

## 2011 first half results:

Revenue: €4.7m (+165%) Net loss reduced by nearly half

## **Confirmation of 2011 targets**

Signature of 7 new EB66<sup>®</sup> licenses
Signature a new commercial agreement for VIVA|Screen™
Year-end net cash: ~ €30m

Nantes & Lyon (France) – August 30, 2011: VIVALIS (NYSE Euronext Paris: VLS), a biopharmaceutical company, today released its audited consolidated results for the 2011 first-half period ended June 30, 2011 approved by the Supervisory Board on August 29 as well as its strategic outlook.

## 1 - Significant improvement in 2011 first-half results

2011 first half results reflect VIVALIS' sustained development and positive momentum for its different businesses. Driven by a 165% surge in revenue from VIVALIS' core business, total recurring operating income rose 85% to €5.8m versus an increase of only 14% for recurring operating expenses to €8.9m despite reinforced research teams and the integration of the ISAAC technology.

Excluding capital investments and acquisition expenses, cash burn in the first half remained stable (€3.1m) in relation to last year's same period. This good performance was the result of major commercial successes and R&D advances achieved by VIVALIS over the last three years with its EB66® cell line technology for the production of vaccines and therapeutic proteins, and by the development of the human monoclonal antibody discovery technology, VIVA|Screen™.

VIVALIS presents its audited condensed consolidated IFRS financial statements for the 2011 first half.

€ thousands - IFRS	H1 2011	H1 2010	Change (%)
Recurring operating income	5,826	3,152	+85%
Purchase of raw materials & other supplies.	939	1,083	-13%
Other purchases and external expenses	2,339	2,255	+4%
Wages and salaries	3,789	3,334	+14%
Depreciation, amortisation & other operating expenses	1,815	1,123	+62%
Total recurring operating expenses	8,880	7,796	+14%
Net income/(loss) from continuing operations	-3,053,	-4,644	-34%
Non-recurring operating expenses	-	-882	NS
Net financial income/(expense)	-19	-235	-92%
Income/(loss) before tax	-3,072	-5,761	-47%
Tax	-	-163	NS
Net income/(loss)	-3,072	-5,924	-48%
Net income per share (in €)	-0.15	-0.40	-63%
Cash and cash equivalents (cash + marketable securities) and current financial assets	35,970	14,904	+141%

The interim financial report, including notably detailed presentations of IFRS accounts is available at the company's website: www.vivalis.com, under Investors/Financial information/Financial documents.

### Sustained revenue growth in first half

€k - IFRS	H1 2011	H1 2010	Change (%)
Revenue from services	830	507	+64%
Licensing income (upfront & milestone payments)	3,859	1,263	+205%
Revenue	4,688	1,770	+165%
Change in inventory of own production of goods and services	-	21	NS
Own production of goods and services capitalised	38	125	-70%
Operating grants	298	363	-18%
Other income	802	873	-8%
Recurring operating income	5,826	3,152	+85%

Recurring operating income amounted to €5.8m in the 2011 first half, up 85% over last year's same period driven mainly by strong year-on-year revenue growth of 165%.

Operating grants were down €0.1m (-18%) while other income including mainly Research Tax Credit declined slightly by 8% despite increased R&D expenditures after payments made by customers in France and French public entities.

The make-up of recurring operating income evolved significantly from the same prior-year period. Revenue (from commercial partners) accounted for 81% of recurring operating income in the 2011 first half, up from 56% one year earlier.

# Operating expenses: increase kept under control following the acquisition of antibody discovery technologies

In the first six months, VIVALIS continued to pursue its investment strategy both through internal development and external growth. VIVALIS accordingly has continued to invest in its laboratory facilities in Nantes and Lyon, and at the end of April 2011 acquired the ISAAC high-throughput screening (HTS) single-cell antibody discovery technology developed by the Japanese company, SC World. Following this acquisition, VIVALIS opened a subsidiary in Japan with six people to develop agreements in Asia.

These developments were the main factors behind the limited year-on-year increase in recurring operating expenses in the 2011 first half.

As the main operating expense item (nearly 43% of the total), personnel costs rose 14% to €3.8m from the same period one year earlier. This increase resulted from the 16% rise in the average number personnel of VIVALIS Group from 88.2 FTE (full-time equivalents) in the 2010 first half to 102.4 FTE for the same period in 2011.

Between the first six months of 2010 and 2011, expenditures for raw materials and other supplies declined 13% to €0.9m while other purchases and external expenses rose only 4% to €2.3m.

Depreciation, amortisation and provisions rose significantly in the period (+75%) from €0.9m to €1.6.m. This includes depreciation expenses for the new research and development laboratory in Nantes commissioned in June 2010 and related equipment, as well as those for the new antibody discovery technologies acquired in 2010 and 2011.

In the 2011 first half, the breakdown for expenses that was comparable to 2010 reflected VIVALIS' strategic priorities: R&D expenditure totalling €6.8m accounted for 77% of recurring operating expenses and general

and administrative expenses of €2.1m only 23%.

On that basis, the loss from continuing operations improved significantly, declining from €4.6m for the first six months of 2010 to €3.1m for the same period this year.

Non-recurring operating expenses of €0.9m for the 2010 first half reflected the revaluation at June 30, 2010 of debt for the earnout payment in connection with the acquisition of Humalys in January 2010 remeasured after the agreement was signed with Sanofi Pasteur for the discovery of new human monoclonal antibodies announced on June 8, 2010.

As a result, for the 2011 first half, income before taxes represented a loss €3.1m, down from a loss of €5.5m for the same period in 2010.

## Net income/(loss)

Net financial income was nearly positive for the 2011 first half compared with a net expense of €0.2m one year earlier. This improvement reflects a much stronger cash balance compared with the 2010 first half following the rights issue carried out in July 2010.

On this basis, VIVALIS' net loss showed significant improvement, declining 48% to €3.1m from €5.9m one year earlier.

## A healthy and solid financial structure

Shareholders' equity at June 30, 2011 was €41.7m compared to €44.3m at December 31, 2010. Long-term borrowings amounted to €7.6m compared to €6.8m at December 31, 2010.

Cash and cash equivalents and current financial assets amounted to €36.0m at June 30, 2011 compared with €42.5m at December 31, 2011, reflecting well managed cash burn.

The total balance sheet at June 30, 2011 was €79.4m, remaining stable in relation to €79.5m at 31 December 2010.

VIVALIS continues to have a strong financial position to successfully pursue its program for developing proprietary products with high potential for creating value.

# 2 - 2011 first-half operating highlights: sustained pace of scientific and commercial successes and accelerating growth

The 2011 first half saw major developments for each of VIVALIS' core activities, in line with its business model.

# The VIVA|Screen™ platform for human monoclonal antibody discovery strengthened with the acquisition of ISAAC technology developed by SCWorld in Japan

In connection with the collaboration agreement signed in June 2010 with Sanofi Pasteur for the discovery and development of fully human monoclonal antibodies against several infectious disease targets, in January 2011 VIVALIS announced the launch of a second development program. This new agreement highlights strong interest by a major international pharmaceutical group for the VIVA|Screen™ technology developed by VIVALIS in the field of human monoclonal antibodies.

Within the framework of another collaboration agreement focusing on another target, in early 2011, VIVALIS and the Singapore Immunology Network (SIgN), an institute of the Agency of Science, Technology and Research (A\*STAR), discovered two new fully human monoclonal antibodies that may be used to combat the Chikungunya virus. There currently exists no available vaccine or specific treatment for this disease.

Finally, VIVALIS has considerably strengthened its technological leadership in the field of human monoclonal antibodies with the acquisition late April 2011 of the ISAAC high-throughput screening (HTS) single-cell antibody discovery technology based on isolated B-lymphocytes for the discovery of human monoclonal antibodies.

## Ongoing commercial and scientific advances by the EB66® technology platforms

At the same time, commercial momentum for the EB66<sup>®</sup> platform continued with the signature of two new commercial licenses with Kyoto Biken and Transgene for the production of vaccines. VIVALIS also concluded two new research license agreements with Okairos and a company whose name has not been disclosed. These developments confirm the EB66<sup>®</sup> cell line's status as the cell substrate industry standard for the manufacture of viral vaccines. And after GlaxoSmithKline (GSK) received the green light from the US Food and Drug Administration (FDA) in late 2010 for Phase 1 clinical trials, approval to conduct human injections in clinical trials granted by the Japanese health authorities in early 2011 to Kaketsuken, a licensee of GlaxoSmithKline, further reinforced this position.

In addition, the co-exclusive licence EB66<sup>®</sup> concluded between GSK and VIVALIS in 2007 in the influenza vaccine field became a fully exclusive agreement in the first half after the termination of the influenza license agreements with Nobilon and CSL. The now exclusive nature of GSK's influenza license will trigger the payment of other additional milestone payments and higher royalties under the terms of the agreement.

#### **R&D** investments

In addition to the SC World acquisition in Japan, in the first half VIVALIS pursued R&D investments to further accelerate its research programmes and the commercial development of its technologies:

- Reinforcing teams with the addition of 16 new employees devoted in large part to developing the VIVA|Screen™ technology;
- Opening a new research laboratory in Toyama (Japan) following the acquisition of SC World, to accelerate penetration of the Japanese and Asian market;
- Filing three new patent applications to strengthen the intellectual property protection for its technologies and products. During the same period two patents have been granted to VIVALIS.

## 3 - Outlook and objectives

On the strength of 2011 first-half commercial, scientific and financial performances, VIVALIS will pursue its developments and confirms all its annual targets, with certain already met (signature of two commercial licenses for the EB66<sup>®</sup> technology, a new clinical trial for a vaccine product on the EB66<sup>®</sup> cell line, industrialisation of the VIVA|Screen™ platform):

- The signature of 6 to 7 new license agreements for the EB66<sup>®</sup> cell line in 2011 including 2 commercial licenses (with 4 already signed);
- A new clinical trial for a human vaccine product on the EB66<sup>®</sup>: trial already launched for an influenza vaccine in Japan by Kaketsuken;
- A new commercial agreement for antibody discovery:
- Consolidated year-end cash of approximately of €30m after factoring in capital investments of €8m.

Franck Grimaud, CEO and Majid Mehtali, CSO, co-managers of VIVALIS, concluded: "The 2011 first-half was particularly eventful for each of the Company's activities. Commercial and scientific advances drove very strong revenue. Our EB66<sup>®</sup> technology continues to make progress in establishing its position as a solution for replacing the use of eggs in the manufacturing process for both human and veterinarian vaccines as well as for prophylactic and therapeutic vaccines. At the same time, we have been successful in strengthening the performance of the VIVA|Screen™ antibody discovery platform and making progress in our collaboration with Sanofi Pasteur. This first half also was marked by further international expansion with the opening of VIVALIS' first foreign subsidiary in Japan, strengthening our presence with a number of customers we already have in this region. Finally, we continue to have a sound and solid financial position, a significant advantage in the current economic climate. With technological and human assets and our solid financial position, we have thus the resources to pursue VIVALIS' development with considerable confidence and enthusiasm."

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Next financial press release: 2011 third-quarter sales October 20, 2011, 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 proteins, and develops drugs for the prevention and treatment of unmet medical needs. VIVALIS' expertise and intellectual property are leveraged in three main areas:

## 1. EB66<sup>®</sup> Cell Line:

VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of therapeutic and prophylactic viral vaccines, virosomes, VLP's, and recombinant proteins (with a focus on monoclonal antibodies having enhanced cytotoxic activity). EB66® cell line based vaccines are currently in clinical trials in USA and in Japan. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees' net sales.

## 2. VIVA|ScreenTM Human Antibody Discovery Platform

Customized solutions for the discovery, development, and production of fully human monoclonal antibodies are now offered by VIVALIS. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees' net sales.

## 3. <u>3D-Screen Drug Discovery Platform</u>

VIVALIS performs discovery and development, up to pre-clinical evaluation, of original small chemical molecules identified with its proprietary platform, 3D-SCREEN. This unique screening platform is designed to identify original molecules that alter the three-dimensional structure of a target protein, thus modulating its biological function through an innovative mode of action. VIVALIS is building a portfolio of proprietary new chemical entities for the treatment of hepatitis-C virus infection. VIVALIS also proposes, on a fee for service basis, to develop ready to use customized 3D-Screen HTS assays directed against client's target protein of interest.

Based in Nantes & Lyon (France) and in Toyama (Japan) VIVALIS was founded in 1999 by the Grimaud Group (ca. 1,500 employees), a worldwide leader in animal genetic selection. VIVALIS has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Pfizer Animal Health, Kaketsuken, Kitasato Daiichi Sankyo Vaccine, Merial, Intervet, SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES and LYON BIOPOLE bioclusters.

**VIVALIS** 

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

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