

**Consolidated 2012 Financial Results**

Net loss from continued operations: €13.0m

Cash and current financial assets: €12.1m

**Nantes & Lyon (France) – 26 March 2013:** VIVALIS (NYSE Euronext Paris: VLS), a biopharmaceutical company, has released its consolidated results (IFRS) for 2012, approved by the Supervisory Board on March 20, 2013. Audit procedures have been done on consolidated accounts with the auditor's report still in process.

The proposed merger between Vivalis and Intercell to form Valneva SE, announced on December 16, 2012, has received broad support from shareholders of both groups since the two EGM have voted over 97% in favor of the merger. The merger is expected to be definitive early May 2013, after the completion of certain administrative tasks. Subject to the approval of the French market authorities, Valneva SE will launch a capital increase shortly after the completion of the merger.

**1 - 2012 Results**

As previously announced, and in line with expectations, total operating income was down 53% from 2011 to €5.9m.

For this same period, recurring operating expenses increased 7% to €17.4m. In consequence, total recurring operating loss rose to €11.4m for 2012 fiscal year, up from €3.7m in 2011, and the net loss from continuing operations to €13.0m, up from €3.0m.

The condensed consolidated financial statements for fiscal year 2012 are presented below.

<i>€ thousands</i> <i>IFRS</i>	<b>FY 2012</b>	<b>FY 2011(*)</b> <b>(**)</b>	<b>Change</b> <b>(%)</b>
<b>Recurring operating income</b>	<b>5,909</b>	12,555	<b>-53%</b>
R&D expenses	12,885	12,165	+6%
SG&A expenses	4,177	3,837	+9%
Other expenses	292	286	+2%
<b>Total recurring operating expenses</b>	<b>17 354</b>	16 289	<b>+7%</b>
<b>Net income/(loss) from continuing operations</b>	<b>-11,445</b>	-3,733	<b>+207%</b>
Net income from non current operations	-1,388	655	<i>Ns</i>
<b>Net income/(loss) from continuing operations</b>	<b>-12,833</b>	-3,078	<b>+317%</b>
Net income from financial operations	<b>-56</b>	58	<i>NS</i>
Tax	-96	-26	+269
<b>Net income from continuing operations</b>	<b>-12,984</b>	-3,046	<b>+326%</b>
Income (loss) from assets held for sale or discontinued operations	-1,856	-1,373	+35%
<b>Net income/(loss)</b>	<b>-14,841</b>	-4,419	<b>+236%</b>
Net income per share (in €)	- 0.61	- 0.14	+336%
<b>Cash and cash equivalents (cash + marketable securities) and current financial assets</b>	<b>12,057</b>	<b>30,555</b>	<b>-61%</b>

\* Restated (IFRS 5)

VIVALIS had launched a program for the search of partners for the development or sale of rights for anti-hepatitis C molecules and the 3D-Screen technology. Because this operation is destined to be sold, financial statements for the period ended 31 December 2011 have been restated according to IFRS 5.

\*\* For 2012, Vivalis decided to change the presentation of its income statement. Fiscal Year 2011 has been restated consequently.

The financial report for 2012, including notably detailed presentations of IFRS accounts, is available at the company's website, [www.vivalis.com](http://www.vivalis.com), under Investors/Financial information/Financial documents.

### **Recurring operating income**

<i>€ thousands IFRS</i>	<b>FY 2012</b>	<b>FY 2011*</b>	<b>Change (%)</b>
Revenue from services	2,139	1,598	+34%
Licensing income (upfront & milestone payments)	1,292	8,666	-85%
<b>Revenue</b>	<b>3,431</b>	<b>10,263</b>	<b>-67%</b>
Revenues from public sources	2,478	2,292	+8%
<b>Recurring operating income</b>	<b>5,909</b>	<b>12,555</b>	<b>-53%</b>
Of which:			
<i>EB66<sup>®</sup> and biomanufacturing</i>	3 455	9 844	-65%
<i>VIVA Screen<sup>™</sup></i>	2 440	2 533	-4%
<i>Unallocated</i>	14	178	NS

\* Restated (IFRS 5)

Recurring operating income came to €5.9m in 2012, down 53% from the same period last year, reflecting a significant decline in revenue from the EB66<sup>®</sup> cell line. As previously announced, this decline was a consequence of the end of revenue recognition from certain licenses in 2012 compared with 2011 in addition to non-recurring revenue in 2011 first half from the exclusive license concluded with GSK for the EB66<sup>®</sup> cell line.

At the same time, revenues from public sources (grants and research tax credit) increased slightly to €2.5m (+8%).

The make-up of recurring operating income evolved significantly from the last year. Revenue from commercial partners accounted for 58% of recurring operating income in 2012, down from 82% one year earlier while revenue from the discovery technologies (VIVA|Screen<sup>™</sup>) accounted for 41% of the total compared with 20% in 2011.

### **Rise in operating expenses remains contained**

VIVALIS pursued its strategy of capital investments. VIVALIS continued to invest in its laboratories in Nantes, Lyon, and Toyama and also launched the first proprietary antibody discovery program in the field of oncology.

The increase in recurring operating expenses remained contained at +7%. This slight increase came both from a 6% increase in R&D expenses and a 9% increase in SG&A expenses. For 2012, R&D expenses represented 74% a stable number compared to 2011.

The increase in R&D expenses is linked to a 17% progression of the costs related to the VIVA|Screen<sup>™</sup> activity between 2011 and 2012 as a result of the development and a full year of activity of the Japanese laboratory.

The increase in SG&A expenses results from the higher fees incurred in continuing to develop and maintain the IP portfolio of Vivalis.

These increases also reflect the following items:

- Staff costs accounted for 40% of total recurring operating expenses in 2012 vs 42% in 2011. The average number of personnel for continuing operations progressed from 97.0 FTE (full-time equivalents) for 2011 to 98.5 FTE (+2%) in 2012. This expense progresses in line (+2%) to reach €7.0m for 2012;
- Between the two periods, expenditures for raw materials and other supplies (including changes in inventory) rose significantly (+25% or +€0.5m). This increase is mainly linked to the development of the VIVA|Screen™ antibody discovery activities, especially in Japan;
- Other purchases and external expenses remained stable (+1%) at €4.1m for 2012 and accounted for 24% of total recurring operating expenses.
- Finally, depreciation and amortization continued to rise (+15% or +€0.5m). This included amortization expenses for the full year in 2012 relating to technologies acquired to form the VIVA|Screen™ antibody discovery platform and investments made throughout 2011 especially the new laboratory in Lyon. These expenses accounted for 21% of total recurring expenses in 2012 vs. 19% for 2011.

On that basis, the loss from continuing operations was €11.4m for 2012, up from €3.7m for the same period last year.

#### **Net results from non-current operations**

This line showing a loss of €1.4m in 2012 gathers the expenses resulting from the proposed Intercell merger. In 2011, the gain resulted to a decrease in the earn-out payment estimated to be paid in the framework of the Humalys acquisition following renegotiation of the agreement terms.

#### **Net financial income and income (loss) from continuing operations**

Net financial income was negative for 2012 (€0.06m) compared with a net financial product of €0.06m for 2011.

In consequence, in 2012, VIVALIS reported a loss from continuing operations of €13.0m, up from €3.0m one year earlier.

#### **Income (loss) from assets held for sale or discontinued operations**

Drug discovery (3D-Screen platform and anti-hepatitis C molecules) showed a loss of €1.9m in 2012, of which €1.1m of exceptional depreciation on intangibles assets, compared with a loss of €1.4m in 2011.

#### **Net income/(loss)**

In consequence, the Group had a net loss of €14.8m in 2012 compared with €4.4m for 2011.

#### **A solid financial structure**

Shareholders' equity at December 31, 2012 was €29.2m compared to €40.4m at 31 December 2011.

Long-term borrowings remained stable at €6.7m at December 31, 2012 compared with €6.8m at December 31, 2011.

Cash and cash equivalents and current financial assets amounted to €12.0m at December 31, 2012 compared with €30.6m at December 31, 2011 and €18.0m at June 30, 2012.

The breakdown for cash burn is as follows: €13.2m for operating activities, €5.3m for investing activities and +€0.1m for financing activities.

Total assets at December 31, 2012 amounted to €53.7m compared to €73.1m at December 31, 2011.

#### **Historical Scientific and Commercial Development Continued to be Strong in 2012**

Primarily, the EB66® cell line has achieved new development milestones in 2012 with:

- The initiation of Phase III clinical trials in Japan for a pandemic flu vaccine developed by Kaketsuken in collaboration with GSK Biologicals for vaccines produced in the EB66<sup>®</sup> cell line,
- A granted marketing authorization given to Kaketsuken for a veterinary vaccine in Japan against egg drop syndrome (“EDS”) produced in EB66<sup>®</sup> cells, and,
- The initiation of a new product registration process for a veterinary vaccine in Europe.

A total of 11 new licenses and agreements were executed in 2012, including Merck Animal Health (USA), Farvet (Peru), Merial (France), BioFactura (USA) and Kyoto Biken (Japan), for use of the EB66<sup>®</sup> cell line for the production of vaccines and monoclonal antibodies, two of which are commercial licenses. Since the company’s inception, this is our highest performing year for licensing, surpassing its own objectives set at beginning of 2012. These new licenses amount to a total of 32 active worldwide EB66<sup>®</sup> licenses.

Lastly, in the beginning of 2012 Sanofi Pasteur launched their third discovery program in the framework of the VIVA|Screen<sup>™</sup> technology agreement (discovery of monoclonal antibodies), signed in June 2010. This agreement has been expanded to include another target, increasing the potential of this strategic agreement and confirming the strong interest of Sanofi for the VIVA|Screen<sup>™</sup> platform. In parallel, Vivalis has initiated its first proprietary discovery program and generated the first monoclonal antibodies against a cancer target. These antibodies have now entered a rigorous selection process.

## **2013 Outlook**

Vivalis expects revenue to increase in 2013 compared to 2012 as a result of its aggressive commercial strategy.

Vivalis will continue to commercialize its technology platforms to:

- Further establish the EB66<sup>®</sup> cell line as a dominant standard for vaccine production, with the signature of six to seven new licenses, of which two will be commercial.
- Increase the penetration of the VIVA|Screen<sup>™</sup> platform with the signature of two new licenses and commercial agreements.

In addition, the company expects its partners to continue progressing in the development of their own products, and within the next 18 months the possible marketing authorization for three royalty bearing products produced in EB66<sup>®</sup> cells: two new veterinary vaccines and the pandemic flu vaccine in Japan. The latter approval, if achieved in the timeframe believed to be by Vivalis, would be the first ever EB66<sup>®</sup> cell line-produced human vaccine to be approved.

Vivalis announced that it intends to divest its CMO activity in 2013. This is expected to decrease the recurring operating expenses of Vivalis by €4.0m on a yearly basis.

Should the merger between Vivalis and Intercell become definitive as expected in early May 2013 to form Valneva SE, it would have a major impact on business with the creation of a European biotech leader in vaccines and antibodies with complementing talents and capabilities, a broad portfolio of product candidates, diversified revenues and enhanced financial strength to fund its future growth.

*Franck Grimaud, CEO and Majid Mehtali, CSO, co-managers of VIVALIS, concluded, "2012 has been a pivotal year for VIVALIS and we are very excited to team up with Intercell to consolidate and accelerate our growth over the years to come. The assets we have built over the last 12 years provide us with strong foundations to build a European biotechnology leader specialized in vaccines and monoclonal antibodies. Our EB66<sup>®</sup> technology for the production of vaccines has achieved its best year ever with the conclusion of 11 license agreements. Meanwhile our partners have reached significant milestones, including the first marketing authorization received by a veterinary vaccine produced in EB66<sup>®</sup> cells, the initiation of the registration process for a second veterinary vaccine, and the start of a Phase III clinical trial for an influenza vaccine produced in Vivalis' cell line. In our EB66<sup>®</sup> business, we are entering a new development phase where we will receive recurrent revenues from royalties while at the same time our investment decreases as this technology has reached maturity. On our VIVA|Screen<sup>™</sup> technology for the discovery of novel fully human monoclonal antibodies, we have also continued to make progress, both internally and with our partner Sanofi, with the first antibodies delivered to our partner and the initiation of our first internal discovery programs. These assets and this momentum together with the work done at Intercell to refocus the company and develop its vaccines and technologies put us in an ideal situation to boost our growth and offer our shareholders a more secure path to profitability that we target at the 2015 horizon."*

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**Next financial press release: 2013 first-quarter sales  
25 April 2013, after NYSE Euronext market closing**

**About VIVALIS (www.vivalis.com)**

Vivalis (NYSE-Euronext: VLS) is a biopharmaceutical company that provides innovative cell-based solutions to the pharmaceutical industry for the manufacture of vaccines and recombinant proteins, and develops monoclonal antibodies for the prevention and treatment of pathologies with unmet medical needs. Vivalis' expertise and intellectual property are leveraged in two main areas:

**1. EB66<sup>®</sup> Cell Line**

Vivalis offers research and commercial licenses for its EB66<sup>®</sup> cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of therapeutic and prophylactic viral vaccines, virosomes, VLPs and recombinant proteins, with a focus on monoclonal antibodies having enhanced cytotoxic activity. Clinical trials of EB66<sup>®</sup> produced vaccines are currently on-going in the USA and Japan. Through these programs, Vivalis receives upfront payments, clinical stage milestone payments and royalties on licensees' net sales.

**2. VIVA|Screen<sup>™</sup> Human Antibody Discovery Platform**

Customized solutions for the discovery, development and production of rare, fully human monoclonal antibodies are offered by Vivalis. Through these programs, Vivalis receives payments associated with the funding of discovery phase, upfront payments, clinical stage milestone payments, and royalties on net sales of licensed antibodies that are commercially developed and sold by our clients.

Based in Nantes and Lyon (France) and in Toyama (Japan), Vivalis was founded in 1999 by the Grimaud Group (ca. 1,700 employees), one of the worldwide leaders in animal genetic selection. Vivalis has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Transgene, Zoetis, Kaketsuken, Kitasato Daiichi Sankyo Vaccine, Merial, Merck Animal Health and SAFB Biosciences. Vivalis is a member of the French ATLANTIC BIOTHERAPIES and LYON BIOPOLE bio-clusters and a member of the Japanese HOKURIKU INNOVATION CLUSTER FOR HEALTH SCIENCE in Toyama.

**VIVALIS**

Listed on Euronext Paris – Compartment B of NYSE Euronext

Reuters: VLS.PA – Bloomberg: VLS FP

Included in NYSE Euronext's SBF 250, CAC Small 90 and Next Biotech indexes



*This document contains forward-looking statements and comments on the company's objectives and strategies. No guarantee can be given to any of the events anticipated by the forward-looking statements contained in this document, which are subject to inherent risks, including risk factors described in the company's Document E, changes in economic conditions, the financial markets or the markets in which the company operates.*

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