# BIOLINERX

# **BioLineRx Reports First Quarter 2012 Results**

May 15, 2012

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Jerusalem, May 15, 2012--BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, today reported its results for the quarter ended March 31, 2012.

## Highlights for the First Quarter of 2012:

• BL-7040 - Received approval to commence a Phase 2 clinical trial to evaluate the safety and efficacy of BL-7040 for the treatment of Inflammatory Bowel Disease (IBD); results expected by the end of 2012

• BL-1020 - European patent granted for BL-1020, an orally available molecule for the treatment of schizophrenia, valid through September 2022; CLARITY phase 2/3 trial, with cognition as primary endpoint, progressing on schedule with results expected in mid-2013

• BL-1040 – Announced commencement by Ikaria of PRESERVATION I clinical trial, a CE Mark registration trial for BL-1040 (BCM), a novel medical device for the prevention of cardiac remodeling following an acute myocardial infarction; issue notification received from U.S. Patent and Trademark Office (USPTO) granting almost five years of Patent Term Adjustment, extending BL-1040's patent through at least April 2029

• BL-8020 - Signed a worldwide, exclusive license agreement with Genoscience, a French company focused on viral disease therapeutics, for BioLineRx to develop and commercialize BL-8020, an add-on, synergistic, orally available treatment for Hepatitis C

• BL-8030 - Signed a worldwide, exclusive license agreement with Genoscience and RFS Pharma for BioLineRx to develop and commercialize BL-8030, a second-generation, orally available, NS3 protease inhibitor for the treatment of Hepatitis C

• Capital Raise - \$15 million private placement completed in February; increased base of U.S. healthcare-focused institutional investors

**Kinneret Savitsky, Ph.D., CEO of BioLineRx**, remarked, "We are pleased with the progress achieved during the quarter by our clinical and pre-clinical therapeutic compounds, and are confident in their potential. With respect to our clinical assets, we recently received approval from the Israeli Ministry of Health to commence a Phase 2 clinical trial for BL-7040, which is a key milestone in the development of this promising orally-available treatment for IBD. In addition, a European patent was granted for one of our two leading therapeutic candidates, BL-1020, valid through September 2022. The Phase 2/3 CLARITY clinical trial for BL-1020 is progressing on schedule and we expect it to be completed in mid-2013. In parallel to the trial, we are conducting discussions with potential partners for the out-licensing of this drug, which has demonstrated improved cognitive function in schizophrenic patients."

Dr. Savitsky added, "In January 2012, we announced the commencement of the PRESERVATION I clinical trial, a CE Mark registration trial for BL-1040 (BCM), led by Ikaria. We look forward to the results of this trial during 2013. We were also just informed that the USPTO extended the patent covering BL-1040 through April 2029. This patent extension will be commercially significant for BioLineRx if the compound delivers positive results during the trial and receives the required regulatory approvals. In addition, we continue to have a strong pre-clinical pipeline, and expect at least one program to enter the clinic every 12-24 months. During the first quarter, we signed in-license agreements for two orally-available treatments for Hepatitis C, BL-8020 and BL-8030. We are looking to develop these compounds at an accelerated pace, as we tap into the HCV space, an estimated \$16.5 billion dollar market in 2015. Another promising pre-clinical candidate is BL-7010 for the treatment of celiac disease. We are excited that BL-7010's pre-clinical data demonstrated efficacy and reduction of gluten toxicity, and was published in Gastroenterology, a major medical journal. For the remainder of 2012, we plan to continue the aggressive development of our compounds as they successfully pass each phase of testing, in addition to the continued pursuit of strategic licensing agreements."

"In February 2012, BioLineRx completed a \$15 million private placement to healthcare-focused U.S. institutional investors, following the listing of our American Depositary Shares (ADS) on NASDAQ in mid-2011. We see both of these accomplishments as important steps in the development and growth of our company, as we establish and expand our presence in the global biopharmaceutical industry, in addition to the U.S. financial markets. The financing places us on a secure financial footing, with sufficient capital to implement our approved development plans over the next two years," Dr. Savitsky concluded.

## Financial Results for Q1 2012:

During the three months ended March 31, 2012 and 2011, no revenues were recorded.

Research and development expenses for the three months ended March 31, 2012 were NIS 14.7 million (\$3.9 million), an increase of NIS 8.3 million (\$2.2 million), or 130%, compared to NIS 6.4 million (\$1.7 million) for the three months ended March 31, 2011. The increase resulted primarily from expenses associated with the CLARITY clinical trial in respect of BL-1020, which commenced at the end of June 2011. In addition, the increase reflects a ramp-up in spending on a number of other existing projects, including new projects introduced during 2011 and the ?rst three months of 2012.

Sales and marketing expenses for the three months ended March 31, 2012 were NIS 0.8 million (\$0.2 million), similar to the three months ended March 31, 2011.

General and administrative expenses for the three months ended March 31, 2012 were NIS 3.5 million (\$1.0 million), an increase of NIS 0.6 million (\$0.2 million), or 20%, compared to NIS 2.9 million (\$0.8 million) for the three months ended March 31, 2011. The increase resulted primarily from professional services and travel expenses associated with the Company being listed on NASDAQ since July 2011.

The Company's operating loss for the three months ended March 31, 2012 amounted to NIS 19.0 million (\$5.1 million), compared with an operating loss of NIS 10.1 million (\$2.7 million) for the comparable period in 2011.

Non-operating income for the three months ended March 31, 2012 results from a NIS 4.0 million (\$1.1 million) fair-value adjustment of derivative liabilities on account of the warrants issued in the private placement which the Company conducted in February 2012, offset by issuance expenses in the amount of NIS 1.2 million (\$0.3 million) from the private placement related to the warrants.

The Company recognized net ?nancial expenses of NIS 1.8 million (\$0.5 million) for the three months ended March 31, 2012, an increase of NIS 0.2 million (\$0.1 million), compared to net ?nancial expenses of NIS 1.6 million (\$0.4 million) for the three months ended March 31, 2011. The increase in net ?nancial expenses resulted primarily from a decrease in the average exchange rate of foreign currencies in relation to the NIS during the three months ended March 31, 2012, which had a negative effect on the Company's net assets denominated in such foreign currencies during that period.

Net loss for the three months ended March 31, 2012 amounted to NIS 17.9 million (\$4.8 million), compared with a net loss of NIS 11.6 million (\$3.1 million) for the comparable period in 2011.

As of March 31, 2012, BioLineRx had NIS 135.2 million (\$36.4 million) in cash, cash equivalents and short-term bank deposits, compared with NIS 98.8 million as of December 31, 2011 (\$26.6 million). The increase in cash, cash equivalents and short-term deposits is mainly due to the private placement completed in February 2012, less cash outflows for the Company's operating activities during the period.

Net cash used in operating activities was NIS 12.9 million (\$3.5 million) for the three months ended March 31, 2012, compared with net cash used in operating activities of NIS 8.4 million (\$2.3 million) for the three months ended March 2011. The NIS 4.5 million (\$1.2 million) increase in net cash used in operating activities during the three-month period in 2012, compared to the three-month period in 2011, was primarily the result of increased research and development spending.

Net cash provided by investing activities for the three months ended March 31, 2012 was NIS 22.1 million (\$5.9 million), compared to net cash used in investing activities of NIS 48.0 million (\$12.9 million) for the three months ended March 2011. The cash ?ows provided by investing activities relates primarily to a net increase in the amount of short-term bank deposits that matured during the quarter.

Net cash provided by financing activities for the three months ended March 31, 2012 was NIS 52.4 million (\$14.1 million), compared to an insignificant amount of net cash used in financing activities for the three months ended March 2011. This increase relates to the private placement completed in February 2012.

## **Conference Call and Webcast Information**

BioLineRx will hold a conference call to discuss its first quarter 2012 results today, May 15, 2012, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-281-1167 from the U.S. or +972-3-918-0644 internationally. The call will also be available via live webcast through BioLineRx's website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-295-2634 from the U.S. or +972-3-925-5918 internationally. The replay will be available through May 18, 2012.

#### About BioLineRx

BioLineRx Ltd. is a publicly-traded biopharmaceutical development company. It is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of five clinical stage candidates: BL-1020 for schizophrenia has commenced a Phase 2/3 study; BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions has completed a Phase 1/2 study; BL-1021 for neuropathic pain is in Phase 1 development and BL-7040 for treating Inflammatory Bowel Disease (IBD) is commencing Phase 2. In addition, BioLineRx has 11 products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase 3) and commercialization.

For more information on BioLineRx, please visit www.biolinerx.com.

Various statements in this release concerning BioLineRx's future expectations, plans and prospects, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may", "expects", "anticipates", "believes", and "intends", and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's Form 20-F filed with the Securities and Exchange Commission on March 22, 2012. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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