



## BioLineRx: Financial Results for 2010

March 28, 2011

Jerusalem, March 28, 2011. BioLineRx (TASE: BLRX) announces its financial results for 2010.

- 2010 revenue increased to NIS 113.2 million from NIS 63.9 million in 2009
- Cash and short term investments at December 31 2010 were NIS 139.8 million

**Dr. Kinneret Savitsky, BioLine's CEO**, stated, "We are pleased with our achievements and progress during 2010. During the year, we signed an out-licensing agreement with Cypress Bioscience Inc. for the development and commercialization of an additional product from our portfolio - BL-1020 for schizophrenia. This is less than a year following the out-licensing deal we signed in 2009 with Ikaria Inc. for the development and commercialization of BL-1040 - a medical device for patients following myocardial infarction. As previously reported, in our Phase IIb EAGLE study completed in late 2009, BL-1020 demonstrated a statistically significant and clinically relevant improvement in cognitive function in schizophrenia patients, which is particularly noteworthy, as this is an unmet medical need in schizophrenia. We are working in full cooperation with Cypress and are confident in their abilities to conduct the upcoming CLARITY clinical trial - with its primary focus on cognitive function. In addition, we are pleased about the acquisition of Cypress by Royalty Pharma, both in light of Royalty Pharma's vast experience and deep knowledge of the pharmaceutical industry, as well as their financial strength. We are also fully cooperating with Ikaria on the continuation of BL-1040's development and are eagerly anticipating Ikaria's commencement of a first pivotal trial, expected to begin in the second half of 2011, and of a second pivotal trial, which will partially overlap with the first trial."

"We continue to seek additional projects to expand our portfolio. At present our portfolio includes twelve products for a variety of important indications, including central nervous system diseases, oncology, infectious diseases, and cardiovascular and autoimmune diseases. We are investing significant resources to advance our pipeline in the most efficient way possible. In addition, we have ten more early stage projects in our Early Development Program (EDP) pipeline. All this is in line with our business model - to reduce risk and increase our chances of success by simultaneously working on a number of projects, so that we have a continual flow of business opportunities."

### **Significant Events During 2010**

- **BL-1020:** In June 2010, BioLineRx signed an out-licensing agreement with Cypress Bioscience, Inc. for the territory of North America. Under the terms of this agreement, Cypress will manage and finance all future development, including completion of clinical trials, and will be responsible for filing all regulatory applications required for obtaining approval by the FDA and the relevant health authorities in Canada and Mexico. The agreement has a total value of up to \$365 million, in addition to sales royalties. The Company recognized revenue of NIS 113 million (\$30 million) relating to this agreement in 2010. BioLineRx retains the right to all regulatory data produced by Cypress and to use such data for regulatory applications outside North America, whether by BioLineRx or via additional out-licensing agreements signed with other companies. In January 2011, Cypress was acquired by Royalty Pharma, which has expressed its commitment to continue the development of BL-1020 (under the name CYP-1020). Cypress is currently finalizing preparations for an additional clinical trial focusing on cognitive function in schizophrenia. This trial will be double-blind and placebo-controlled, and aims to determine the acute (six-week) and long-term (six-month) anti-psychotic and cognitive efficacy and safety of CYP-1020.
- **BL-1040:** In July 2009, BioLineRx signed an exclusive out-licensing agreement with Ikaria Inc. for continuation of development and commercialization of BL-1040, a unique medical device injected into patients following acute myocardial infarction (under the name IK-5001). This deal has a total value of up to \$282.5 million, in addition to sales royalties. The Company recognized revenue of NIS 64 million (\$17 million) relating to this agreement in 2009. In February 2011, BioLineRx announced that, in accordance with Ikaria's development program, the first pivotal trial, examining efficacy and safety, is expected to begin in the second half of 2011. It will include approximately 270 patients who will be monitored for six months following treatment with BL-1040. In addition, Ikaria is planning a second pivotal clinical, which will be partially overlapping with the first trial.
- **In September 2010**, BioLineRx filed a registration statement for a \$35 million public offering on NASDAQ. The timing, extent and the structure of the offering have not yet been finalized, and the Company will reach a decision regarding the offering based on current developments in the capital markets.
- Developments regarding the remaining assets in BioLineRx's portfolio are summarized later on in this release.

### **2010 Operating Results**

- **Revenues in 2010** increased to NIS 113.2 million, from NIS 63.9 million in 2009. This revenue derived from the initial payment on the out-licensing agreement signed with Cypress for BL-1020, received in August 2010. Revenues in 2009 related to the initial and first milestone payments from the out-licensing deal signed with Ikaria for BL-1040, in the amounts of NIS 26 million and 38 million, respectively.
- **Research and development (R&D) expenses in 2010** were NIS 55.0 million, compared with NIS 90.3 million in 2009. R&D expenses decreased primarily due to completion of most of the clinical trial activity on BL-1020 and BL-1040 during 2009, as well as a reduction in the number of new projects in-licensed during 2009 and the first half of 2010. The Company has invested significant resources to bring in new projects during the latter half of 2010 and in 2011, and believes that development costs will gradually increase during 2011 as a result of these efforts.
- **Operating profit** in 2010 amounted to NIS 13.1 million, compared with an operating loss of NIS 63.3 million in 2009.
- **Net profit** in 2010 amounted to NIS 7.4 million, compared with a loss of NIS 61.5 million in 2009.
- **Cash flows** from operating activities amounted to NIS 40.7 million in 2010, compared with cash used for operating activities of NIS 84.5 million in 2009. The increase in operating cash flows reflects the payment received on the Cypress deal, as well as the decrease in R&D expenses.

## **BioLineRx's Portfolio**

BioLine currently has twelve projects in various pre-clinical and clinical stages.

### **Partnered projects:**

#### **BL-1020 (CYP-1020) for schizophrenia**

BL-1020 is a novel, first-in-class, oral therapeutic for schizophrenia. Pre-clinical and clinical trials to date have shown that BL-1020 is effective at treating schizophrenia symptoms and has a good safety profile. These trials have shown that BL-1020 blocks activity of the neurotransmitter dopamine and enhances the activity of another neurotransmitter, GABA. In addition, clinical trials have shown that BL-1020 improves cognitive function in schizophrenia patients. Many schizophrenia patients suffer from a significant decrease in cognitive function, which is an unmet medical need not addressed by current therapies.

In July 2010, BioLine out-licensed BL-1020 to Cypress Bioscience for continuation of development and commercialization in North America. In January 2011, Cypress was acquired by Royalty Pharma, which has expressed its commitment to continuing the development of BL-1020. Cypress is currently finalizing preparations for an additional clinical trial focusing on cognitive function in schizophrenia.

#### **BL-1040 (IK-5001) for prevention of pathological cardiac remodeling following acute myocardial infarction**

BL-1040 is a unique medical device, injected into patients following acute myocardial infarction, intended for prevention of pathological cardiac remodeling and subsequent congestive heart failure. It is a liquid polymer creating a scaffold within injured cardiac muscle, designed to enhance cardiac mechanical strength during the healing period and prevent pathological ventricular dilation. BL-1040 degrades within several weeks of injection. Pre-clinical studies in various animal models have demonstrated BL-1040's safety and efficacy.

BioLineRx has successfully completed a phase I/II clinical trial, which examined the safety and feasibility of treating patients with BL-1040 following acute myocardial infarction. An Independent Safety Monitoring Board reviewed the data from the study and concluded that the treatment is safe and that clinical development of the device may continue.

Ikaria Inc., which acquired the license for continuation of development and commercialization of BL-1040 from BioLineRx in July 2009, is leading BL-1040's clinical development. BioLineRx recently announced that, in accordance with Ikaria's development program, BL-1040's first pivotal trial, examining safety and efficacy, is expected to commence in the second half of 2011. This trial aims to evaluate the safety and effectiveness of BL-1040 in the prevention of ventricular remodeling and congestive heart failure when administered following AMI. The trial will be a placebo-controlled, double-blind trial including approximately 270 patients. These patients will be treated with BL-1040 following AMI and will then be monitored for six months. The trial is the first of two partially overlapping pivotal clinical trials to be carried out by Ikaria.

### **Clinical-stage projects:**

#### **BL-5010 for non-surgical removal of skin lesions**

BL-5010 is a novel formulation for non-surgical removal of benign skin lesions such as Seborrheic Keratosis, which also enables preservation of the lesion for histological examination. BL-5010 has recently completed a phase I/II clinical trial conducted in 60 patients with Seborrheic Keratosis. The objectives of the study were to determine the safety and efficacy of BL-5010 in completely removing the lesion and to assess the cosmetic outcome of the treatment. The study also aimed at evaluating BL-5010's feasibility in preserving the lesions for subsequent histological examination.

The results of the trial show that, for almost all patients (96.7%), the lesion fell off within 30 days of a single application of BL-5010. Furthermore, the results show that BL-5010 has a good safety profile, as no persistent irreversible adverse effects were observed at the treated site. In addition, most of the investigators and patients who participated in the trial reported that they were very satisfied with the cosmetic outcome of the treatment. 94.6% of the investigators and 84% of the patients stated that the results were good or excellent 180 days following treatment. Histological examination of the lesions showed that BL-5010 enables preservation of the histological structure of the treated lesion.

BioLineRx is currently examining the next steps for BL-5010 from a regulatory, clinical and business perspective.

### **Pre-clinical projects:**

#### **BL-1021 for neuropathic pain**

BL-1021 is an orally available New Chemical Entity (NCE) indicated for the treatment of neuropathic pain. Multiple pre-clinical studies have demonstrated BL-1021's anti-neuropathic profile, its efficacy and high tolerability. Moreover, BL-1021 was found in certain animal models of neuropathic pain to be more effective than currently used drugs.

BioLineRx has recently made the regulatory submissions in Israel for a clinical trial to examine the molecule's safety and has received approval to conduct a phase I trial to examine the safety and pharmacokinetic profile of BL-1021.

#### **BL-4040 for acute kidney injury**

BL-4040 is a protein-based particle composed of the VP1 protein, the major constituent of the Simian Virus 40 (SV40) capsid. BL-4040 protects kidney cells from apoptosis (programmed cell death) induced by kidney injury by boosting the natural stress response and survival pathways in these cells. In pre-clinical trials, BL-4040 has been shown to target the kidneys and to dramatically increase survival and improve kidney function in animal models of acute kidney injury.

BioLineRx is currently performing efficacy studies on BL-4040 in additional models of kidney injury.

#### **BL-5040 for inflammatory bowel disease**

BL-5040 is an effective antagonist of human leptin (a hormone involved in metabolic and inflammatory pathways). Studies performed in animal models of inflammatory bowel disease (IBD) and hepatitis have demonstrated that BL-5040 prevents weight loss and increases food intake due to its anti-inflammatory activity.

Additional advanced efficacy studies are now being carried out on BL-5040.

#### **BL-6010 for type 2 diabetes**

BL-6010 is a first-in-class small molecule for the treatment of type II diabetes. It is a purine receptor agonist that promotes insulin secretion in the presence of glucose by a novel mechanism. Preliminary experiments in animal models of diabetes have demonstrated that BL-6010 induces insulin secretion and reduces hyperglycemia.

BioLineRx is now working on improved synthesis methods for the molecule and intends to perform advanced safety and efficacy studies.

#### **BL-6020 for cancer cachexia**

BL-6020 is a first-in-class small molecule indicated for the treatment of cancer cachexia. *In vitro* studies have shown that BL-6020 is a selective and potent melanocorticotrophin MC-4R inhibitor. Preliminary pre-clinical animal studies have demonstrated that it increases food intake and prevents weight loss. BL-6020 has demonstrated a favorable safety profile in the models tested.

BioLineRx is continuing safety and efficacy studies on the molecule.

#### **BL-6030 for bacterial infections**

BL-6030 is a novel small molecule inhibiting bacterial communication (quorum sensing), which inhibits bacterial biofilm formation. Cell culture studies have demonstrated that BL-6030 inhibits biofilm formation in a number of bacteria. In addition BL-6030 augments the activity of various antibiotics. In an animal model of infected wounds, BL-6030 has been shown to inhibit biofilm formation and assist in its breakdown.

BioLineRx is currently performing additional efficacy studies on BL-6030.

#### **BL-6040 for rheumatoid arthritis**

BL-6040 is a synthetic, non-psychotropic cannabidiol derivative with anti-inflammatory properties. Preliminary experiments in murine models of rheumatic arthritis have shown that BL-6040 has anti-inflammatory activity and reduces symptoms of rheumatoid arthritis.

#### **BL-7010 for celiac disease**

BL-7010 is a novel, non-absorbable, high molecular weight polymer. It has a high affinity for gliadins, the immunogenic peptides present in gluten that cause celiac disease. Experiments in a murine model of celiac disease have shown that BL-7010 prevents pathological damage to the small intestine, helps to preserve the integrity of the intestinal mucosa and reduces inflammation. In addition it has been shown to have no effect on weight gain and to have no other toxic effects.

BioLineRx is now working on improved synthesis methods for the molecule and intends to perform advanced safety and efficacy studies

#### **BL-7020 for psoriasis**

BL-7020 is a protein belonging to the family of insulin-like growth factor binding proteins (IGFBP), intended as a novel intradermal treatment for psoriasis. It has been shown to be involved in the regulation of keratinocyte proliferation and differentiation, processes which are typically abnormal in psoriasis.

### **Early Development Program**

BioLineRx's unique Early Development Program (EDP) was initiated to identify and advance early stage innovative therapeutic projects, particularly in Israel, before their activity has been demonstrated in animal models. Selected projects benefit from funding, guidance and experimentation led by BioLineRx's professional drug development team. The EDP projects receive up to 2 years of funding until sufficient scientific data has accumulated for the project to enter BioLineRx's main pipeline. The EDP is funded by a \$6 million grant from the Pan Atlantic Group and BiolineRx. The program was launched in June 2007 and there are currently 10 projects in its pipeline.

### **About BioLineRx**

BioLineRx Ltd. is a publicly-traded (TASE: BLRX) biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. **BioLineRx's business model** is based on acquiring molecules, mainly from biotechnological incubators and Israeli academic institutions. The next stages, which include feasibility assessment studies and development through pre-clinical and clinical stages, are performed with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium to large pharma companies to continue advanced clinical development and commercialization.

**BioLineRx's current portfolio** consists of three clinical stage candidates (BL-1040, BL-1020 and BL-5010), as well as nine products in various pre-clinical development stages spanning a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases. BioLineRx also operates a unique Early Development Program (EDP) to develop innovative early-stage projects until sufficient data is obtained for entry into the Company's main portfolio.

**To date BioLineRx has signed two out-licensing agreements.** In July 2009, BL-1040, for treatment following acute myocardial infarction, was out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties. BL-1020 (CYP-1020), for schizophrenia treatment, was out-licensed in June 2010 to Cypress Bioscience Inc. for continuation of development and commercialization in North America, for a total deal value of \$365 million, in addition to sales royalties.

For more information about BioLineRx, please visit [www.biolineRx.com](http://www.biolineRx.com).

### **Forward Looking Statement**

*The estimates and judgments included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates, including clinical trial commencement dates, may not*

*be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.*