



## ***BioAlliance Pharma publishes its Q2 2008 turnover***

### ***An expanded commercial presence in Europe***

Paris, 21 July, 2008 – BioAlliance Pharma SA (Euronext Paris ISIN code: FR0010095596–BIO), the specialty pharmaceutical company focused on the treatment of opportunistic infections in cancer and HIV, has published a turnover of €1,749,000 for the second quarter of 2008, compared with €199,000 recorded for the same period in 2007. The company also presented the initial trends for Loramyc® sales in France and its plan for marketing in Europe.

BioAlliance Pharma will host two conference calls tomorrow (Tuesday July 22), including one in English at 9.30am (London time). Connection information is available on BioAlliance Pharma's web site.

As was seen for the first quarter of 2008, the increase in turnover achieved in the second quarter is mainly due to revenue from licensing agreements on Loramyc® (in the United States, Europe and Asia). Initial payments are spread out over time, depending on the terms of the various agreements. Over this period, they represented a total of €1,523,000.

Revenue from direct sales of Loramyc® in the second quarter amounted to €200,000. The increase in number of prescriptions in France has been growing steadily: it grew by more than 35% at the end of March (compared with the end of December 2007) and by 60% at the end of June relative to the end of March. This growth rate confirms the product's progressive market penetration and appropriate response for oropharyngeal candidiasis in immunosuppressed patients, observed mainly in HIV-positive patients and during chemotherapy or radiotherapy in cancer patients.

The company, focused on niche markets in oncology and infectious diseases, has been relying on innovative products with solid advantages:

- A portfolio of 9 promising development programs, designed so that the respective product risks are independent.
- A first marketed product (Loramyc®), now available in four European countries.
- An international strategy set to deploy in the United States (with a positive, pivotal US phase III trial for Loramyc™) and Asia.
- In 2007-2008 alone, signed contracts for Loramyc® represented a potential total of €83 million, plus significant royalties.

The company is pursuing its growth strategy, which is to target several products on the market in 2012 (either from its own portfolio or from targeted acquisitions).

## **Key events in the second quarter of 2008:**

### **Commercial activity in France and Europe:**

- Loramyc® in France:

On the basis on market surveys and previous benchmark launches for supportive care products, the company considers that the launch to specialists (mainly those in hospitals) is going exactly as planned. To date, more than 8,000 patients have received a prescription for Loramyc®. BioAlliance Pharma's ambition in France is to double this number of patients by the end of December 2008. Clinicians and patients both welcome this innovation, designed to give targeted efficacy against oropharyngeal candidiasis in immunosuppressed patients.

Feedback from the medical profession has taught the company that candidiasis is often under-reported by the patient although this pathology worsens the patient's life and makes eating difficult.

In order to find out more about candidiasis, the company (aware of the leadership it can attain in this field) has drawn a Scientific Advisory Committee to set up an epidemiological study called a "candidoscope". This study was carried out with a month of observation of more than 2,000 patients observed in 35 specialist oncology centres. The analysis of this study is under way and clearly provides a lot of information about risk factors for candidiasis and mucitis. Systematic research into this pathology is necessary because the latter alone can compromise anti-cancer treatments and blight the patient's future. This study will give rise to a number of scientific publications in the coming months.

In the second semester, the company intends to intensify its work with specialists for the systematic screening of oral mycosis and the treatment with Loramyc® specifically intended for this pathology.

The overall market for oropharyngeal candidiasis in all 7 industrialised countries was estimated (IMS Health ad hoc study, re-evaluated in 2007) at €330 million. The European market represents 30% of the total. France represents 20% of the European market.

- Loramyc® in Europe:

Preparation for the European launch in the United Kingdom, Germany and Denmark with the European subsidiary SpeBio BV (a joint-venture with the company SpePharm):

During this quarter, the necessary authorisations for reimbursement were obtained in these three countries, with a sales price ranging from €6 to €70, depending on the country. On the operational level, a medical, marketing and sales organisation specifically intended for Loramyc® has been set up with country managers in Germany, the United Kingdom and the Nordic countries, in order to prepare and perform the launch in close coordination with BioAlliance and SpePharm.

The company has since announced the market launch (at the beginning of July) in these three countries.

In terms of the other European countries (Northern countries, Benelux, the Netherlands, Italy and Spain), reimbursement price negotiations with the competent authorities are continuing.

### **Licence Agreements for Loramyc®**

After signing an agreement with Handok Pharmaceuticals for commercialization in Korea, Taiwan, Singapore and Malaysia, the company has continued its licensing policy in Asia and has chosen the company NovaMed Pharmaceuticals for China. NovaMed has a specialized oncology sales force. The BioAlliance – NovaMed partnership will help Loramyc™'s entry in China - a very dynamic, emerging market. The agreement could eventually generate 4.5 million dollars, with a down payment on signature followed by regular instalments. High royalties related to the product's state of progress have also been fixed.

## **Product portfolio under development:**

- The Loramyc® registration file is being prepared for the United States:

In April 2008, the company announced positive preliminary results of its Phase III trial in North America for Loramyc™ (miconazole Lauriad®).

The company is actively continuing the preparation of the final reports for the registration file in the US - a file that requires a full summary of all the European and US preclinical, clinical and pharmaceutical data. The company plans to file an application at the end of 2008, subject to further requirements from the regulatory agencies. The company PAR Pharmaceuticals (which owns the licence for Loramyc® for the United States) is working closely with BioAlliance on this file.

- Phase III acyclovir Lauriad® in recurrent labial herpes:

We are continuing international recruitment in Phase III as planned. In a placebo-controlled trial, the main efficacy endpoint is the time taken to heal the lesions.

European registration is planned for 2009, subject to further requirements from the registration agencies. A further pharmacology trial will be presented to the FDA at the end of 2008, with a view to a marketing application in the USA.

- Phase II/III doxorubicin Transdrug® trial in primary liver cancer:

This quarter, the company has continued to recruit patients internationally in Phase II, and the trial has been continually monitored (as stipulated in the protocol) by the independent Drug Safety Monitoring Board and the Steering Committee.

After the end of the period (on 16 July), the company announced the suspension of this Phase II trial, since the preliminary results prompted the committees to report a clinical benefit but also acute pulmonary adverse events that were more frequent and more serious than expected. The committees recommended suspending the trial due to the incidence of this type of effect.

An investigation is underway in order to evaluate whether risk factors concerning acute pulmonary lesions can be identified. Depending on the results, the committees will decide whether appropriate measures may be taken to prevent or limit the observed undesirable effects.

- Other promising developments in the pipeline:

The company will accelerate entry into the clinic for candidate products from its own portfolio including:

- AMEP™, a biotherapy product used in the treatment of invasive melanomas; results enabling systemic, intramuscular administration were presented last May.
- Irinotecan Transdrug®, for novel oral administration in colon cancer.
- Fentanyl Lauriad®, for severe chronic pain.

Other therapeutic applications (concerning the gingival muco-adhesive pill Lauriad) may also be accelerated especially in new mucitis-related applications in inflammation. This decision will be made at the end of 2008.

The company has a total portfolio of 9 promising programs. All have risks but these risks are independent of each other.

**Acquisition of licensed products for Europe:**

In May 2008, the company announced the acquisition of the European marketing rights for Ondansetron OS (Oral Spray) from the company NovaDel Pharma Inc. (Amex: NVD).

Ondansetron, the leading antagonistic antiemetic 5-HT<sub>3</sub> product, is used to prevent nausea and vomiting caused by chemotherapy, radiotherapy and surgery and is formulated as a pill or a solution for intravenous injection. This active principle could be the first anti-emetic available in Europe in the form of a buccal spray, depending on the success of this development and approval by the regulatory agencies. This innovative deliverance system would be a particularly pertinent therapeutic alternative in Europe for improving quality of life for patients suffering from severe nausea and vomiting. In Europe, anti-emetic treatments represent the most important element of supportive care in oncology and Ondansetron is the most-used product in this class.

This quarter, Strativa (Par Pharmaceutical's specialty branch and a co-manager with NovaDel for the clinical development of this product) has initiated bioequivalence studies in humans vis-à-vis the Ondansetron pill. BioAlliance Pharma will use their US registration dossier for the registration of the product in Europe. The company hopes to submit the drug candidate's European registration file in 2009-2010.

The product fits very well with the company's strategy of expanding its presence in supportive care for oncology patients. In this field, it is essential to have a variety of innovative delivery systems in order to better satisfy the patients' increasing needs.

## **About BioAlliance Pharma**

BioAlliance Pharma SA is a specialty pharmaceutical company focused on the treatment of opportunistic infections in cancer and HIV. The company develops and commercializes innovative products which address resistance issues. The company has launched its first portfolio product (Loramyc®) in France and already received European Marketing Authorizations in UK, Germany, Belgium, Denmark and Luxemburg. The compound has completed the pivotal Phase III clinical development in oropharyngeal candidiasis in the USA. In addition, two other innovative products are currently in Phase III clinical trials: acyclovir Lauriad® in oral herpes (based on the same Lauriad® muco-adhesive technology as Loramyc®, which enables targeted release at the disease site) and doxorubicin Transdrug® in primary liver cancer (based on the Transdrug® nanoparticle technology, designed specifically for intracellular targeting of resistant cells - this trial is currently suspended on the advice from the Data Safety Monitoring Board and Steering Committee, while waiting for additional clinical functional data). The company is also developing a new therapeutic entities program focused on the oncology and infectious disease markets.

In 2007, the company has established strategic alliances for commercializing Loramyc® in Europe (with JV SpeBio) and in the USA with Par Pharmaceutical. In March 2008, BioAlliance Pharma signed a partnership agreement with Handok Pharmaceuticals for commercializing Loramyc® in Korea, Taiwan, Singapore and Malaysia and with Novamed Pharmaceuticals in June 2008 for commercialization of Loramyc™ in China. In May 2008, the company expanded its product portfolio via acquisition of the European commercial rights to ondansetron Oral Spray (OS) from NovaDel Pharma Inc. (Amex: NVD).

For more information, visit BioAlliance Pharma's website at [www.bioalliancepharma.com](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 reference document approved by the AMF on April 11 2008 under the number R. 08-021, which is available on the AMF website (<http://www.amf-france.org>) or on BioAlliance Pharma S.A.'s website (<http://www.bioalliancepharma.com>).*

## **BioAlliance Pharma SA**

Dominique Costantini, President and CEO

Tel.: +33 1 45 58 76 01

[dominique.costantini@bioalliancepharma.com](mailto:dominique.costantini@bioalliancepharma.com)

Nicolas Fellmann, CFO

Tel.: +33 1 45 58 71 00

[nicolas.fellmann@bioalliancepharma.com](mailto:nicolas.fellmann@bioalliancepharma.com)

### **ALIZE RP**

Caroline Carmagnol

Tel.: +33 6 64 18 99 59

[caroline@alizerp.com](mailto:caroline@alizerp.com)