# Q4 Report 2012

intercell
SMART VACCINES

## Intercell AG announces Q4 and preliminary full year 2012 financial results and business update

### Further increase in product sales and reduction of net loss in 2012

### Pediatric approval of Intercell's Japanese Encephalitis vaccine in Europe

### Merger between Intercell AG and Vivalis SA to create Valneva SE progressing well

#### Solid Japanese Encephalitis vaccine performance

» Product sales for IXIARO®/JESPECT®, a vaccine to protect against Japanese Encephalitis (JE), increased by 41.6% to EUR 8.6m in Q4 2012 (compared to EUR 6.1m in Q4 2011); Full year 2012 sales of EUR 26.8m compared to EUR 21.6m in 2011 representing year on year sales growth of 24.2%

» Pediatric indication for IXIARO® was granted Marketing Authorisation by the European Medicines Agency (EMA) and the European Commission (EC)

» Partner Biological E. Ltd. launched JE vaccine with the brand name JEEV® in India

» In the U.S. the pediatric label extension is currently under review by the FDA

#### Q4 and preliminary full year 2012 financial results

» Total revenues in 2012 increased by 8.5% to EUR 35.7m

» R&D expenses reduced by 33.9% to EUR 19.8m

» SG&A expenses stable at EUR 15.8m despite increase in sales and marketing costs and one-time expenses due to announced merger

» Revenue growth and further cost savings led to reduction of full year 2012 net loss to EUR 25.3m compared to EUR 29.3m in 2011

» Cash position of EUR 44.9m at year-end

» Further growth in JEV product sales expected in 2013; financial strategy of targeted R&D spending and reduction of net loss to be continued as part of Valneva

#### Key Financial Figures

| | 3 months ended December 31, | | Year ended December 31, | | |
|---|---|---|---|---|---|
| EUR in thousands | 2012 | 2011 | 2012 | 2011 | 2010 |
| Revenues | 10,072 | 6,980 | 35,665 | 32,884 | 34,215 |
| Net loss | (10,737) | (8,645) | (25,337) | (29,265) | (255,182) |
| Net operating cash flow | (11,354) | (10,918) | (21,726) | (42,858) | (65,120) |
| Cash, short-term deposits and marketable securities, end of period | 44,933 | 50,859 | 44,933 | 50,859 | 86,182 |

Thomas Lingelbach, CEO of Intercell, commented:

*"This is an exciting time for the Company and its shareholders. The solid sales growth for the JE vaccine along with positive news of pediatric approval in Europe and the launch of the vaccine in India, demonstrates the potential for this important vaccine. Following Intercell's shareholder approval of the merger with Vivalis to form Valneva, we can build a leading European biotechnology company with greater scale and diversification, strengthened financial profile, complementary talent and capabilities, and most importantly, to deliver shareholder value."*

**Vienna (Austria), March 5, 2013** – Today, Intercell AG (VSE: ICLL) announced its financial results for Q4 and the preliminary results for the full financial year 2012 and provided a business update.

## BUSINESS HIGHLIGHTS

### Solid IXIARO®/JESPECT® sales growth performance

Full year product sales of IXIARO®/JESPECT®, a vaccine to protect against Japanese Encephalitis (JE), increased to EUR 26.8m in 2012 compared to EUR 21.6m in 2011. This corresponds to a growth of 24.2% for the full year and 41.6% in Q4 2012 (EUR 8.6m) compared to Q4 2011 (EUR 6.1m). The continuous sales growth of IXIARO®/JESPECT® confirms the strong potential of the product.

In February 2013, the European Medicines Agency (EMA) and the European Commission (EC) granted Marketing Authorisation for the pediatric indication for IXIARO®. The EC decision ratifies the positive opinion from the European Committee for Human Medicinal Products (CHMP) in December 2012. The approval in the European Union provides formal Marketing Authorisation for the pediatric indication of IXIARO® in all 27 member states as well as Norway, Liechtenstein and Iceland.

Intercell's next-generation vaccine to protect travelers against JE has been licensed in more than 30 countries worldwide, and is the Company's first product on the market. Extension of the approved indications to include the pediatric age segment in the EU allows the vaccine to be administered to adults and children aged 2 months and above who travel to, or live in, endemic areas. Intercell and its marketing and distribution partners are committed to introducing the IXIARO® product for administration in all approved age groups as soon as possible. In the U.S. the pediatric label extension is currently under review by the FDA.

In September 2012, Intercell's partner Biological E. Ltd. launched the JE vaccine under the brand name JEEV® in India. This is the first time this next-generation Japanese Encephalitis vaccine is available in an endemic country.

Biological E. Ltd. plans to focus its sales efforts of JEEV® primarily on private market customers including pediatricians and general practitioners. To ensure a successful product launch, Biological E. Ltd. has recruited and trained its own sales force, which will initially be fully dedicated to the product.

## R&D PIPELINE PROGRESSION

### Pseudomonas aeruginosa vaccine candidate – a high unmet medical need

Intercell's investigational Pseudomonas aeruginosa vaccine is currently being tested in a pivotal Phase II/III efficacy trial. 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 a randomized, placebo-controlled double-blind study which will enroll a total of 800 ventilated intensive-care unit patients in approximately 40 study sites across five European countries. The study 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 is progressing and first interim data from a futility analysis (planned after approximately 400 patients enrolled) are expected in H2 2013.

The Pseudomonas aeruginosa program is part of Intercell's strategic alliance with Novartis. The trial is being conducted by Intercell and costs are being shared between both parties.

### Clostridium difficile vaccine candidate – leading cause of nosocomial Diarrhea

Intercell's vaccine candidate IC84 to prevent C. difficile infection is currently in the second part of the Phase I clinical trial (Phase Ib). This follows positive first data from a Phase I study (Phase Ia) in a population of healthy adults aged 18-65 years.

This Phase Ib trial will enroll 80 healthy elderly subjects above 65 years of age, representing the main target population for a C. difficile vaccine. Two vaccine concentrations will be tested with and without alum to confirm the vaccine dose and necessity of the adjuvant in the elderly. Following the Phase Ia study in healthy young adults, the vaccination schedule has been modified to potentially optimize the immune response in elderly subjects who might respond differently to the vaccination due to their immunosenescence. The Phase Ib study is progressing according to plan and results are expected in Q2 2013.

### Additional vaccine candidates with high medical need progressing through development

Tuberculosis: In addition to the Phase II study announced in January 2012, the Statens Serum Institut (SSI) and Intercell have initiated a second clinical Phase II study in August 2012 to assess the safety and immunogenicity of the vaccine candidate in healthy adolescents.

The collaboration between SSI and Intercell in the field of Tuberculosis currently includes three clinical vaccine candidates, all formulated with Intercell's IC31® adjuvant.

IC31® adjuvant: The Phase I clinical study (undisclosed indication) by Novartis with the adjuvant IC31® is ongoing. Furthermore, Intercell maintains research collaborations with different partners to evaluate IC31® in new vaccine formulations and additional collaborations have been initiated in the field of cancer.

### Pre-clinical proof of concept for vaccine candidate against Lyme borreliosis

The Company's pre-clinical lead vaccine candidate against Lyme borreliosis is progressing towards pre-clinical proof of concept studies according to plan. The proprietary vaccine candidate, based on a novel technology, has passed all pre-clinical research steps and is moving towards pre-clinical development in preparation for clinical entry in 2014.

Intercell's goal is to develop a new vaccine for the prevention of Lyme borreliosis to meet an important unmet medical need. In Europe, the infectious disease is mainly caused by the three bacterial species Borrelia burgdorferi, Borrelia garinii and Borrelia afzelii, transmitted to humans through the bite of infected ticks. Lyme borreliosis is a multi-systemic infection, which can affect the skin, nervous system, joints and heart. It is a danger to health for humans of every age and also causes an enormous economic burden, primarily because both the treatment and the diagnosis of chronic diseases are difficult. In Europe, there is currently no vaccine available to protect humans against Lyme borreliosis, however, the development of such a vaccine is of major importance.

## CORPORATE/OTHER

In December 2012, the Management Boards of Vivalis and Intercell announced that they have agreed the terms of a merger to create the newly-named Valneva, a leading European biotechnology company in vaccines and antibodies. The merger will create an integrated company with greater scale and diversification, strengthened financial profile, and complementary talent and capabilities.

On February 27, 2013 the Extraordinary General Meeting of Intercell AG approved the proposed merger of equals between Intercell AG and Vivalis SA to create Valneva SE. The Extraordinary General Meeting of Vivalis SA will take place on March 7, 2013.

The merger is expected to close in May 2013, after which Valneva SE intends to launch a EUR 40m capital increase, subject to regulatory approval.

At the time of the announcement of the proposed merger of equals between Vivalis SA and Intercell, Michel Greco, a member of both Intercell's and Vivalis' Supervisory Boards, resigned from the Supervisory Board of Intercell. Upon closing of the merger, he will be a Supervisory Board member of the newly created company Valneva SE.

## FINANCIAL OUTLOOK 2013

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The merger is expected to close in May 2013, after which Valneva SE intends to launch a EUR 40m capital increase, subject to regulatory approval.

Through the proposed merger with Vivalis SA and the planned subsequent financing, the combined company will have a significantly strengthened financial profile and de-risked path to profitability. As part of Valneva, the Company expects continued further growth in JEV product sales and will continue its financial strategy of targeted R&D spending and reduction of net loss.

## Q4 2012 FINANCIAL REVIEW (PRELIMINARY)

### Revenues

Intercell's product sales in the fourth quarter of 2012 increased by 41.6% to EUR 8.6m (Q4 2011: EUR 6.1m). Aggregate fourth quarter 2012 revenues increased by 44.3% to EUR 10.1m driven by increased product sales as well as higher revenues from collaborations, licensing and grants.

### Operating results

Cost of goods sold for Q4 2012 amounted to EUR 8.1m (Q4 2011: EUR 4.5m). This increase was due to higher sales quantities and higher write-offs of finished and unfinished inventory, which negatively impacted the gross margin in Q4 2012.

Research and development (R&D) expenses for Q4 2012 decreased by EUR 1.1m, or 16.5%, to EUR 5.5m (Q4 2011: EUR 6.6m). This decrease mainly resulted from the implementation of a re-structuring and cost-saving program and from timing effects in connection with clinical trial costs.

General, selling and administrative expenses for Q4 2012 increased by 18.4% to EUR 5.4m (Q4 2011: EUR 4.5m), mainly due to additional sales and marketing costs as well as one-time advisory fees and other service expenses in connection with the proposed merger with Vivalis.

Net other operating expenses for Q4 2012, which were primarily due to currency fluctuations, amounted to EUR 0.3m (Q4 2011: net other operating income EUR 0.4m).

Intercell's operating loss for Q4 2012 increased by 11.7% to EUR 9.2m (Q4 2011: EUR 8.2m).

### Net result, finance and tax

Net finance expenses of EUR 1.0m in Q4 2012 (Q4 2011: EUR 0.9m) were mainly due to interest on the convertible debt and other borrowings. In Q4 2012, income tax expenses of EUR 0.5m were reported (Q4 2011: income tax income EUR 0.5m).

The net loss for Q4 2012 was EUR 10.7m (Q4 2011: EUR 8.6m). The net loss per share for Q4 2012 was EUR 0.20 (Q4 2011: EUR 0.18).

## FULL YEAR 2012 FINANCIAL REVIEW (PRELIMINARY)

### Revenues

Intercell's product sales revenues in the full year 2012 increased by EUR 5.2m to EUR 26.8m (2011: EUR 21.6m), or by 24.2%. Aggregate revenues increased by 8.5% compared to 2011 to EUR 35.7m (2011: EUR 32.9m). Revenues from collaborations and licensing decreased by EUR 2.3m to EUR 8.5m (2011: EUR 10.8m) and grant income decreased by EUR 0.1m to EUR 0.4m (2011: EUR 0.6m). Revenues from collaborations and licensing mainly included revenues under Intercell's strategic alliance with Novartis and a payment from GSK in connection with the termination of the collaboration on potential patch vaccines.

### Operating results

Cost of goods sold for the year 2012 amounted to EUR 22.2m (2011: EUR 18.0m) yielding a positive gross margin of EUR 4.6m, or 17.0%, on the Japanese Encephalitis product. The gross margin was negatively impacted by write-offs of finished and unfinished inventory in the fourth quarter.

R&D expenses for the year 2012 decreased by EUR 10.2m, or by 33.9% to EUR 19.8m (2011: EUR 29.9m). This decrease mainly resulted from an R&D pipeline rationalization, implemented as part of the Company's re-structuring and cost-saving program, and from timing effects in connection with clinical trial costs.

General, selling and administrative expenses for the year 2012 remained stable at EUR 15.8m (2011: EUR 15.8m) despite an increase in sales and marketing costs as well as one-time advisory fees and service expenses in connection with the proposed merger with Vivalis.

Net other operating income for the year 2012 was EUR 2.5m (2011: EUR 3.4m). The decrease mainly resulted from positive currency effects in the prior year period.

Intercell's operating loss for the year 2012 decreased by 28.3% to EUR 19.6m (2011: EUR 27.4m) reflecting a significant improvement of the operating performance during the year 2012.

### Net result, finance and tax

The increase of net finance expenses to EUR 5.2m in 2012 (2011: EUR 1.9m) resulted primarily from higher interest expense in connection with the issuance of new debt in Q2 2012. Income tax expense in 2012 was EUR 0.5m (2011: zero) and resulted from tax provisions of the Company's UK subsidiary.

The net loss for the year 2012 was EUR 25.3m, which corresponded to a reduction of EUR 3.9m or 13.4% compared to the same period in 2011 (2011: EUR 29.3m). The net loss per share for the year 2012 was EUR 0.49 (2011: EUR 0.61).

### Cash flows and liquidity

Intercell's net cash used in operating activities in the year 2012 was EUR 21.7m (2011: EUR 42.9m). The significant reduction of operating cash out-flow reflects the progress in operational re-structuring and growth in product sales.

Cash used in investing activities for the year 2012 amounted to EUR 1.3m. In 2011, cash generated from investing activities totaled EUR 12.1m and resulted mainly from the sale of securities. Without giving effect to investments in and proceeds from sale of securities, net cash used in investing activities in the year 2012 was EUR 2.8m (2011: EUR 12.0m) and included the following: EUR 0.6m for purchases of property, plant and equipment, EUR 4.2m for purchases of intangible assets (capitalized development costs), interest received in the amount of EUR 1.1m, and EUR 0.9m proceeds from sale of property, plant and equipment.

Cash generated from financing activities in 2012 was EUR 18.9m (2011: 23.5m) and included net proceeds of EUR 19.7m (after reduction of transaction costs) from a loan provided by BB Biotech and of EUR 13.6m from the issuance of new shares. These financing proceeds were partly offset by repayments of convertible debt of EUR 12.0m and of other borrowings of EUR 1.5m as well as a capital tax payment of EUR 1.5m in connection with an equity financing completed in 2007.

Liquid funds at the end of December 2012 amounted to EUR 44.9m (December 31, 2011: EUR 50.9m) and included cash and short-term deposits of EUR 12.1m as well as marketable securities of EUR 32.8m.

## Company Profile

Intercell AG is a vaccine-biotechnology company with the clear vision to develop and commercialize novel immunomodulatory biologicals to prevent disease and reduce suffering across the world.

Intercell's vaccine to prevent Japanese Encephalitis (JE) – IXIARO®/JESPECT® – is the Company's first product on the market. This is a next generation vaccine against the most common vaccine-preventable cause of encephalitis in Asia licensed 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 and is currently under review for WHO prequalification.

The Company's technology base includes novel platforms, such as the patch-based vaccine delivery system and the proprietary human monoclonal antibody discovery system eMAB®, in addition to well-established technologies upon which Intercell has entered into strategic partnerships with a number of leading pharmaceutical companies, including Novartis, Merck & Co., Inc., and Sanofi.

The Company's pipeline of investigational products includes a development program for the pediatric use of Intercell's JE vaccine IXIARO®/JESPECT® in non-endemic markets. Furthermore, the portfolio comprises different product candidates in clinical trials: a Pseudomonas aeruginosa vaccine candidate (Phase II/III) partnered with Novartis, 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. As such, the facility is subject to routine inspection by the MHRA, FDA and other Competent Authorities in connection with the manufacture, sale and supply of Japanese Encephalitis vaccine (trade name IXIARO®/JESPECT®).

Intercell is listed on the Vienna Stock Exchange under the symbol "ICLL" (U.S. level one ADR symbol "INRLY").

For more information, please visit: www.intercell.com

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## CONDENSED CONSOLIDATED INCOME STATEMENT (UNAUDITED)

| EUR in thousands (except per share amounts) | Three months ended December 31, 2012 | Three months ended December 31, 2011 | Year ended December 31, 2012 | Year ended December 31, 2011 |
|---|---|---|---|---|
| Revenues | 10,072 | 6,980 | 35,665 | 32,884 |
| Product sales | 8,570 | 6,052 | 26,772 | 21,552 |
| Revenues from collaborations, licensing and grants | 1,503 | 928 | 8,893 | 11,332 |
| Cost of goods sold | (8,132) | (4,524) | (22,211) | (17,983) |
| GROSS PROFIT | 1,940 | 2,456 | 13,454 | 14,901 |
| Research and development expenses | (5,488) | (6,573) | (19,770) | (29,927) |
| General, selling and administrative expenses | (5,376) | (4,540) | (15,799) | (15,785) |
| Other income and expenses, net | (293) | 408 | 2,472 | 3,395 |
| OPERATING LOSS | (9,217) | (8,248) | (19,644) | (27,416) |
| Finance income | 68 | 206 | 462 | 2,595 |
| Finance expenses | (1,077) | (1,123) | (5,679) | (4,488) |
| LOSS BEFORE INCOME TAX | (10,225) | (9,165) | (24,861) | (29,309) |
| Income tax | (512) | 520 | (476) | 44 |
| LOSS FOR THE PERIOD | (10,737) | (8,645) | (25,337) | (29,265) |
| Losses per share for loss attributable to the equity holders of the Company, expressed in EUR per share (basic and diluted) | (0.20) | (0.18) | (0.49) | (0.61) |

## CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED)

| EUR in thousands | Three months ended December 31, 2012 | Three months ended December 31, 2011 | Year ended December 31, 2012 | Year ended December 31, 2011 |
|---|---|---|---|---|
| LOSS FOR THE PERIOD | (10,737) | (8,645) | (25,337) | (29,265) |
| Other comprehensive income/(loss) | | | | |
| Items that are or may be reclassified subsequently to profit or loss | | | | |
| Fair value gains/(losses) on available-for-sale financial assets | 227 | (41) | 1,263 | 1,316 |
| Currency translation differences | 57 | (1,042) | 509 | (1,934) |
| Total items that are or may be reclassified subsequently to profit or loss | 284 | (1,083) | 1,772 | (618) |
| Other comprehensive income/(loss) for the period, net of tax | 284 | (1,083) | 1,772 | (618) |
| TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY | (10,453) | (9,728) | (23,565) | (29,883) |

## CONDENSED CONSOLIDATED BALANCE SHEET (UNAUDITED)

| EUR in thousands | December 31, 2012 | 2011 |
|---|---|---|
| ASSETS | | |
| Non-current assets | 114,855 | 118,109 |
| Property, plant and equipment | 40,726 | 44,220 |
| Intangible assets | 62,832 | 62,304 |
| Other non-current assets | 11,296 | 11,481 |
| Deferred income tax assets | - | 104 |
| Current assets | 68,073 | 73,841 |
| Inventory | 7,624 | 9,737 |
| Trade receivables and other current assets | 15,515 | 13,245 |
| Available-for-sale financial assets | 32,796 | 34,486 |
| Cash and short-term deposits | 12,137 | 16,373 |
| TOTAL ASSETS | 182,927 | 191,950 |
| EQUITY | | |
| Capital and reserves attributable to the Company's equity holders | 82,079 | 92,328 |
| Nominal capital | 55,184 | 48,592 |
| Additional capital paid in | 415,784 | 409,061 |
| Other reserves | 25,450 | 23,678 |
| Retained earnings | (414,340) | (389,003) |
| LIABILITIES | | |
| Non-current liabilities | 69,855 | 65,340 |
| Borrowings | 57,400 | 50,105 |
| Other long-term liabilities | - | 152 |
| Deferred income | 12,336 | 15,083 |
| Deferred income tax liabilities | 119 | - |
| Current liabilities | 30,993 | 34,281 |
| Trade and other payables and accruals | 13,540 | 14,712 |
| Borrowings | 14,423 | 13,842 |
| Deferred income | 2,955 | 3,337 |
| Provisions | 75 | 2,389 |
| Total liabilities | 100,848 | 99,621 |
| TOTAL EQUITY AND LIABILITIES | 182,927 | 191,950 |

## CONDENSED CONSOLIDATED CASH FLOW STATEMENT (UNAUDITED)

| EUR in thousands | Year ended December 31, 2012 | 2011 |
|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Loss for the year | (25,337) | (29,265) |
| Depreciation and amortization | 7,228 | 7,519 |
| Impairment fixed assets/intangibles | - | 4,435 |
| Share-based payments | (257) | 1,157 |
| Income tax | 476 | (44) |
| Other adjustments for reconciliation to cash used in operations | 2,262 | 111 |
| Changes in working capital | (2,345) | (24,886) |
| Cash used in operations | (17,973) | (40,973) |
| Interest paid | (3,749) | (1,756) |
| Income tax paid | (3) | (129) |
| Net cash used in operating activities | (21,726) | (42,858) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Acquisition of other businesses | - | (5,000) |
| Purchases of property, plant and equipment | (584) | (1,403) |
| Proceeds from sale of property, plant and equipment | 896 | 29 |
| Purchases of intangible assets | (4,198) | (7,225) |
| Purchases of financial assets | (35,597) | - |
| Proceeds from sale of financial assets | 37,148 | 24,116 |
| Interest received | 1,065 | 1,611 |
| Net cash generated from/(used in) investing activities | (1,269) | 12,127 |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of common stock, net of costs of equity transactions | 12,120 | (61) |
| Proceeds from issuance of convertible bonds, net of transaction costs | - | 32,417 |
| Repayment of convertible bonds | (12,000) | (5,800) |
| Proceeds from other borrowings | 20,212 | 311 |
| Repayment of other borrowings | (1,468) | (3,338) |
| Net cash generated from financing activities | 18,864 | 23,529 |
| Net decrease in cash | (4,131) | (7,203) |
| Cash at beginning of the year | 16,356 | 26,904 |
| Exchange losses on cash | (105) | (3,346) |
| Cash at end of the year | 12,120 | 16,356 |
| Cash, short-term deposits, and marketable securities at end of year | 44,933 | 50,859 |