



## **Consolidated accounts for the first half of 2009**

- **Loramyc® sales triple**
- **submission of a marketing authorization application for Setofilm® in Europe**
- **submission of a new drug application for Loramyc® in the USA**
- **significant progress in the supportive care portfolio**
- **OSEO funding validates the company's innovations**

**Paris, August 26, 2009** – BioAlliance Pharma SA (Euronext Paris – BIO), a company dedicated to the treatment and supportive care of cancer and AIDS patients, today presented its consolidated half-year accounts to June 30, 2009.

Consolidated accounts (Normes IFRS) in thousands of euros	<b>30/06/2009</b>	30/06/2008
Revenues	<b>4,145</b>	4,896
<i>Loramyc sales in France</i>	<b>882</b>	313
Operating profit/loss	<b>(8,952)</b>	(8,991)
Financial profit/loss	<b>134</b>	1,067
Net profit/loss	<b>(8,818)</b>	(7,924)
Available cash and cash equivalents as at June 30, 2009	<b>22,149</b>	

The first half of 2009 was marked by several significant events that testify to the company's progress:

- Submission of a new drug application (NDA) for Loramyc® to the United States Food and Drug Administration (FDA) and a marketing authorization application (MAA) for Setofilm® in Europe.
- The preparation of clinical trial applications (CTAs) for four products (fentanyl Lauriad® for cancer-related pain, AMEP™ in metastatic melanoma, clonidine Lauriad® for post-chemotherapy/post-radiotherapy mucitis and corticoid Lauriad® for erosive lichen planus) for submission by the end of 2009 or in early 2010.
- Progression and completion of recruitment in the first Phase III clinical trial of acyclovir Lauriad® in labial herpes (results expected in Q3 2009).
- Promising preclinical results for the company's programs in cancer (AMEP™ and irinotecan Transdrug®) and AIDS (HIV integrase inhibitor).
- Receipt of €6.4 million in funding from OSEO (the French state innovation agency) for two cancer programs (AMEP™ and Zyxine).

Commenting on BioAlliance Pharma's performance in the first half of 2009, President and CEO Dominique Costantini said: *“Our first product, Loramyc®, is continuing to make progress, with steadily growing sales in France and submission of an NDA for marketing authorization in the United States, which will constitute a key milestone in commercial and financial terms. In the first half of 2010, we should be able to commercialize our second product, Setofilm®, which is currently being registered in 16 countries across Europe. Loramyc® (for the treatment of oropharyngeal candidiasis (OPC) in immune-compromised patients) and Setofilm® (for the treatment of post-chemotherapy and post-radiotherapy nausea and vomiting) are spearheading the high-quality supportive care franchise that BioAlliance is building. With two other products (fentanyl Lauriad® and clonidine Lauriad®) set to enter the clinic before the end of the year, BioAlliance will be able to offer a therapeutic arsenal in a field with many unmet needs and in which innovative approaches will significantly improve patient care. These are significant assets for attracting new corporate partners notably in Europe - a strategic objective for the company”.*

Chief Financial Officer Nicolas Fellmann added: *“We are very proud to have obtained €6.4 million in OSEO funding in the field of invasive cancers for our AMEP™ and Zyxine programs. The grant will part-finance the product development through to market launch. Furthermore, this non-dilutive funding reinforces our short- and medium-term cash position and fits well with other initiatives, such as the Seroplex® co-promotion agreement that we signed with Lundbeck for the second half of the year”.*

#### Analysis of the H1 2009 accounts

Revenues for the first half of 2009 amounted to €4.1 million. In France, Loramyc® posted sales of €0.9 million – a threefold increase on the €0.3 million generated in the first half of 2008. Besides revenues include €3.2 million received under the terms of Loramyc® out-licensing agreements.

In addition to R&D expenditure of €5.2 million, the operating loss of €9 million includes the following items:

- Promotional expenses related to the commercialization of Loramyc® in France.
- A €1.1 million research tax credit (a similar amount to that accounted for during H1 2008).
- Various general and administrative expenses, including intellectual property costs and those related to the ongoing litigation with SpePharm/SpeBio and Eurofins. As of June 30, 2009, BioAlliance Pharma had not made any provisions for potential liabilities related to this litigation.
- IFRS accounting adjustments, including a €0.4 million expense related to the warrants, stock options and free shares awarded by the company (IFRS 2).

The accounts show a financial profit of €0.1 million, compared with €1.1 million in 2008. These amounts correspond mainly to revenue from the sale of short-term investment products used by the company to manage its cash reserves. The significant year-on-year drop was due to both a decrease in available cash reserves and the sharp fall in money market interest rates.

The net loss for the half-year was €8.8 million, versus a loss of €7.9 million for the equivalent period in 2008.

Available cash and cash equivalents stood at €22.1 million as at June 30, 2009, versus €31.7 million as at December 31, 2008. This €9.6 million decrease is essentially due to R&D investments and promotional efforts related to the commercialization of Loramyc®. During the first half of 2009, BioAlliance Pharma also paid \$1.25 million on filing of the NDA for

Loramyc® in the United States, the repayment of which will take place during the second half of 2009. Lastly, during the first half of 2009, the company obtained full reimbursement of the research tax credit owed to it for the period 2004-2008, which amounted to a total of €4.6 million.

#### Post-closing events and outlook

On July 28, 2009, the company announced the submission of a CTA for fentanyl Lauriad® to the French Drug Agency (AFSSaPS) and its approval by the appropriate independent ethics committee (*Comité de Protection des Personnes*). This Phase I clinical trial will start patient recruitment before the end of 2009.

BioAlliance Pharma also announced on August 19<sup>th</sup> 2009 that the FDA has accepted the NDA for miconazole Lauriad® (Loramyc®) Mucoadhesive Buccal Tablets for treating OPC. If the NDA is approved, Strativa Pharmaceuticals (the proprietary products division of Par Pharmaceutical, Inc. (NYSE: PRX), and BioAlliance Pharma's partner for commercialization in the USA) could launch miconazole Lauriad® in the second half of 2010.

Furthermore, BioAlliance Pharma announced that Loramyc® has obtained marketing authorization in Switzerland for the treatment of OPC in immunocompromised patients.

Dominique Costantini stated that *"in the second half of 2009, we shall be focusing our efforts on two priorities: setting up a strategic alliance in Europe for Loramyc® in supportive care and initiating first-in-man trials for several products based on our validated Lauriad® technology and for our biotherapy AMEP™ in the treatment of metastatic melanoma"*.

#### Analyst meeting and conference call (in English)

BioAlliance Pharma will hold a meeting at 9 am Paris time (GMT+1) on Thursday, August 27, 2009, at its corporate headquarters (49 boulevard Martial Valin, Paris, France). A conference call in English will start at 11 am Paris time. The access numbers and codes are given below.

**Conference call dial-in number (from within France and from abroad): +33 (0)1 72 28 01 56**

Replay number: +33 (0)1 72 28 01 49, followed by 296453#

BioAlliance Pharma today announced the filing of its financial report for the half year to June 30, 2009. The half-year financial report, including the consolidated accounts to June 30, 2009, can be viewed in the "Investors" section of the company's web site ([www.bioalliancepharma.com](http://www.bioalliancepharma.com)).

The half-year accounts have been approved by the Executive Board, verified by the statutory auditor and examined by the Supervisory Board on August 26, 2009.

## **About BioAlliance Pharma**

As a preferred partner for hospital-based specialists, BioAlliance Pharma is a company which develops and markets innovative products in France, especially in the fields of opportunistic infections and chemotherapy complications. In areas where medical needs are insufficiently met, our targeted approaches help overcome drug resistance and improve patient health & quality of life. BioAlliance Pharma's ambition is to become a leading player in these fields by coupling innovation to patient needs.

For more information, visit the BioAlliance Pharma web site at <http://www.bioalliancepharma.com>.

## **Disclaimer**

*This communication expressly or implicitly contains certain forward-looking statements concerning BioAlliance Pharma SA and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of BioAlliance Pharma SA to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. BioAlliance Pharma SA is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.*

*For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of BioAlliance Pharma SA to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the 2008 Reference Document filed with the AMF on April 7, 2009, which is available on the AMF website (<http://www.amf-france.org>) or on BioAlliance Pharma S.A.'s website (<http://www.bioalliancepharma.com>).*

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