSED CONSOLIDATED INTERIM INCOME STATEMENT (UNAUDITED)

| EUR IN THOUSANDS<br>(EXCEPT PER SHARE AMOUNTS)   | THREE MONTHS ENDED<br>SEPTEMBER 30 |         | NINE MONTHS ENDED<br>SEPTEMBER 30 |         |
|--|------------------------------------|---------|-----------------------------------|---------|
|  | 2013                               | 2012    | 2013                              | 2012    |
| Product sales  | 11,365                             | -       | 16,697                            | -       |
| Revenues from collaborations and   | 2,461                              | 1,032   | 4,870                             | 2,536   |
| licensing  Revenues  | ,                                  | 1,032   | •                                 | ,       |
|  | 13,826                             | •       | 21,567                            | 2,536   |
| Grant income   | 854                                | 718     | 2,784                             | 1,960   |
| Revenues and Grants  | 14,680                             | 1,750   | 24,351                            | 4,496   |
| Cost of goods sold   | (6,625)                            | -       | (10,181)                          | -       |
| Research and development expenses  | (7,816)                            | (2,558) | (14,841)                          | (8,783) |
| General, selling and administrative expenses   | (7,001)                            | (707)   | (12,123)                          | (3,366) |
| Other income and expenses, net   | (855)                              | (162)   | (1,183)                           | (330)   |
| Amortization of intangible assets  | (1,990)                            | (734)   | (3,340)                           | (1,275) |
| OPERATING PROFIT/(LOSS)  | (9,607)                            | (2,411) | (17,318)                          | (9,258) |
| Finance income   | 144                                | 88      | 240                               | 375     |
| Finance expenses   | (506)                              | (67)    | (974)                             | (333)   |
| PROFIT/(LOSS) BEFORE INCOME TAX  | (9,969)                            | (2,390) | (18,052)                          | (9,217) |
| Income tax   | 1                                  | (38)    | (29)                              | (57)    |
| PROFIT/(LOSS) FROM CONTINUING OPERATIONS   | (9,968)                            | (2,428) | (18,082)                          | (9,274) |
| Loss from assets held for sale or discontinued operations                                | 0                                  | 0       | 0                                 | (657)   |
| PROFIT/(LOSS) FOR THE PERIOD   | (9,968)                            | (2,428) | (18,082)                          | (9,931) |
| Earnings/(Losses) from continuing operations per share for profit/(loss) attributable to |                                    |         |                                   |         |
| the equity holders of the<br>Company, expressed in EUR per<br>share - basic and diluted  | (0.19)                             | (0.11)  | (0.52)                            | (0.44)  |





# CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED)

| EUR IN THOUSANDS  | THREE MONTHS ENDED<br>SEPTEMBER 30 |         |          |         |
|---|------------------------------------|---------|----------|---------|
|   | 2013                               | 2012    | 2013     | 2012    |
| Loss for the period   | (9,968)                            | (2,428) | (18,082) | (9,931) |
| Other comprehensive income/ (loss)  |                                    |         |          |         |
| Items that are or may be reclas sified subsequently to profit or loss             |                                    |         |          |         |
| Currency translation differences  | 1,125                              | 82      | 1,186    | 125     |
| Total items that are or may be re-classified subsequently to profit or loss       | 1,125                              | 82      | 1,186    | 125     |
| Other comprehensive income/ (loss) for the period, net of tax                     | 1,125                              | 82      | 1,186    | 125     |
| TOTAL COMPREHENSIVE LOSS<br>FOR THE PERIOD ATTRIBUTA-<br>BLE TO THE OWNERS OF THE |                                    |         |          |         |
| COMPANY   | (8,842)                            | (2,346) | (16,896) | (9,806) |





# CONDENSED CONSOLIDATED INTERIM BALANCE SHEET (UNAUDITED)

| EUR IN THOUSANDS                             | SEPTEMBER 30, 2013 | DECEMBER 31, 2012 |
|--|--------------------|-------------------|
| ASSETS                                       |                    |                   |
| Non-current assets                           | 189,840            | 38,446            |
| Intangible assets and Goodwill               | 124,869            | 17,371            |
| Property, plant and equipment                | 45,715             | 12,091            |
| Other non-current assets                     | 19,256             | 8,984             |
| Current assets                               | 46,303             | 15,083            |
| Inventories                                  | 6,678              | -                 |
| Trade receivables                            | 12,342             | 1,047             |
| Other current assets                         | 9,104              | 1,979             |
| Current financial assets                     | 0                  | 11,225            |
| Cash and short-term deposits                 | 18,179             | 832               |
| Assets held for sale                         | 5,759              | 137               |
| TOTAL ASSETS                                 | 241,902            | 53,667            |
| EQUITY                                       |                    |                   |
| Capital and reserves attributable to the     |                    |                   |
| Company's equity holders                     | 150,953            | 26,194            |
| Share capital                                | 8,375              | 3,219             |
| Additional capital paid in                   | 198,913            | 62,414            |
| Retained earnings and other reserves         | (38,254)           | (24,598)          |
| Net result for the period                    | (18,082)           | (14,841)          |
| LIABILITIES                                  |                    |                   |
| Non-current liabilities                      | 62,000             | 17,664            |
| Borrowings                                   | 44,735             | 5,073             |
| Other non-current liabilities and provisions | 17,265             | 12,592            |
| Current liabilities                          | 28,767             | 9,808             |
| Borrowings                                   | 6,859              | 1,641             |
| Trade payables and accruals                  | 10,948             | 1,896             |
| Tax and employee-related liabilities         | 5,327              | 1,786             |
| Other current liabilities and provisions     | 5,632              | 4,485             |
| Liabilities classified as held for sale      | 183                | -                 |
| TOTAL LIABILITIES                            | 90,950             | 27,472            |
| TOTAL EQUITY AND LIABILITIES                 | 241,902            | 53,667            |





# CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENT (UNAUDITED)

| EUR IN THOUSANDS   | NINE MONTHS ENDED SEPTEMBER 30 |         |
|--|--------------------------------|---------|
|  | 2013                           | 2012    |
| CASH FLOWS FROM OPERATING ACTIVITIES                                 |                                |         |
| Loss for the period  | (18,082)                       | (9,931) |
| Depreciation and amortization  | 5,832                          | 2,752   |
| Share-based payments   | 71                             | 226     |
| Income tax   | 29                             | -       |
| Other adjustments for reconciliation to cash used in                 | 700                            | (1145)  |
| operations   | 389                            | (1,145) |
| Changes in working capital   | (9,060)                        | (682)   |
| Cash used in operations  | (20,819)                       | (8,780) |
| Interest paid  | (918)                          | -       |
| Income tax paid  | (296)                          | -       |
| Net cash used in operating activities                                | (22,033)                       | (8,780) |
| CASH FLOWS FROM INVESTING ACTIVITIES                                 |                                |         |
| Acquisition of other businesses, net cash acquired                   | 11,615                         | (2,753) |
| Purchases of property, plant and equipment                           | (1,190)                        | (2,058) |
| Purchases of intangible assets                                       | (983)                          | -       |
| Proceeds from sale of financial assets                               | 10,035                         | 5,100   |
| Purchases of financial assets  | -                              | (26)    |
| Interest received  | 323                            | 206     |
| Net cash generated from investing activities                         | 19,800                         | 469     |
| CASH FLOWS FROM FINANCING ACTIVITIES                                 |                                |         |
| Proceeds from issuance of common stock, net of                       |                                |         |
| costs of equity transactions   | 38,777                         | 39      |
| Purchase of treasury shares  | (647)                          | -       |
| Proceeds from borrowings   | 6,254                          | 1,500   |
| Repayment of borrowings  | (28,606)                       | (1,182) |
| Net cash generated from financing activities                         | 15,779                         | 357     |
| Net change in cash and cash equivalents                              | 13,545                         | (7,954) |
| Cash at beginning of the period                                      | 832                            | 9,792   |
| Exchange gains/(losses) on cash                                      | 93                             | 87      |
| Cash at end of the period  | 14,470                         | 1,925   |
|  |                                |         |
| Cash, short-term deposits, and financial assets at end of the period | 18,179                         | 15,589  |





# CONDENSED CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

| EUR IN THOUSANDS  | SHARE<br>CAPITAL | SHARE<br>PREMIUM | RETAINED<br>EARNINGS<br>AND<br>OTHER<br>RESERVES | NET<br>RESULT | TOTAL<br>EQUITY |
|---|------------------|------------------|--|---------------|-----------------|
| Balance as of<br>January 1, 2012  | 3,168            | 62,117           | (20,420)   | (4,419)       | 40,446          |
| Total comprehensive loss  |                  | -                | 125  | (9,931)       | (9,806)         |
| Income appropriation  | _                | _                | (4,419)  | 4,419         | -               |
| Employee share option plan  |                  |                  | (1,110)  | .,            |                 |
| - value of employee services  | -                | _                | 226  | -             | 226             |
| - exercise of share options   | 21               | 19               | _  | -             | 40              |
| Treasury shares   | -                | _                | (40)   | -             | (40)            |
|   | 21               | 19               | (4,108)  | (5,512)       | (9,580)         |
| Balance as of<br>September 30, 2012<br>Balance as of                        | 3,189            | 62,136           | (24,528)   | (9,931)       | 30,866          |
| January 1, 2013   | 3,219            | 62,414           | (24,598)   | (14,841)      | 26,194          |
| Total comprehensive loss  | -                | -                | 1,186  | (18,082)      | (16,896)        |
| Income appropriation  | -                | -                | (14,841)   | 14,841        | -               |
| Employee share option plan  |                  |                  |  |               |                 |
| - value of employee services  | -                | 71               | -  | -             | 71              |
| - exercise of share options   | 27               | 214              | -  | -             | 240             |
| Treasury shares   | -                | (646)            | -  | -             | (646)           |
| Issuance of common stock<br>(merger with Intercell see<br>note 7), May 2013 | 2,854            | 100,599          | -  | -             | 103,453         |
| Issuance of common stock,<br>July 2013                                      | 2,275            | 37,913           | -  | -             | 40,188          |
| Cost of equity transactions,<br>net of tax                                  | -                | (1,651)          | -  | -             | (1,651)         |
|   | 5,155            | 136,499          | (13,655)   | (3,241)       | 124,759         |
| Balance as of<br>September 30, 2013   | 8,375            | 198,913          | (38,254)   | (18,082)      | 150,953         |





# SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT (UNAUDITED)

#### 1. Basis of preparation

This condensed consolidated interim financial report of Valneva SE (hereafter referred to as "Group") for the first nine months ended September 30, 2013 has been prepared in accordance with International Financial Reporting Standards as adopted by the EU applicable to interim financial reporting (IAS 34) authorising the presentation of selected explanatory notes. In consequence, these condensed consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2012 (registration document filed with AMF under No. D.13-0479 on April 30, 2013 available in French and in English at the company's website: www.valneva.com).

Due to the merger between Vivalis SA and Intercell AG (for more details see note 7), the Group structure of consolidated operations at September 30, 2013 has changed and consequently includes the following companies:

- + Valneva SE (formerly Vivalis SA)
- + Smol Therapeutics SAS
- + Vivalis Toyama Japan KK
- + Valneva Austria GmbH (formerly Intercell Austria AG) with its fully owned subsidiaries:
  - > Intercell USA Inc.
  - Valneva Scotland Ltd (formerly Intercell Biomedical Ltd)
  - > Elatos GmbH

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of euros. However, calculations are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

#### 2. Segment reporting

The Group has identified the following operating segments for purpose of analyzing its business and results:

- + Cell line platform (EB66®)
- + Antibody discovery platform (VivalScreen®)
- + Ex-Intercell operations

In light of the decision to dispose the Drug Discovery business by the end of 2012, the segment "Platform for the development of small molecules (3DScreen)" no longer exists and the relevant items have been consequently reclassified to "discontinued operations" in accordance with IFRS 5.

Following its merger with Intercell AG to form Valneva SE, the Group has added "Ex-Intercell operations" as a new operating segment. The Group is currently performing a comprehensive business integration project which includes the introduction of new financial business reporting structures. As a result of this project, the Group expects further changes in its segment reporting in future financial statements.





Income statement aggregates by segment:

| EUR IN THOUSANDS                              | NINE MONTHS ENDED SEPTEMBER 30 |         |
|---|--------------------------------|---------|
|   | 2013                           | 2012    |
| Revenues and grants by business sector*       | 24,351                         | 4,496   |
| EB66® cell line                               | 2,334                          | 2,447   |
| VivalScreen® technology                       | 1,951                          | 2,049   |
| Ex-Intercell operations                       | 19,989                         | -       |
| Income not attributed to an operating segment | 77                             | -       |
| Net income/(loss) by business sector          | (18,082)                       | (9,274) |
| EB66® cell line                               | (2,134)                        | (3,886) |
| VivalScreen® technology                       | (2,800)                        | (1,849) |
| Ex-Intercell operations                       | (8,376)                        | -       |
| Income not attributed to an operating segment | (4,774)                        | (3,539) |

<sup>\*</sup> no intersegment revenues occurred

#### 3. Fluctuation of revenues

Revenues comprise grant income, revenues from collaborations and licensing and product sales. Revenues have fluctuated in the past and the Company expects that they will continue to fluctuate over different reporting periods in the future.

#### 4. Financial instruments

There were no financial assets in Level 2 and Level 3 as of September 30, 2013. The fair values correspond to the book values of the financial assets and financial liabilities except for the derivatives, composed of rate SWAPs, which are measured at market fair value as at September 30, 2013.

#### 5. Assets and liabilities held for sale

Assets and liabilities held for sale result from the Group's decision to divest its Clinical Manufacturing Operations (CMO) in Nantes and its eMAB® technology in Vienna as a part of its strategy to realize synergies from the merger with Intercell AG. For segment reporting purposes, the CMO business is recorded as part of the EB66 cell line segment and the eMAB® technology is recorded as part of the Ex-Intercell operations segment.

In June 2013, the Group signed a binding term sheet to sell its CMO business to Biological E, a leading Indian biopharmaceutical company for a purchase price of approximately EUR 5 million.

Upon closing of the transaction, assets with a book value of EUR 3,901 thousand and liabilities with a book value of EUR 183 thousand as of September 30, 2013 will transition to the purchaser.





#### 6. Share capital

EUR 27 thousand.

In connection with its merger with Intercell AG to form Valneva SE (see Note 7), the Company issued 17,836,719 new ordinary shares and 17,836,719 new preferred shares, resulting in an overall increase in the share capital of the Company of EUR 2,854 thousand. At the same time, the Company adopted the legal form of a European company (SE), incorporated in Lyon, France.

The new ordinary shares carry the same rights as the existing ordinary shares, including dividend rights as of January 1, 2013. Each preferred share will convert into 0.4810 new ordinary shares upon the issuance before the end of a 7-year period starting on the day of completion of the merger (and subject to certain financial requirements) of a marketing authorization for the Group's Pseudomonas vaccine in the U.S. or in Europe. If the condition is not met within the 7-year period the preferred shares will be cancelled and redeemed at their nominal value of EUR 0.01 per share. In addition, the Company issued 177,423 new ordinary shares in connection with the exercise of stock options during the reporting period, resulting in an increase in the share capital of

On July 4, 2013 Valneva SE completed a capital increase with pre-emptive subscription rights launched in June 2013. The gross proceeds from this financing amounted to EUR 40,188 thousand and resulted from the issuance of 15,165,215 new ordinary shares at an offering price of EUR 2.65 per share. The settlement-delivery and the listing of the new ordinary shares occurred on July 5, 2013. The new ordinary shares carry full rights ("jouissance courante").

On September 30, 2013 the Company's share capital was EUR 8,375 thousand, representing a total number of 54,641,886 ordinary shares with a nominal value of EUR 0.15 per share and 17,836,719 preferred shares with a nominal value of EUR 0.01 per share.

#### 7. Business Combination

On May 28, 2013, the Company completed its merger with Intercell AG. Intercell AG, with its fully owned subsidiaries Intercell Austria AG, Intercell Biomedical Ltd, Intercell USA, Inc. and Elatos GmbH (together "Intercell") is a biotechnology company engaged in the research, development and commercialization of vaccines and monoclonal antibodies against a variety of infectious diseases to tackle high unmet medical needs and reduce suffering across the world.

Intercell's marketed vaccine to prevent Japanese Encephalitis (JE) - IXIARO®/JESPECT® is a next generation vaccine against the most common vaccine-preventable cause of encephalitis in Asia licensed for use in adults and children in more than thirty countries. A comparable vaccine for endemic markets based on Intercell's technology was launched in 2012 by Biological E. Ltd. under the trade name JEEV® in India. Intercell's technology base includes novel platforms, such as the IC31® adjuvant technology and the proprietary human monoclonal antibody discovery system eMAB®, upon which Intercell has entered into strategic partnerships with a number of leading pharmaceutical companies, including Merck & Co., Inc., and Sanofi. The Company's pipeline of investigational products includes a Pseudomonas aeruginosa vaccine candidate (Phase II/III), a vaccine candidate against infections with C. difficile (Phase I) as well as numerous investigative vaccine programs using the Company's IC31® adjuvant, e.g. in a Tuberculosis vaccine candidate (Phase II). Intercell has in-house cGMP capability to manufacture both clinical and commercial biologicals at its fully owned site in Livingston, Scotland. The manufacturing site is currently dedicated to the production of the Company's novel Japanese Encephalitis vaccine. It is licensed and operates under a Manufacturing Authorisation granted by the Medicines and Healthcare products Regulatory Agency (MHRA) and it is also registered by the FDA.





The merger was accomplished through a stock-for-stock exchange of 17,836,719 newly issued ordinary Valneva shares, totalling a fair value of EUR 101.0m, and 17,836,719 newly issued preferred Valneva shares, totalling a fair value of EUR 2.5m.

The acquired assets and liabilities remain located in Austria, UK and USA, and have been included in the Company's assets and liabilities as of June 1, 2013. Intercell was consolidated from June 1, 2013 onwards.

From the merger completion date through September 30, 2013, the acquired business contributed revenue and grants of EUR 19,989 thousand and a net loss of EUR 8,376 thousand to the Group's consolidated income. If the transaction had occurred on January 1, 2013, the Group's consolidated revenues and grants would have been EUR 32,045 thousand, and its net loss would have been EUR 47,494 thousand, of which EUR 14,615 thousand result from non-recurring merger transaction costs and costs related to the repayment of Intercell debt in connection with the merger.

Details of net assets acquired are as follows:

| PURCHASE CONSIDERATION                                     | EUR IN THOUSANDS |
|--|------------------|
| - Fair value of exchange shares issued as ordinary shares  | 100,956          |
| - Fair value of exchange shares issued as preferred shares | 2,497            |
| Total purchase consideration                               | 103,453          |
| Fair value of net assets acquired                          | 103,453          |
| Goodwill   | 0                |

The fair value of the Valneva ordinary and preferred shares issued as consideration for the acquisition of Intercell shares was determined using the opening stock exchange price on the merger completion date.

The fair value of the assets and liabilities acquired through the business combination are as follows:

| EUR IN THOUSANDS                            | FAIR VALUE | ACQUIREE'S<br>CARRYING AMOUNT |
|---|------------|-------------------------------|
| Cash, cash equivalents and financial assets | 16,220     | 16,220                        |
| Property, plant and equipment, hardware     | 39,150     | 39,150                        |
| Intangible assets                           | 111,832    | 62,080                        |
| Other non-current assets                    | 11,299     | 11,299                        |
| Inventories                                 | 10,354     | 10,354                        |
| Trade and other receivables                 | 10,381     | 10,381                        |
| Non-current liabilities                     | (45,772)   | (45,772)                      |
| Trade and other payables                    | (18,592)   | (18,592)                      |
| Other current liabilities                   | (31,419)   | (25,866)                      |
| Net assets acquired                         | 103,453    | 59,254                        |





In the initial accounting for the business combination, the fair values assigned to the identifiable assets and liabilities have been determined on a provisional basis. Any adjustments to those provisional values as a result of completing the initial accounting shall be recognized within twelve months of the acquisition date.

The cash consideration paid, net of cash acquired through the acquisition, is as follows:

| Cash inflow through acquisition                | 13,619 |
|--|--------|
| Cash and cash equivalents in acquired business | 13,619 |
| Cash consideration                             | 0      |
| EUR IN THOUSANDS                               |        |

#### 8. Related parties transactions

During the reporting period, the following related parties' transactions were entered into between Valneva and its shareholders and subsidiaries.

+ On March 20, 2013 the Supervisory Board authorized two guarantees by Grimaud Group (a holder of 21.7% of the Company's ordinary shares) in favour of a lender of the Company to secure a loan of EUR 500 thousand and a credit facility of EUR 50 thousand granted to the Company.

**Translation disclaimer:** This is a free translation into English of the original French language version of the interim financial report provided solely for the convenience of English speaking. While all possible care has been taken to ensure that this translation is an accurate representation of the original French document, this English version has not been audited by the company's statutory auditors and in all matters of interpretation of information, views or opinions expressed therein, only the original language version of the document in French is legally binding. As such, the translation may not be relied upon to sustain any legal claim, nor be used as the basis of any legal opinion and the VALNEVA expressly disclaims all liability for any inaccuracy herein.

