

**2009: commercial and technological successes**  
**Solid financial position confirmed**

**2010 objectives: meeting major new milestones**

7 new licenses of EB66®

1<sup>st</sup> authorization for clinical trials in humans for vaccines manufactured using the EB66® platform

1<sup>st</sup> commercial agreement for the Humalex® platform

Year-end cash position > €15 million

**Nantes (France) – 6 April 2010:** VIVALIS (NYSE Euronext Paris: VLS), a biopharmaceutical company, today announces its audited results approved by the Management Board and reviewed by the Supervisory Board for the fiscal year ended 31 December 2009 and strategic outlook.

**1 - 2009 highlights: scientific and commercial successes**

In fiscal 2009, VIVALIS reinforced the scientific and commercial foundations of its EB66® technology for both the production of vaccines and therapeutic proteins. With a worldwide penetration of the vaccine manufacturing industry of currently more than 75%, the notoriety and position as the future global manufacturing standard of VIVALIS' technology has further strengthened. In the antibody market, there were also major scientific advances, notably in terms of productivity. Finally, VIVALIS has continued to focus on developing proprietary products.

Efforts in 2009 were also devoted to a major transformative undertaking for VIVALIS, the acquisition in early 2010 of Humalys, owner of the Humalex® platform for the generation of human monoclonal antibodies.

**New commercial successes for the EB66® technology**

In 2009, VIVALIS signed 9 new licenses including 3 commercial licenses plus one commercial sub-license granted by GSK to Kaketsuken for Japan. These new agreements both for vaccines and therapeutic proteins highlight once again the interest of all major players in the human and veterinary pharmaceutical industries in the EB66® technology.

With its portfolio of 28 technology licenses (22 for vaccines and 6 for antibodies), at 2009 year-end VIVALIS has solid and convincing foundations for sustained growth.

**Major scientific advances for the EB66® technology**

In the field of vaccines, major milestones were achieved in the period, notably with GSK in connection with the development of influenza vaccines and the completion of the characterization of the cell line.

For antibodies, substantial improvements in productivity were introduced on the EB66® platform. One year ahead of target, VIVALIS had reached a yield exceeding 1 gram per litre and per production campaign at 2009 year-end.

## **Proprietary products developments**

Developments in this area that offer high potential for generating value in the event of success were pursued in line with the roadmap. These included in particular the program for anti-hepatitis C molecules. Advances were achieved in all three programs launched and the objective to have a candidate ready to be licensed in 2010-2011 remains on track.

With the acquisition of the Humalex<sup>®</sup> platform, VIVALIS now has the tools to develop proprietary products in the antibody sector. Along with licensing income from the EB66 technology and the Humalex platform, VIVALIS has added a third strategic growth driver expected to significantly contribute to future earnings, developing proprietary antibody products.

## **Strengthened intellectual property**

Protecting its technology remains a key ongoing priority for VIVALIS. The Group filed 3 patent applications in 2009 and at year-end had a portfolio covering 13 patent families with more than 180 patents.

This intellectual property strategy represents a formidable barrier to entry, especially when added to the considerable technological know-how of its teams.

## **New R&D investment**

VIVALIS has continued to invest in R&D to further accelerate its research programmes and the commercial development of its technologies:

- Recruitment of 25 employees, including 5 with PhDs;
- Equipping of a third production area;
- Launch of construction in the summer 2009 of the new 3,300 m<sup>2</sup> R&D laboratory expected to be operational in mid-2010.

## **Acquisition of Humalys and the Humalex<sup>®</sup> technology: an important new step in the company's development**

In early 2010, VIVALIS acquired the Lyon-based company Humalys, specialised in the generation of human monoclonal antibodies. This acquisition, financed from the Company's own funds and without impacting its financial solidity, will provide VIVALIS significant additional potential for growth and the creation of value. In effect, VIVALIS now has not only a comprehensive and integrated offering of human antibodies with its EB66<sup>®</sup> and CHO cell lines and a biomanufacturing unit for clinical materials, but also one of the last remaining independent technology platforms for the generation of fully human antibodies that will enable it to develop proprietary products.

## **2 - 2009 annual results: important investments and a stronger financial base**

### **Operating income: robust growth in licensing income**

<i>€ thousands French GAAP</i>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>Chan ge (%)</b>
Services	0.2	2.5	0.7	-71%
License fees and milestone payments	0.8	2.9	4.0	+35%
Grants	0.7	0.7	2.1	x3.2
<b>Revenue subtotal</b>	<b>1.7</b>	<b>6.1</b>	<b>6.8</b>	<b>+11%</b>
Capitalised R&D expenditure	1.4	2.1	0.3	-
Expense reclassifications	0.0	0.7	0.3	-
<b>Total operating income</b>	<b>3.2</b>	<b>8.9</b>	<b>7.5</b>	<b>-16%</b>

Operating income for fiscal 2009 totalled €7.5 million, declining 16% from 2008 though representing a multiple of more than 2.3 operating income for 2007. Total revenue from services, license fees, milestone payments plus grants increased 11% between 2008 and 2009 and fourfold between 2007 and 2009. License

fees and milestone payments surged 35% between 2008 and 2009 and fivefold over 2007-2009. On this basis, their contribution to operating income has risen to 53%, up from 33% in 2008 and 25% in 2007. The increasing share of licensing income linked to upfront fees and milestone payments, highlights the scientific and commercial advances achieved by VIVALIS, enhancing visibility for the medium and long-term.

The strong increase in operating grants reflects the recognition of a portion of the amount from the OSEO innovation agency of €1.6 million.

Capitalized research and development expenditure declined significantly in 2009 from the prior year after the majority of R&D expenditures ceased to be recognized under intangible assets once these major programmes advanced to the commercial phase.

It should however be noted that operating income does not have a material impact on VIVALIS' development and may fluctuate significantly from one year to the next and even from one quarter to another until VIVALIS receives royalty fees from the sale of its products by its customers.

## **2009 annual results**

In fiscal 2009 the company pursued its development accompanied by further major capital investments. VIVALIS was able to accelerate its scientific and commercial expansion without however negatively impacting cash and cash equivalents that ended the year up 4% with a balance of €23.6 million at 31 December 2009.

Now that the commercial phase of the EB66<sup>®</sup> platform has begun for the production of vaccines and proteins, virtually no R&D expenditures are capitalized but are instead recognized by VIVALIS directly under operating expenses. This new accounting treatment is the primary reason for the change in net income between 2008 and 2009.

<i>€ thousands French GAAP</i>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>Change (%)</b>
<b>Operating income</b>	3,199	8,916	<b>7,476</b>	<b>-16%</b>
Purchase of raw materials & other supplies.	975	1,172	1,801	+54%
Other purchases & external expenses	2,129	3,893	3,897	0%
Wages and salaries	2,723	3,597	4,690	+30%
Depreciation and amortization	1,291	1,497	1,787	+19%
<b>Operating expenses</b>	<b>7,267</b>	<b>10,396</b>	<b>12,369</b>	<b>+19%</b>
<b>Income/(loss) from ordinary activities</b>	<b>-4,068</b>	<b>-1,480</b>	<b>-4,893</b>	-
Net financial income	280	591	351	-
<b>Income/(loss) from ordinary activities before tax</b>	<b>-4,295</b>	<b>-1,408</b>	<b>-4,411</b>	-
Tax (research tax credit)	+1,027	+1,886	+1,138	-40%
<b>Net income/(loss)</b>	<b>3,268</b>	<b>478</b>	<b>-3,273</b>	-
Net income per share (in €)	-0.28	0.03	-0.22	-
<b>Net cash (cash + marketable securities)</b>	<b>24,956</b>	<b>22,712</b>	<b>23,561</b>	<b>+4%</b>

The corporate report including French GAAP and IFRS accounts is available at the company's website: [www.vivalis.com](http://www.vivalis.com).

## **Operating expenses: an increase reflecting sustained R&D**

To accelerate the scientific and commercial deployment of its technology, VIVALIS maintained the pace of its investments in 2009. In line with these efforts, operating expenses increased 19% from the prior year, reflecting in large part a 20% increase in R&D expenditure to €9.9 million, and split as follows:

- Raw material purchases increased +54% to €1.8 million from a new acceleration in tests of the EB66<sup>®</sup> platform and, in consequence, representing progress towards developing a manufacturing process;
- Payroll expenses rose 30% to €4.7 million on an increase in the average number of employees for 2009 of 14 to a total of 72;
- Other purchases and external charges remained stable through tight control of overhead expenses.

This increase in operating expenses is entirely in line with VIVALIS' priority over the period to focus on R&D and the development of test.

In light of the above, the loss from ordinary activities for fiscal 2009 totalled €4.9 million, up from €1.5 million last year

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

Net financial income declined 40% on the prior year to €0.4 million on reduced investment income from cash and cash equivalents on lower interest rates combined with a marginal increase in debt.

The research tax credit was €1.1 million in the period compared with €1.9 million the last year. This decline does not indicate a deceleration in the pace of R&D investments but rather the receipt of grants and payments from French customers that are deducted from research tax credits.

As a result, VIVALIS had a net loss of €3.3 million in 2009.

### **A healthy and solid financial structure**

Shareholders' equity at 31 December 2009 was €31.1 million. The Company has in addition other equity in the form of subordinated grants for €4.6 million. These amounts correspond to OSEO advances of €2.8 million under the VIVABIO programme in addition to financing received for the portion of the new company premises provided by the Pays de Loire and the Nantes Metropolitan Regions. Total equity increased in consequence from €33.8 million at 31 December 2008 to €35.6 million 2008 at year-end 2009.

Long-term borrowings rose 38% in the year to €6.4 million. VIVALIS' objective at all times is to optimize its development financing structure, notably through bank borrowings. The gross gearing ratio nevertheless remains limited at 20%.

Property, plant and equipment at 31 December 2009 increased 48% to €8.7 million. This increase included notably installations for the new production area plus the recognition of a portion of the expenses for the new R&D laboratory.

The total balance sheet was €49.3 million at 31 December 2009 compared with €45.1 million at 31 December 2008.

Cash and cash equivalents amounted to €23.6 million at 31 December 2009, significantly surpassing the initial objective of €20 million set for 2009 and up 4% from €22.7 million at the end of the 2008.

## **3 - Outlook and objectives**

On the strength of its solid foundation of 28 licenses for the EB66<sup>®</sup> technology that has been enhanced by major scientific and industrial advances and a new platform with significant potential for generating further value, Humalex<sup>®</sup>, VIVALIS has set ambitious targets for 2010:

- Execute 7 new license agreements for the EB66<sup>®</sup> cell line including 2 commercial licenses;
- A first authorization to launch clinical trials in humans for vaccines manufactured using the EB66<sup>®</sup> platform;
- Signature of a commercial agreement for the Humalex<sup>®</sup> platform;
- Year-end cash position of more than €15 million.

For 2011-2012, VIVALIS expects to further accelerate its development and confirm its unique technological position for vaccine production and for developing proprietary products:

- The commercial launch of the first veterinary vaccine produced using the EB66<sup>®</sup> cell line;
- A first authorization to launch clinical trials in humans for antibodies manufactured using the EB66<sup>®</sup> cell line;
- Launch of the first program to develop proprietary monoclonal antibodies;
- Signature of a first at commercial agreement for an anti-Hepatitis C small molecule.

Franck Grimaud, CEO and Majid Mehtali, CSO, co-managers of VIVALIS, concluded: "Over the last two years, VIVALIS has implemented major developments that have progressively transformed its profile. The result is a company that today has a portfolio of 28 licenses, an established reputation and expertise recognized by all key players in the vaccine and antibody markets and that has been enhanced by added value from major scientific advances achieved on its EB66® technology. Its financial profile has also evolved as increasing revenue streams from licensing income progressively contribute to more solid foundations. Finally, through its low cash burn model, it has been successful in maintaining a strong cash position. In this way, VIVALIS is now well prepared for a new phase of significant development, notably in antibody generation with the acquisition of Humalys. We are thus fully confident in the ability of VIVALIS and its teams to pursue the development of the EB66® technology while accelerating projects offering significant potential for shareholder value creation with Humalex®"

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**Next financial press release: 2010 first-quarter sales  
4 May 2010, after NYSE Euronext market closing**

**About VIVALIS ([www.vivalis.com](http://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 viral diseases. VIVALIS' expertise and intellectual property are exploited in three main areas:

1. VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck stem cells, to pharmaceutical and biotechnology companies for the production of vaccines and monoclonal antibodies. VIVALIS receives upfront fees, milestone payments and royalties on its licensees' net sales.
2. Through the Humalex® platform, VIVALIS proposes customers solutions for the generation, development and production of human antibodies. VIVALIS receives upfront fees, milestone payments and royalties on its licensees' net sales.
3. The construction of a portfolio of proprietary products in the area of vaccines and anti-viral molecules (hepatitis C).

Based in Nantes (France), VIVALIS was founded in 1999 by the Grimaud group (1,500 employees), the second largest group worldwide in animal genetic selection. VIVALIS has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Novartis Vaccines, Merck, CSL Kaketsuken, Merial, Intervet, SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES bio-cluster.

**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



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