BioLineRx Reports Second Quarter 2011 Financial Results

August 23, 2011 9:38 AM ET

Jerusalem, August 23, 2011 - BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, today reported its results for the second quarter ending June 30, 2011.

"During the second quarter we continued developing, advancing and enriching our pipeline, while focusing on products in advanced clinical stages. This includes commencement of the CLARITY Phase II/III clinical trial for BL-1020 in Romania, with patient enrollment starting on schedule during the second quarter. We are pleased with the progress of the trial thus far, and look forward to starting patient enrollment at the trial's designated sites in India," stated Kinneret Savitsky, Ph.D., CEO of BioLineRx. "Regarding BL-1040, our collaboration with Ikaria continues, and we look forward to commencement of the first pivotal clinical trial in the second half of 2011."

Dr. Savitsky continued, "We also added two new projects to our portfolio during the second quarter, including BL-7040 for treatment of inflammatory bowel disease, which is expected to enter Phase II clinical trials at the beginning of 2012. Currently, our pipeline includes 13 compounds actively being developed, with five in clinical stages.

"In order to accelerate the commercialization efforts of our product pipeline, I am pleased to announce that we recently hired Mr. David Malek as our new Vice President of Business Development. David joins us from Sanofi, where he served as Director of Oncology - New Products and Business Development. We welcome David to our team, and look forward to his contributions."

Highlights of the second quarter of 2011:

- **BL-1020:** In May, BioLineRx announced that it reacquired the development and commercialization rights in North America of BL-1020, for treatment of schizophrenia, from Cypress Bioscience Inc. and terminated the license agreement with Cypress. BioLineRx received a $30 million upfront payment upon the signing of the original agreement, which was not affected by the reacquisition of the rights. In addition, based on information received from Cypress, as well as BioLineRx's own assessment, over $10 million was invested by Cypress in preparation for the CLARITY Phase II/III clinical trial. In consideration for the reacquisition of the rights, BioLineRx is obligated to pay Cypress a 1% royalty on future worldwide sales of the product, up to an aggregate cumulative royalty of $80 million. In addition, BioLineRx is obligated to pay Cypress 10% of all future one-time payments, not to exceed a total of $10 million, as reimbursement for costs that Cypress incurred in developing the intellectual property portfolio, designing the trial and conducting substantially all the preparations to launch the trial. BioLineRx estimates that an additional $12-14 million will be required to complete the trial. While BioLineRx has the financial resources to complete the trial, the Company intends to seek, in the near term, partnering arrangements or additional sources of financing to complete the trial without delay, as well as to allow the Company to continue to develop the rest of its product portfolio without any significant change in its current operating plan. In addition and in parallel with the conduct of the trial, BioLineRx intends to renew its efforts to seek an out-licensing partner for the continued development and commercialization of the product at its more advanced stages.

In June, the Company announced the enrollment of the first patient in Romania and commencement of the CLARITY trial. In addition, BioLineRx is expected to shortly receive approval from the Indian regulatory authorities for commencement of the trial in India.

- **BL-7030:** In May, BioLineRx announced the addition of a new project to its portfolio, BL-7030 an innovative and targeted cancer therapy. In experiments performed so far, BL-7030 exhibited specific binding to the target receptor in cell cultures, high efficacy in animal models for various cancer types, and also completely eliminated tumors in particular models without side effects.

- **BL-7040:** In June, the Company in-licensed a new project for the treatment of inflammatory bowel disease (IBD) and other inflammatory diseases from Yissum, the technology transfer company of the Hebrew University of Jerusalem. The drug was proven safe in Phase I clinical trials, and is expected to commence Phase II trials at the beginning of 2012.

- **BL-1021:** In July, the Company announced enrollment of the first participant in a Phase I clinical trial on healthy subjects for BL-1021, for the treatment of neuropathic pain. Studies in several animal models have shown that BL-1021 is effective

for acute and neuropathic pain. Pre-clinical studies suggest that the drug has higher efficacy and a better safety profile than anti-depressants from the same family (TCAs).

Financial results for the second quarter and first six months of 2011:

Research and development expenses were NIS 10.4 million for the second quarter of 2011, compared with NIS 26.3 million for the second quarter of 2010. Research and development expenses for the first six months of 2011 were NIS 16.8 million, compared with NIS 37.0 million in corresponding 2010 period. The decrease in research and development expenses stems primarily from a provision for the one-time payment of royalties to the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, which was recorded in the second quarter of 2010, as well as due to the closing of a number of projects in 2010 and the addition of several new projects in the second half of 2010 and first half of 2011, as new projects are generally characterized by relatively low costs at the initial stages of the projects. The Company expects that development costs will gradually increase in the second half of 2011.

The Company's operating loss for the second quarter of 2011 amounted to NIS 15.1 million, compared with NIS 30.8 million for the second quarter of 2010. Operating loss in the first half of 2011 totaled NIS 25.1 million, compared with NIS 45.4 million in the second half of 2010.

Net loss for the most recent quarter was NIS 16.4 million, compared with NIS 28.1 million for the corresponding quarter of 2010. Net loss for the first six months of 2011 amounted to NIS 28.0 million, compared with NIS 43.6 million for the corresponding period in 2010.

Cash flows used for operating activities in the second quarter of 2011 amounted to NIS 12.8 million, compared with NIS 8.1 million in the corresponding quarter of 2010. Cash flows used for operating activities in the first six months of 2011 totaled NIS 21.3 million, compared with NIS 18.7 million in the corresponding period last year.

As of June 30, 2011, BioLineRx had NIS 113.4 million in cash, cash equivalents and short-term bank deposits, compared with NIS 139.8 million as of December 31, 2010. The decrease in cash, cash equivalents and short-term deposits is mainly due to cash outflows for the Company's operating activities during the period.

ADR listing on NASDAQ and extension of Series 2 warrants:

In July, the Company listed its ADRs for trading on the NASDAQ Capital Market. Each BioLineRx ADR represents 10 ordinary shares and trades on NASDAQ under the symbol "BLRX." In July, the Company also filed a formal motion with the District Court of Jerusalem to approve extending the exercise period of the Company's outstanding Series 2 warrants, until June 30, 2013.

"As part of our strategy to establish a presence in the U.S., we have listed the Company's shares on the NASDAQ Capital Market through ADRs. We have accompanied this listing with efforts to enhance our exposure to U.S. investors, including, among other things, participation in several leading financial conferences in the U.S. towards the end of the year," concluded Dr. Savitsky.

About BioLineRx

BioLineRx Ltd. is a publicly-traded 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 current portfolio consists of five clinical stage candidates: BL-1020 for schizophrenia is in Phase II/III clinical trials; BL-1040 for treatment of patients following a myocardial infarction has completed a Phase I/II study and has been out-licensed to Ikaria Inc. for a total deal value of $282.5 million, in addition to sales royalties; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I development; and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed Phase I. In addition, BioLineRx has eight products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, 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 III) and commercialization. For more information on BioLineRx, please visit www.biolinerx.com.

The estimates and judgments with respect to the projects 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.

Contacts:
Garth Russell / Todd Fromer
KCSA Strategic Communications
1 212-896-1250 / 1 212-896-1250
grussell@kcsa.com / tfromer@kcsa.com

Tsipi Haitovsky (Public Relations)
+972-3-6240871
tsipih@netvision.net.il