

Results for the 1st half-year in line with VIVALIS targets and strategy

A solid commercial dynamic: 4 new license agreements since the beginning of 2008

Enhanced financial strength and visibility with a new €6m grant from Oséo through its new strategic industrial innovation support program

Nantes (France) – August 28, 2008

VIVALIS (Euronext Paris: VLS), a biopharmaceutical company that provides to the pharmaceutical industry innovative cell-based solutions for the manufacture of vaccines and proteins, and develops drugs to prevent and treat viral diseases, today announces its results for the 1st half of 2008, ended on June 30, 2008 and a €6m grant from Oséo.

New €6m grant from Oséo

On July 23 last, VIVALIS received a commitment from Oséo (a French organisation that provides assistance and financial support to French SMEs and VSEs in the most decisive phases of their life cycle) for a grant of €6m in the form of a repayable grant and advance, as part of the programme for developing two comprehensive production processes and the manufacture of clinical batches of vaccines and proteins. This programme is linked to a partnership with a partner of the biopharmaceutical industry in the field of antibodies, and with Geovax (USA) in the field of vaccines.

This grant, granted through the new strategic industrial innovation support program of Oséo, will be repayable only if the project is successful. Repayment will be on the basis of a limited percentage on VIVALIS' initial royalty revenue on the first vaccine and the first antibody following market approval, this over a set period.

This grant enhances the financial strength of VIVALIS and its long term visibility, and its capacity to speed up its research and development investments in order to offer the most rapidly to its customers, comprehensive production processes for vaccines and proteins.

Lastly, the participation of VIVALIS in this new program of Oséo demonstrates one more time the innovative character of the breakthrough EBx[®] technology developed by VIVALIS as well in the vaccine production and in the protein production field.

Results for the 1st half of 2008

1 - Results for the 1st half of 2008 in line with VIVALIS targets and strategy

The results for the 1st half of 2008 are a perfect illustration of VIVALIS' strategy implementation, highlighted by its pursuance of its R&D efforts leading to promising results for the EBx[®] technology and some major commercial successes, notably including the signing of 4 new licenses, 2 of them commercial. The growth of operating revenues, with accelerated growth during the 2nd quarter, means that the company is beginning to reap the financial rewards for some promising R&D results obtained with the EBx[®] platform with the triggering of the first milestone payments by VIVALIS' partners.

Operating expenses are up, indicating that major efforts continue to be made in R&D, in terms of recruitment and sales policy. The cash position at the end of June stood at €21.4m, not including the €6m granted by Oséo. So, as of June 30, 2008, VIVALIS enjoyed unique financial visibility, thereby ensuring its development over the next 4 years.

<i>In € thousands</i> <i>French standards</i>	30/06/2008	30/06/2007
Sales	931	940
Other income	1 699	1 053
Total operating revenue	2 630	1 993
Total operating expenses	(4 845)	(3 435)
Income from operations	(2 215)	(1 442)
Current pre tax result	(2 067)	(1 480)
Net result	(1 822)	(1 534)
Net result per share (euro)	(0.13)	(0.17)
Net cash flow variation during the 1 st half-year	(3 601)	(876)
Available cash (Cash flow + VMP)	21 355	920

The detailed accounts for the 1st half of 2008 and the interim financial report are available on the company website at www.vivalis.com, under Investors / Statutory information

Operating revenue

The operating revenue for the 1st half of 2008 stands at €2.6m, as compared with €2m in the first half of 2007. This revenue includes:

- provision of service supplied by the company and the proceeds of license agreements (= sales) amounting to €0.9m, identical to the same period in 2007.
- operating subsidies amounting to €0.3m as compared with €0.2m in the first half of 2007;
- immobilized production, concerning the costs relating to the development programmes, amounting to €1.1m as compared with €0.8m for the same period in 2007, and reflecting the pursuance of a very active research policy;

It should be noted that operating revenue will not be significant of VIVALIS's growth and will vary from year to year, and from quarter to quarter within any single year, for as long as VIVALIS receives no royalties on the sale of products by its customers. In fact, the current revenue is bound to vary from year to year and from quarter to quarter, coming as it does mainly from the initial down payments and milestone payments under the EBx[®] platform license agreements.

Investment grants have not been consolidated in these sums, they are included in non operating income for around €0.1m. The tax credit, which has not been consolidated either, amounts to €0.5m for the 1st half of 2008, a substantial increase as compared with the same period in 2007. This trend takes into account both the changes to the method of calculating the Research Tax Credit (RTC) occurring in 2007 and coming into effect on January 1st 2008, and the reappraisal of the RTC approach within VIVALIS and the thinking on this question at the start of financial year 2008.

Accelerated development leading to a significant increase in operating expenses.

In line with the strategy presented by the company at the IPO in 2007, operating expenses are up due to the company's accelerated development. The strategy being applied since the second half of 2007 is therefore being continued, while preserving a very strict management policy.

Operating expenses amount to €4.8m on June 30, 2008, as compared with €3.4m. This 41.2% rise reflects development efforts on VIVALIS' part. It chiefly concerns two areas:

- payroll expenses which are up 25%, the headcount rising from 46 to 57 staff between the end of June 2007 and the end of June 2008. It stood at 49 at the end of financial year 2007.
- the accelerating pace of programmes also results in an increase in other purchases and external expenses, which had doubled by June 30, 2008 as compared with the same period in 2007, and which notably include non recurring analyses of the EB66[®] cell line Master Cell Bank, and services carried out outside of the company.

General and administrative expenses: they amount to €1.1m or 24 % of VIVALIS corporate operating expenses, in line with the level for the previous financial year. They notably include sales expenditures and the costs involved in protecting VIVALIS intellectual property rights.

Research and development expenses: they amount overall to €3.4m, including expenses invoiced back as part of service agreements, or 76 % of VIVALIS operating expenses. These expenses also include the costs of the pilot clinical batches production unit, accounting for €1.1m of VIVALIS operating expenses. By way of comparison, on December 31, 2007, VIVALIS research and development expenses stood at €5.5m, or 75.8% of corporate operating expenses.

The net loss stands at €1.8m on June 30, 2008 as compared with €1.5m on June 30, 2007 and a loss of €3.3m on December 31, 2007. The expected positive impact on the accounts after changing the method of calculating the RTC has been partly offset by the deduction of new repayable advances expected during the second half of 2008, notably the €6m in grant from Oséo.

A solid capital structure

Cash burn totalled €3.6m for the 1st half of 2008, as compared with €0.9m for the first 6 months of 2007. Due to the capital increase that took place when the company was first listed on the stock exchange in 2007, the net variation in cash in hand for that financial year had been €+23.2m

On June 30, 2008, available cash and saleable financial assets amounted to €21.4m.

The company's shareholders' equity stands at €31.1m.

This amount will enable the company fully to implement the internal development of its activities over the course of the current financial year.

2 – Main events in the 1st half of 2008

- High conclusive R&D results: filing of the Biologics Master File (BMF) for the EB66[®] cell line with the US Food and Drug Administration (FDA) on June 27, 2008.
- Commercial success in the vaccine field: signature of four new agreements, including two commercial licenses.
- Promising results for therapeutic proteins with new license agreements at negotiating stage,
- Enhanced financial visibility with the €6m grant granted by Oséo.

Filing of the BMF

With the filing of the BMF, VIVALIS passed a major hurdle for obtaining regulatory approval of the EBx[®] technology from the health authorities.

This file includes all tests and controls carried out over a period of several months to characterise the EB66[®] cell line, and demonstrated the high level of sanitary quality produced with this innovative technology developed by VIVALIS for manufacturing vaccines and therapeutic proteins. Following the filing of this BMF, all partners of VIVALIS that have signed a commercial license with the Company can file applications for clinical tests for their products expressed on the EB66[®] cell line. In this way, VIVALIS is demonstrating its ability to meet its commitments and the timetable for development announced during the IPO. In the wake of this filing, the first IND applications for clinical testing should be coming through some time in 2009 or early 2010.

Confirmation of the timetable with the world's leading players in the field of vaccines.

The EBx[®] technology is currently being used or tested by 75% of vaccine manufacturers worldwide, including Sanofi Pasteur, GSK, Novartis Vaccines, CSL, Schering Plough (Nobilon), Bavarian Nordic, Kaketsuken, Geovax, Merial, Intervet Schering Plough, Fort Dodge (Wyeth), and Virbac.

4 new agreements have been signed in the field of vaccines since the beginning of 2008:

- a commercial license with Intervet-Schering Plough, the world leader in animal medications,
- a letter of intent for a commercial license with Geovax for their portfolio of AIDS vaccines, and,
- 2 research licenses with Acambis, an independent human vaccine producer, and a new partner whose name has not been made public.

In addition, a research license with the Bavarian Nordic company has been extended. The agreement concerns the production of their recombinant vaccines against measles (in phase I/II clinical studies), RSV (phase I/II) and cancer (phase II).

Lastly, Kaketsuken, a leading company on the Japanese market, has decided to extend its research license to 2 new viruses, taking them to 7 viruses; and the Virbac corporation has taken up an option for a commercial license on 4 biological drugs.

Following the filing of the BMF, laboratories worldwide working in partnership with VIVALIS are now going to be able to file applications for clinical testing of their vaccines or antibodies produced on the EB66[®] cell line. The regulating authorities will be analysing the regulatory dossier describing the therapeutic product, and the BMF file that characterises the EB66[®] cell line. The first authorisations to carry out clinical testing are expected some time in 2009 or early 2010.

To date, taking into account the letter of intent with Geovax, VIVALIS now has 10 commercial licenses and 15 research licenses or partnerships in the field of vaccines with the world's leading players.

EBx[®] platform on the therapeutic protein market: promising results

VIVALIS has continued developing its EBx[®] platform in the field of anti-cancer antibodies, a market valued at \$20 billion in 2006, which is twice the size of the vaccine market. The main focus today is on improving productivity.

One research license and two research agreements are in progress in order to evaluate the production of monoclonal antibodies with the EBx[®] technology by Sanofi-Aventis, Innate Pharma and MAT Biopharma.

In the scope of these 3 partnerships, VIVALIS has demonstrated that the glycosylation profile of monoclonal antibody of IgG1 subtype produced in avian EB66[®] cells is similar to human antibodies glycosylation profile, with the remarkable feature of having a reduced fucose content. This latter feature is known to be associated with a better antibody-dependent cell cytotoxicity activity, a biological activity particularly attractive for treating cancerous cells. Indeed, the pharma and biotech industry is looking for new cell lines to produce monoclonal antibodies with a better therapeutic effect than the traditional CHO cell line.

VIVALIS has also demonstrated that EB66[®] cells can be easily genetically engineered and efficiently produce several antibodies in bioreactors, in an animal serum-free cell culture medium.

These initial results show that EB66[®] avian cells have the potential to constitute a new cellular platform for the production of recombinant proteins, in particular monoclonal antibodies with increased cytotoxic activity. There is a big demand today for monoclonal antibodies having improved biological activities, in order to reduce therapeutic doses and production costs.

To date, VIVALIS now has one research license and two research agreements in the field of therapeutic proteins.

Further agreements in this area are currently at the negotiating stage.

Proprietary products: new promising results in the development of anti-hepatitis C molecules

The anti-hepatitis C molecules development programme is proceeding in line with company expectations.

Screening with VIVATHEQUE (a chemical library of 23,300 molecules) using the proprietary 3D-SCREEN platform has enabled identification of several molecules that inhibit polymerase of the hepatitis C virus, and the anti-viral activity of these molecules has been confirmed in vitro. Characterisation and chemical optimisation of the best "top seed" molecule is underway in partnership with Idealp-Pharma (Lyons, France).

In addition, a new chemical library containing a wide range of 35,000 molecules has been purchased amounting to 36k€, in order to provide a useful complement and enhance the company's molecule collection, and thereby optimise the possibilities of identifying promising new molecules. This new chemical library will also be screened on the 3D-SCREEN platform targeting polymerase and also on the 3D-SCREEN platform targeting the hepatitis C virus protease/Helicase complex. This last target is an important one, being crucial to propagation of the virus, but there is no molecule targeting this complex currently available either on the market or under development.

Strengthening of the intellectual property position

The company has extended to all countries worldwide the patent application covering the EB66[®] duck cell line for all applications and the patent application covering the EB66[®] cell line for its application in the field of protein production.

The company is awaiting the issue of a number of patents in the coming months.

New coverage of VIVALIS shares:

On May 20, 2008, SOCIETE GENERALE initiated coverage of VIVALIS shares with a "Purchase" recommendation and a target price of €8.10.

VIVALIS was already being covered ever since the IPO in June of 2007, by financial analysts at NATIXIS SECURITIES, and then since November 2007 by the PORTZAMPARC brokerage firm.

The coverage initiated by SOCIETE GENERALE is complementary to existing analyses on the company's activity and prospects, and affords it increased visibility with investors institutions.

3 - Prospects

On the strength of results obtained during the 1st half 2008 and given its comfortable cash position, VIVALIS intends to pursue its developments and strategy, now focusing on 4 areas:

- Working together with its different partners to obtain the first IND for a vaccine produced on the EB66[®] cell line by 2009 / 2010,
- Increased productivity with the EB66[®] cell line for anti-cancer antibody production, in order to fast track marketing of technology in this field,
- Signing of further license agreements for the EBx[®] technology thus meeting the target of 7 to 9 new licenses for the year 2008.
- Continued research and development of anti-hepatitis C molecules

The growth of the operating revenue observed for the second quarter 2008 should accelerate during the coming quarters with the payment of milestones by VIVALIS' partners for some major R&D results and the payment of milestones linked to the signature of new license such as Geovax.

VIVALIS CEO, Franck GRIMAUD, concludes: « VIVALIS has signed 4 licenses since the beginning of 2008. Negotiations are in progress for several more licenses both for vaccines and therapeutic proteins. So, the company should easily reach and even pass its objective of 7 to 9 new licenses by year's end. Moreover, in addition to this commercial success, proving the great faith the world's leading players have in the EBx[®] technology, VIVALIS will be pursuing its R&D efforts in the coming months, setting itself the target of having the first IND in the vaccine field by the years 2009 / 2010. Coming with the filing of the BMF with the FDA, the latest highly conclusive and promising results are all factors leading us to expect a rapid acceleration of up-front and milestone payments. Lastly the € 6m grant from Oséo will enable Vivalis to gain expertise and to offer its customers production processes for vaccines and complete proteins, which enable it to draw even greater value from its platform. The VIVALIS proprietary EBx[®] technology is becoming increasingly accepted as a breakthrough technology and as a future standard in the manufacture of vaccines and therapeutic proteins. »

Next official statement:

November 13, after Euronext market closing: 3rd quarter sales

About VIVALIS (www.vivalis.com)

VIVALIS (NYSE- Euronext: VLS) is a biopharmaceutical company that provides to the pharmaceutical industry innovative cell-based solutions for the manufacture of vaccines and proteins, and develops drugs to prevent and treat viral diseases. VIVALIS' knowhow and proprietary technologies are commercially exploited in three main areas:

1. Vaccine development and manufacturing. VIVALIS grants research and commercial licenses to its proprietary EBx[®] embryonic stem cell lines to pharmaceutical and biotechnology companies and to the pharmaceutical industry for the production of viral vaccines.
2. Recombinant therapeutic protein and monoclonal antibody production systems development. VIVALIS licenses to pharmaceutical and biotechnology companies its EBx[®] embryonic stem cell lines to manufacture recombinant therapeutic proteins.
3. The build-up of a proprietary portfolio of vaccines and anti-viral molecules (Hepatitis C).

Based in Nantes (France), VIVALIS was created in 1999 by Group Grimaud (1,450 employees), the n°2 group worldwide in animal genetic breeding. VIVALIS has established several partnerships with companies that are worldwide leaders in their respective fields, including Sanofi Pasteur, GlaxoSmithKline, Novartis Vaccines, Kaketsuken, Merial, SAFB Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES cluster.

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Reuters: **VLS.PA** – Bloomberg: **VLS FP**

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