## **BioLineRx Reports Fourth Quarter and Calendar 2011 Results**

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**Jerusalem, March 22, 2012** - BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, today reported its results for the fourth quarter and year ended December 31, 2011.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "2011 was a very significant year for BioLineRx and we are proud of our achievements in expanding and advancing our therapeutic pipeline. We are now working at near capacity with a robust pipeline of 16 therapeutic products, five of which are in various stages of clinical development.

"Initial results from the ongoing clinical trials for our two leading candidates, BL-1020 and BL-1040, are expected in 2013. BL-1020, for the treatment of schizophrenia, is undergoing the CLARITY Phase 2/3 trial, which assays improvement of cognitive function as its primary endpoint. The CLARITY trial is progressing according to plan, and discussions are being conducted in parallel with potential partners for the further development and commercialization of this product. Regarding BL-1040, for the prevention of pathological cardiac remodeling following a myocardial infarction, our partner Ikaria has commenced the PRESERVATION I trial, a CE Mark registration trial for BL-1040 (also known as "BCM"), as planned, and we look forward to the results.

"We have pushed ahead with the development of our other clinical candidates, including BL-5010 for the non-surgical removal of skin lesions, which has completed a Phase 1/2 clinical trial. In 2011, we received notification from the European regulatory authorities regarding the designation of BL-5010 as a medical device and have completed designing its next clinical study. We are currently evaluating the most advantageous ways to progress with the product from a business perspective. In addition, BL-1021, our neuropathic pain product, was shown to be safe and well tolerated in a Phase 1a clinical trial, and we are now assessing its development plan, including the best indication to focus on to maximize its commercial potential. The most recent addition to our clinical pipeline is BL-7040, for the treatment of Inflammatory Bowel Disease. BL-7040 recently received approval from the Israeli Ministry of Health for a Phase 2 study. We plan to commence the study in the second quarter of this year and expect to publish the results by the end of 2012," stated Dr. Savitsky.

Dr. Savitsky added, 'The strategic decision we undertook nearly two years ago to enter the dynamic and rapidly growing field of Hepatitis C has recently gained serious traction for BioLineRx. In the first quarter of 2012, we in-licensed BL-8020 and BL-8030, two promising orally-available treatments for Hepatitis C, both of which will be developed toward the clinic at an accelerated pace. Other high value therapeutic areas, like Celiac Disease, are also being pursued. Also, in 2012, we plan to evaluate alternative funding arrangements for pre-clinical projects that do not benefit from our special funding arrangement with the Office of the Chief Scientist of Israel's Ministry of Trade, Industry and Labor.

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

## Highlights for 2011 and 2012 to Date:

Corporate Highlights

- *ADS listing on NASDAQ:* In July 2011, BioLineRx listed its American Depositary Shares (ADSs) for trading on NASDAQ. The Bank of New York Mellon was appointed as the Company's depositary bank. Each BioLineRx ADS represents 10 ordinary shares.
- *Capital Raising:* In February 2012, BioLineRx completed a private placement to healthcare-focused U.S. institutional investors of 5.2 million ADSs at a purchase price of \$2.86 per ADS, and warrants to purchase up to 2.6 million additional ADSs at an exercise price of \$3.57 per ADS. The offering raised \$15.0 million, with net proceeds of approximately \$14.1 million.
- New VP of Business Development: In October 2011, the Company hired Mr. David Malek as its new Vice President of Business Development in order to enhance the Company's business development strategies and accelerate its commercialization efforts. Mr. Malek joined BioLineRx from Sanofi, where he served as Director of Oncology New

- Products and Business Development.
- *Compugen Partnership:* In December 2011, BioLineRx entered into a collaboration agreement with Compugen Ltd. for the purpose of developing and commercializing mutually selected Compugen-discovered drug candidates for the treatment of various diseases, ranging from acute and chronic inflammatory diseases through cardiac diseases, retinopathy and cancer.

## Pipeline Highlights

- *BL-1020*: In May 2011, BioLineRx re-acquired all of the rights to develop and commercialize BL-1020, an orally available molecule for the treatment of schizophrenia, from Cypress Bioscience and currently holds full global rights to the product. BioLineRx is continuing to develop BL-1020, and commenced the Phase 2/3 CLARITY trial in June 2011 in Romania and India. This 450-patient trial aims to determine the cognitive benefit and anti-psychotic efficacy, safety and tolerability of BL-1020 in schizophrenia patients, compared with Risperidone (one of the leading schizophrenia treatments). In April 2011, BioLineRx announced that a Notice of Allowance was issued by the United States Patent and Trademark Office (USPTO) for a patent application covering the BL-1020 drug and its use for the treatment of schizophrenia. The patent, when formally issued, will be valid through September 2022 and may be eligible for a patent term extension of up to five years. In March 2012, BioLineRx announced that a European patent was granted claiming BL-1020's composition and its use for the treatment of schizophrenia, which will also be valid through September 2022.
- *BL-1040*: In December 2011, Ikaria commenced the PRESERVATION I trial, a CE Mark registration trial for BL-1040 (also known as 'Bioabsorbable Cardiac Matrix,' or BCM), a novel resorbable polymer solution for use in the prevention of cardiac remodeling in patients following an AMI, which is being developed as a medical device. In February 2012, BioLineRx announced that a Notice of Allowance was issued by the United States Patent and Trademark Office (USPTO) for a patent application claiming the composition of BL-1040. This patent, when issued, will be valid until August 2026. Ikaria is developing BCM/BL-1040 under an exclusive, worldwide license agreement signed with BioLineRx in 2009
- *BL-5010*: In September 2011, BL-5010, a novel formulation for the non-surgical removal of skin lesions, received European confirmation from the British Standards Institution Notified Body (BSI) in the UK regarding its regulatory pathway classification as a medical device Class IIa. This considerably reduces the time and resources required for marketing authorization for the product in comparison to the drug approval process. BL-5010 has completed a Phase 1/2 clinical trial in which it demonstrated efficacy in complete removal of benign skin lesions and safety. BL-5010 is applied topically on the lesion for a few minutes and causes the lesion to gradually dry out and shed from the skin within 1-3 weeks.
- **BL-1021:** In December 2011, BioLineRx announced positive results from the Phase 1a study of BL-1021, a new chemical entity for the treatment of neuropathic pain. In the study, it was demonstrated that a single administration of BL-1021 in the dose range examined was safe and well tolerated, with no significant changes noted in vital signs, ECG or laboratory safety parameters at any dose when compared either to baseline measurements or to the placebo group. In addition, BL-1021 demonstrated a favorable pharmacokinetic profile and the potential for once daily oral administration.
- *BL-7040*:In June 2011, BioLineRx in-licensed BL-7040, an orally available Phase 2 ready oligonucleotide polymer for treating Inflammatory Bowel Disease (IBD). In March 2012, the Company received approval from the Israeli Ministry of Health for commencing a Phase 2 study to evaluate the safety and effectiveness of BL-7040 for the treatment of IBD.
- HCV Therapeutic Candidates: In January 2012, BioLineRx signed a worldwide, exclusive license agreement with Genoscience, a French company focused on viral disease therapeutics, to develop and commercialize BL-8020, an orally available treatment for Hepatitis C. BL-8020's safety and efficacy have been demonstrated in pre-clinical studies, which show that BL-8020, when combined with other anti-Hepatitis C virus (HCV) agents, has a synergistic effect. In February 2012, BioLineRx signed a worldwide, exclusive license agreement with Genoscience and RFS Pharma to develop and commercialize BL-8030, an orally available treatment for Hepatitis C. BL-8030 has been shown to have excellent antiviral activity against various HCV genotypes. Pre-clinical studies have demonstrated an improved resistance profile against common protease inhibitor mutants, resulting in a lower probability that the virus will develop resistance to treatment. In addition, BL-8030 has demonstrated a good toxicity profile in pre-clinical studies.
- Addition and Termination of Therapeutic Candidates: As part of its business strategy, BioLineRx continues to actively source, rigorously evaluate and in-license selected therapeutic candidates. Since the beginning of 2011 through the date of this announcement, BioLineRx in-licensed a total of nine projects eight in pre-clinical stages and one (BL-7040) in clinical development. The Company also terminated three projects during this time period due to lack of efficacy or other scientific considerations all in early pre-clinical stages, in line with its business strategy.

#### • High-level View of Pipeline:



## **Summary of 2011 Financial Results:**

During the year ended December 31, 2011, no revenues were recorded. Revenues in 2010 reflect an upfront payment of \$30.0 million received in connection with the out-licensing agreement signed with Cypress Bioscience in 2010 in respect of BL-1020. Cost of revenues in 2010 consisted of payments due to the licensors under the BL-1020 in-licensing agreement.

Research and development expenses for the year ended December 31, 2011 were NIS 42.6 million (\$11.2 million), a decrease of NIS 12.4 million (\$3.2 million), or 22%, compared to NIS 55.0 million (\$14.4 million) for the year ended December 31, 2010. Research and development expenses for the 2010 period included non-recurring payments to the OCS of NIS 17.4 million (\$4.6 million) which were a repayment of funds previously received from the OCS in respect of BL-1020. Those funds had been previously reflected in prior periods as a reduction in research and development expenses. Without regard to these non-recurring payments, research and development expenses for the year ended December 31, 2011 increased by NIS 5.1 million (\$1.4 million), or 14%, over the year ended December 31, 2010. The increase resulted primarily from the commencement of the CLARITY clinical trial in respect of BL-1020 at the end of June 2011.

Sales and marketing expenses for the year ended December 31, 2011 were NIS 3.3 million (\$0.9 million), a decrease of NIS 1.3 million (\$0.3 million), or 28%, compared to NIS 4.6 million (\$1.2 million) for the year ended December 31, 2010. The decrease resulted primarily from a shorter period of time devoted to strategic partnering efforts in connection with BL-1020 during 2011 as compared to 2010, as well as from a reduction in expenses due to the transfer of our business development activities from the U.S. to Israel during the first half of 2011 and the resulting closure of the Company's U.S. office. Sales and marketing expenses are expected to increase in the foreseeable future, as the Company continues to increase its business development efforts in respect of BL-1020, as well as some of its other clinical stage assets.

General and administrative expenses for the year ended December 31, 2011 were NIS 12.7 million (\$3.3 million), a decrease of NIS 2.2 million (\$0.6 million) or 15%, compared to NIS 14.9 million (\$3.9 million) for the year ended December 31, 2010. The decrease resulted primarily from expenses associated with the Company's proposed initial public offering in 2010.

The Company recognized net financial income of NIS 8.5 million (\$2.2 million) for the year ended December 31, 2011, an increase of NIS 14.2 million (\$3.7 million), compared to net financial expense of NIS 5.7 million (\$1.5 million) for the year ended December 31, 2010. The change in net financial income/expense resulted primarily from an increase in the average exchange rate of foreign currencies in relation to the NIS during the year ended December 31, 2011, which had a positive effect on the Company's net assets denominated in such foreign currencies during that period.

Net cash used in operating activities was NIS 42.7 million for the year ended December 31, 2011, compared with cash provided by operating activities of NIS 40.7 million for the year ended December 31, 2010. The NIS 83.4 million increase in net cash used in operating activities during 2011 as compared with 2010 was primarily the result of the upfront payment we received in 2010 from Cypress Bioscience.

Net cash used in investing activities for the year ended December 31, 2011 was NIS 37.6 million, compared to net cash used in investing activities of NIS 29.5 million for the year ended December 31, 2010. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments.

Net cash used in financing activities for the year ended December 31, 2011 was NIS 0.3 million compared to net cash provided by financing activities of NIS 0.8 million for the year ended December 31, 2010. The changes in cash flows from financing activities reflect the proceeds of a bank loan used for the acquisition of laboratory equipment in 2010.

# (Tables follow) 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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