

## 2010 First Half Results

### Integration of Humalys

Total revenue from ordinary activities: €1.8m (+28%)

Total ordinary expenses: €7.8m (+22%)

## 2010 Targets Confirmed

Consolidated cash position end of 2010 > €44m

Signature of seven new EB66<sup>®</sup> cell line licenses

Signature of first Humalex<sup>®</sup> commercial agreement

First IND filing of an EB66<sup>®</sup> cell line produced vaccine

**Nantes, Lyon (France) – August 31, 2010** – VIVALIS (NYSE Euronext:VLS), a biopharmaceutical company, today announced its consolidated accounts (IFRS) for the first half of 2010 ended June 30, as well as its strategic perspectives.

## I. 2010 First Half Results

The first half results of 2010 witness the change of dimension of VIVALIS following the Humalys acquisition on January 8, 2010. Despite a significant decrease of grant-derived revenue, total revenue increased 1% between the first half of 2009 and the first half of 2010. Total revenue from services and licenses, representing the heart of VIVALIS activities, increased by 28% while total recurring operating expenses are up 22% as a result of the strengthening of VIVALIS teams and the Humalys integration.

Excluding CAPEX for our new laboratory (€4.2m) and the acquisition of Humalys (€3.7m), cash burn remained limited (€1.6m). This good performance resulted from commercial successes and significant progress made by VIVALIS in R&D over the last three years on our EB66<sup>®</sup> cell line, vaccine and therapeutic protein production technologies, and of the acquisition of Humalys in January 2010.

In July 2010, the successful capital increase enabled an improvement of shareholders' equity of over €29m. VIVALIS gained access to the resources to, among other things, build its own portfolio of monoclonal antibodies it intends to develop up to early clinical stages.

VIVALIS presents its IFRS accounts, including the Humalys consolidation at 100%.

<i>In € thousand IFRS</i>	<b>H1 2010</b>	<b>H1 2009</b>	<b>Var. (%)</b>
<b>Revenue</b>	<b>3 152</b>	3 128	<b>+1%</b>
Purchase of raw materials & other supplies	1 083	888	+22%
Other purchases & external expenses	2 255	1 776	+27%
Wages and salaries	3 334	2 743	+22%
DD&A and other operating expenses	1 123	961	+17%
<b>Total recurring operating expenses</b>	<b>7 796</b>	6 368	<b>+22%</b>
<b>Results from recurring operations</b>	<b>-4 644</b>	-3 240	<b>+43%</b>
Non recurring expenses	-882		NS
Financial results	-235	113	NS
<b>Results before taxes</b>	<b>-5 761</b>	-3 127	<b>+84%</b>
Taxes	-163		NS

<b>Net results</b>	<b>- 5 924</b>	<b>- 3 127</b>	<b>+89%</b>
Net result per share (in €)	-0,41	- 0,22	NS
<b>Cash, cash equivalents, and current financial assets</b>	<b>14 904</b>	<b>24 582</b>	

The first half financial report that includes detailed IFRS accounts is available on the company's website: [www.vivalis.com](http://www.vivalis.com), under Investors/Financial information/Financial reports.

### **Revenue from ordinary activities: further growth over the first half of 2010**

<i>In € million IFRS</i>	<b>H1 2010</b>	<b>H1 2009</b>	<b>Var.</b>
Service revenues	0.5	0.4	+24%
License and milestone revenues	1.3	1.0	+29%
<b>Revenue from ordinary activities</b>	<b>1.8</b>	<b>1.4</b>	<b>+28%</b>
Change in inventory of own production of good and services	0.0		NS
Capitalized production	0.1		NS
Grants	0.4	1.5	- 73%
Other revenues	0.9	0.2	+350%
<b>Total revenue</b>	<b>3.2</b>	<b>3.1</b>	<b>+1%</b>

Total revenue amounted to €3.2m for first half 2010, representing a 1% increase compared with first half of 2009, mainly due to the increase in revenues from ordinary activities that were up by 28% between these two periods. It is reminded that in accordance to IAS18, "up-front payment" revenue and "milestone" revenue are "spread out" over the period of development.

Revenue from grants decreased from €1.5m for first half 2009 to €0.4m (-73%) for first half of 2010, mainly due to the accounting of the OSEO grant for the first half of 2009, which included some catching up over the previous months following the late signature of the agreement. Meanwhile, other revenues, mainly the Research Tax Credit, were up significantly as a result of the increase of the R&D budget and decrease in received grants.

The revenue structure evolved over these two periods. Revenue from ordinary activities (from commercial partners) represented 56% of total revenue for the first half of 2010 vs. 44% for the same period of 2009.

It should be noted that revenue does not accurately reflect VIVALIS' development. It can be irregular from one year to the next, and even from one quarter to the next, as long as VIVALIS does not receive *royalties* on the sale of its licensees' products.

### **Operating Expenses: Controlled Increase Following the Humalys Acquisition**

Over the first half of 2010 VIVALIS continued investing for future activities. Early January 2010, VIVALIS acquired Lyon-based Humalys and their Humalex<sup>®</sup> platform for fully human monoclonal antibody discovery. In June 2010 the construction of VIVALIS's new R&D laboratory in Nantes was also completed.

The 22% increase of recurring operating expenses between the first half 2009 and the first half 2010 resulted mainly from VIVALIS development and the integration of Humalys as part of the group. As a result, the number of employees increased from 70 at the end of June 2009 to 93 a year later, representing a 33% increase. Excluding Humalys, this increase would have been 19% for VIVALIS alone.

Recurring operating expenses were split as follows:

- Raw material purchases increased by +22% to €1.0 million;
- Payroll expenses, representing the main expense line, rose by 22% to €3.3 million. The average

number of FTE's increased by 24 from 64 for the first half of 2009 to 88 for the first half of 2010, 80% of which are dedicated to R&D activities;

- Other purchases and external costs increased 27%, reflecting the strong activity of the company during the first half 2010;
- Depreciations and other operating expenses increased by 17% to €1.1m. Of note is that Humalys goodwill was not split at June 30, 2010 and thus do not generate any expenses over the period.

For the first half of 2010 the structure of expenses remained close to the 2009 structure and is in line with VIVALIS' strategic plan with R&D expenses amounting to €5.9m and representing 76% of total recurring operating expenses. M&S and G&A expenses amounted to €1.9m (24%) of total recurring expenses.

Loss from recurring activities for fiscal 2010 totalled €4.6 million compared to €3.2 million the previous year.

Non-recurring expenses of €0.9m is the re-evaluation of the debt of the success clause (earn-out) of the January 2010 Humalys acquisition that has been reassessed following the signature of the agreement with Sanofi Pasteur for the discovery of new human monoclonal antibodies which was announced on June 8, 2010. Final operating results thus amounted to €-5.5m for the first half 2010.

### **Net Results**

Financial results were a loss of -€0.2m for the first half 2010, compared to a gain of €0.1m for the first half of 2009, reflecting the decrease of interest we earned on our managed cash following a decrease of interest rates.

For the first half of 2010, VIVALIS posted a net loss of -€5.9m vs. -€3.1m for the first half 2009.

### **Sound and Solid Financial Situation**

Total shareholders' equity as of June 30, 2010 amounted to €16.8m vs. €22.6m from December 31, 2009.

In July 2010 VIVALIS launched a rights issue to increase its capital. The success of this provided the Company with over €30 million gross and increased shareholders' equity by over €29 million.

Long term financial debt amounted to €6.9m vs. €6.4m at December 31, 2009.

Following the Humalys integration, total assets as of June 30, 2010 amounted to €54.8m, a significant increase compared to €46.0m from December 31, 2009.

This amount does not include the above mentioned capital increase.

## **II. – Significant Events Over The First Half of 2010: Continued Scientific and Commercial Success Provides Momentum and Acceleration of Growth**

The first half of 2010 has been marked by a change in dimension and acceleration of development in compliance with VIVALIS' business model.

### **Acquisition of Humalys and signature of the first research agreement and commercial license using the Humalex<sup>®</sup> platform**

In early January 2010 VIVALIS announced the acquisition of Lyon-based Humalys and their Humalex<sup>®</sup> technology for the discovery of fully human monoclonal antibodies. Thanks to this acquisition, VIVALIS now has an integrated offering in the antibody field spanning from the discovery to manufacture of preclinical and clinical batches.

In June 2010 VIVALIS signed a first commercial agreement with Sanofi Pasteur for the discovery of human monoclonal antibodies against several undisclosed targets in the anti-infective field using the Humalex<sup>®</sup> platform. This agreement amounts to €35m of *milestones* by target. Several targets will be developed in the anti-infective field by Sanofi Pasteur. In addition, all R&D fees of VIVALIS during this program will be paid for by Sanofi Pasteur. This agreement is the largest agreement signed by VIVALIS to date for a discovery program.

### **EB66® platform**

The commercial momentum of the EB66® platform continued with the signature of two new licenses during the first half of 2010. As of June 30, 2010, VIVALIS has signed 17 commercial licenses for our EB66® technology. One sublicense has also been granted by GSK to Kaketsuken for influenza in Japan and about 10 research licenses have been executed as well.

These results confirm that the EB66® platform continues to evolve as a world-wide platform for vaccine production, replacing egg-based systems and other cell-based systems.

The first half 2010 has also saw the achievement of a major milestone in the collaboration with GlaxoSmithKline Biologicals through the completion of the regulatory characterization tests of the EB66® cell line. .

The milestones achieved over these last months confirm initial timeframes set by VIVALIS and thus expects the first IND filing by one of our licensee of an EB66® produced vaccine before the end of 2010.

### **R&D investment**

In addition to Humalys acquisition, VIVALIS continued to dedicate the majority of its investments into R&D to accelerate its research programs and the commercialization of our platform technologies :

- Strengthening of teams with recruitment of 23 new employees;
- Construction of a new 3,300 m² R&D laboratory in Nantes;
- Filing of three new patents to strengthen the IP position on our technologies and products. Over this same the period, one patent has been granted in New Zealand and the grant of one patent has been validated in 25 European states.

### **3 - Outlook and Objectives**

Based on the commercial, scientific, and financial success achieved over the first half of 2010 and the increase of shareholders' equity, VIVALIS will continue its planned development and confirms its 2010 targets, of which some have been achieved to date (signature of a first commercial agreement on the Humalex® technology):

- Signature of seven new licenses of the EB66® platform over 2010, of which two have been signed over the first half;
- First IND filing of an EB66® cell line produced vaccine by one of our partners;
- Consolidated cash position of over €44 million at the end of 2010, following the capital increase, or €15 million excluding this capital increase.

Franck Grimaud, CEO, and Majid Mehtali, CSO, co-managers of VIVALIS, said: *"The first half of 2010 has been very active and underlines the solid improvement over the last few months. If we had reported revenue under French GAAP, we would have had combined service and license revenues totalling over €4.6 million for the first half, as compared to €4.7 million for all of 2009. We have achieved several milestones in the execution of our development plan, while respecting our cash-conservative business model; Excluding acquisitions and investments, cash burn has been limited to €1.6 million. The acquisition of the Humalex® platform, quickly followed by the first commercial agreement with Sanofi Pasteur is the most lucrative agreement ever signed by VIVALIS. The successful integration of the Humalys team also enables us to strongly accelerate our product development while diversifying our risk. In addition, the EB66® technology continues to be actively promoted and generates strong commercial activity, increasing our market share in the vaccine and therapeutic protein fields for the pharmaceutical industry. The technological and human assets we have generated and the strengthening of our capital structure following the success of our July 2010 capital increase gives us the ability to begin a new stage of development with both confidence and excitement."*

\*\*\*\*\*

**Next Financial Press Release: Third Quarter Revenue  
October 21, 2010, after the close of the NYSE Euronext Market**

## **About VIVALIS ([www.vivalis.com](http://www.vivalis.com))**

VIVALIS (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<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, VLP's, and recombinant proteins (with a focus on monoclonal antibodies having enhanced cytotoxic activity). Through these programs VIVALIS receives upfront, clinical, and milestone payments along with royalties on licensees net sales.

### **2. Humalex<sup>®</sup> Human Antibody Discovery Platform**

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

### **3. 3D-Screen Platform**

VIVALIS performs discovery and early stage development of small molecules identified with VIVALIS' proprietary 3D-Screen platform which identifies target protein conformational modulators. VIVALIS is building a portfolio of proprietary products for the treatment of hepatitis-C infection using this technology.

Based in Nantes (France), VIVALIS was founded in 1999 by the Grimaud Group (ca. 1,500 employees), a world-wide leader in animal genetic selection. VIVALIS has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Merck, CSL, Kaketsuken, Merial, Intervet, SAFC Biosciences. VIVALIS is a member of both the French ATLANTIC BIOTHERAPIES and LYON BIOPOLE bio-clusters.

## **VIVALIS**

Listed on Euronext Paris – Compartment C 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 de référence, changes in economic conditions, the financial markets or the markets in which the company operates.*

## **Contacts**

### **VIVALIS**

Franck Grimaud, CEO

Email: [investors@vivalis.com](mailto:investors@vivalis.com)

### **NewCap**

Financial communications agency

Steve Grobet / Pierre Laurent

Tel.: +33 (0) 1 44 71 94 91

Email: [vivalis@newcap.fr](mailto:vivalis@newcap.fr)