

## For immediate release

# **BioLineRx Reports Third Quarter 2011 Financial Results**

Jerusalem, November 29, 2011 - BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, today reported its results for the third quarter ending September 30, 2011.

"During the third quarter, we continued to advance and expand our pipeline, while focusing on the development of products in advanced clinical stages. We are pleased with the continued development of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia. In June of this year, we commenced the phase 2/3 CLARITY trial for BL-1020 in Romania, with cognition as a primary endpoint. We are authorized to perform the trial at 14 clinical sites in Romania, and a few days ago, following approval from the Indian regulatory authorities and the Indian local ethics committees, we initiated the trial in India, where we have received authorization to conduct the trial at 18 additional sites. In addition, we are planning to apply for approval to perform the trial at four sites in Israel. The CLARITY trial is progressing well and according to plan, and we look forward to the results from the trial, expected in early 2013," 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 by the end of 2011."

Dr. Savitsky added, "We have also continued to advance our other clinical stage products, including BL-1021 for the treatment of neuropathic pain, which has shown positive preliminary results in a phase 1a clinical trial. Final results are expected in December 2011. In addition, during the third quarter, we announced the confirmation from the European regulatory authorities of the regulatory classification pathway to develop BL-5010 as a medical device, which will enable us to reduce the time and resources required for developing this product. BL-5010, a novel formulation for the non-surgical removal of benign skin lesions, has successfully completed a phase 1/2 clinical trial, and we are currently designing the plan for next clinical study, as well as evaluating the most advantageous ways to progress with this therapeutic candidate from a business perspective."

"In accordance with our business strategy, we continue to screen, evaluate and in-license the most promising novel therapeutic candidates. During the third quarter of 2011, we added BL-7050, a novel orally available treatment for neuropathic and inflammatory pain, to our product pipeline, which currently includes 14 compounds, five of which are in various stages of clinical development."

"In October, we hired Mr. David Malek as our new Vice President of Business Development. We view this appointment as critical in our efforts to enhance our business development strategies and accelerate our commercialization efforts. David joins BioLineRx from Sanofi, where he served as Director of Oncology - New Products and Business Development.

"As part of our strategy to establish a presence in the U.S., in July, we listed our American Depositary Shares on the NASDAQ Capital Market. We have accompanied this listing with efforts to enhance our exposure to U.S. investors, including, among other things, hiring KCSA Strategic Communications, a well-known New York-based communications firm, to direct the Company's investor relations program," concluded Dr. Savitsky.

#### Highlights of the third quarter of 2011:

- *ADR listing on NASDAQ:* In July, BioLineRx listed its ADRs for trading on NASDAQ. Each BioLineRx ADR represents 10 ordinary shares and trades on NASDAQ under the symbol "BLRX." The Bank of New York Mellon has been appointed as the Company's depositary bank.
- *BL-1021:* In July, the Company announced enrollment of the first participant in a phase 1a clinical trial on healthy subjects for BL-1021, a new chemical entity 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).

In September, BioLineRx announced positive preliminary results from the phase 1a clinical trial of BL-1021. Study results demonstrated that a single administration of BL-1021 was safe and well tolerated. In addition, preliminary modeling of the pharmacokinetic data collected in this trial predicts that a once daily administration of BL-1021 at the dose levels assessed in the trial will enable reaching effective doses in patients. Final results are expected to be announced in December 2011.

- *BL-7050:* In September, BioLineRx announced the addition of a new project to its portfolio, BL-7050, a novel, orally available treatment for neuropathic and inflammatory pain. Pre-clinical trials in cell culture and in animal models of neuropathic and inflammatory pain have shown that the molecule is effective at reducing neuronal activity and pain levels. BL-7050 also has an improved safely profile.
- *BL-5010:* In September, the Company announced that BL-5010, a novel formulation for the non-surgical removal of benign skin lesions, has received European confirmation from the British Standards Institution Notified Body (BSI) in the UK, of the 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.
- *New VP BD:* In October, 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 joins BioLineRx from Sanofi, where he served as Director of Oncology New Products and Business Development.

### Summary of financial results for the third quarter and first nine months of 2011:

Revenues for the three months and nine months ended September 30, 2010 reflected 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. No revenues were recorded during the nine months ended September 30, 2011.

Research and development expenses for the three months ended September 30, 2011 were NIS 13.2 million (\$3.6 million) compared to NIS 6.7 million (\$1.8 million) for the three months ended September 30, 2010. The increase resulted primarily from the commencement of the CLARITY clinical trial in respect of BL-1020 at the end of June 2011, along with a ramp-up in spending on a number of other existing projects, including new projects introduced during the second half of 2010 and the first nine months of 2011. Research and development expenses for the nine months ended September 30, 2011 were NIS 30.0 million (\$8.1 million) compared to NIS 43.8 million (\$11.8 million) for the nine months ended September 30, 2010. Research and development expenses for the 2010 period included non-recurring payments to the Israeli Office of the Chief Scientist (OCS) of NIS 17.4 million (\$4.7 million), relating to funds previously received from the OCS in respect of BL-1020, which 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 nine months ended September 30, 2011 increased by NIS 3.7 million (\$1.0

million), or 14%, over the comparable 2010 period. 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 three months ended September 30, 2011 were NIS 0.4 million (\$0.1 million), a decrease of NIS 0.9 million (\$0.3 million), or 73%, compared to NIS 1.3 million (\$0.4 million) for the three months ended September 30, 2010. Sales and marketing expenses for the nine months ended September 30, 2011 were NIS 2.4 million (\$0.7 million), a decrease of NIS 1.1 million (\$0.2 million), or 31%, compared to NIS 3.5 million (\$0.9 million) for the nine months ended September 30, 2010. The decrease resulted primarily from the strategic partnering efforts in connection with BL-1020 during 2010, as well as the transfer of our business development activities from the U.S. to Israel during the first half of 2011 and the resulting closure of our U.S. office. Sales and marketing expenses are expected to increase in the foreseeable future, as we continue to increase our business development efforts in respect of BL-1020, as well as some of our other clinical stage assets.

General and administrative expenses for the three months ended September 30, 2011 were NIS 3.3 million (\$0.9 million), an increase of NIS 0.6 million (\$0.2 million), or 22%, compared to NIS 2.7 million (\$0.7 million) for the three months ended September 30, 2010. General and administrative expenses for the nine months ended September 30, 2011 were NIS 9.5 million (\$2.6 million), an increase of NIS 0.6 million (\$0.2 million), or 7%, compared to NIS 8.9 million (\$2.4 million) for the nine months ended September 30, 2010. The increase resulted primarily from professional fees relating to the listing of our ADRs on NASDAQ in July 2011.

The Company's operating loss for the third quarter of 2011 amounted to NIS 16.9 million (\$4.5 million), compared with operating profit of NIS 76.8 million (\$20.7 million) for the third quarter of 2010. Operating loss in the first nine months of 2011 totaled NIS 42.0 million (\$11.3 million), compared with operating profit of NIS 31.4 million (\$8.5 million) in the first nine months of 2010.

Net loss for the third quarter of 2011 was NIS 7.9 million (\$2.1 million), compared with net profit of NIS 73.1 million (\$19.7 million) for the corresponding quarter of 2010. Net loss for the first nine months of 2011 amounted to NIS 35.9 million (\$9.7 million), compared with net profit of NIS 29.5 million (\$7.9 million) for the corresponding period in 2010.

Cash flows used for operating activities in the first nine months of 2011 totaled NIS 26.9 million (\$7.2 million), compared with cash flows provided by operating activities of NIS 48.8 million (\$13.1 million) in the corresponding nine months of 2010.

As of September 30, 2011, BioLineRx had NIS 112.4 million (\$30.3 million) in cash, cash equivalents and short-term bank deposits, compared with NIS 139.8 million (\$37.7 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.

#### (Tables follow)

#### 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 2/3 clinical trials; BL-1040 for prevention of cardiac remodeling in patients following a myocardial infarction has completed a phase 1/2 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 1/2 study; BL-1021 for neuropathic pain is in phase 1 trials; and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed phase 1. In addition, BioLineRx has nine 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 preclinical 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.

U.S. dollar amounts herein (other than amounts that were originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of September 30, 2011 (1 = NIS 3.712). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

The estimates and judgments with respect to the projects included in this release are considered forwardlooking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates 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.

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## **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

			Convenience translation into USD
	December 31,	September 30,	September 30,
	2010	2011	2011
	NIS in th	nousands	In thousands
Assets			
CURRENT ASSETS	111 746	22.005	0.101
Cash and cash equivalents	111,746	33,895	9,131
Short-term bank deposits	28,037 46	78,564 317	21,165
Prepaid expenses	6,313	2,113	85 569
Other receivables	146,142		
Total current assets	140,142	114,889	30,950
NON-CURRENT ASSETS			
Restricted deposits	2,414	3,401	916
Long-term prepaid expenses	196	195	53
Property and equipment, net	4,509	4,076	1,098
Intangible assets, net	1,352	1,178	317
Total non-current assets	8,471	8,850	2,384
Total assets	154,613	123,739	33,334
Liabilities and equity CURRENT LIABILITIES Current maturities of long-term bank loan	307	307	83
Accounts payable and accruals:	507	507	05
Trade	3,849	5,551	1,495
OCS	5,993	5,993	1,614
Licensors	1,491	-	-
Other	10,551	12,948	3,488
Total current liabilities	22,191	24,799	6,680
LONG-TERM LIABILITIES			
Long-term bank loan, net of current maturities	432	191	51
Retirement benefit obligations	30	30	8
Total non-current liabilities	462	221	59
Total liabilities	22,653	25,020	6,739
EQUITY			
Ordinary shares	1,236	1,236	333
Warrants	6,549	6,549	1,764
Share premium	414,435	414,780	111,740
Capital reserve	27,623	30,023	8,088
Accumulated deficit	(317,883)	(353,869)	(95,330)
Total equity	131,960	98,719	26,595
Total liabilities and equity	154,613	123,739	33,334

### **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE PROFIT (LOSS) (UNAUDITED)

					Convenience translation into USD	
	Three months ended September 30,		Nine months ended September 30,		Three months ended September 30,	Nine months ended September 30,
—	2010	2011	2010	2011	2011	2011
-	NIS in thousands			In thousands		
NET SALES	113,160	-	113,160	-	-	-
COST OF SALES	(25,571)	-	(25,571)	-	-	-
GROSS PROFIT	87,589	-	87,589	-	-	-
RESEARCH AND DEVELOPMENT EXPENSES,						
NET	(6,737)	(13,255)	(43,769)	(30,044)	(3,571)	(8,094)
SALES AND MARKETING EXPENSES	(1,322)	(358)	(3,506)	(2,431)	(96)	(655)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,690)	(3,272)	(8,914)	(9,546)	(881)	(2,572)
OPERATING PROFIT (LOSS)	76,840	(16,885)	31,400	(42,021)	(4,548)	(11,321)
FINANCIAL INCOME	178	8,965	3,056	10,785	2,415	2,906
FINANCIAL EXPENSES	(3,869)	(18)	(4,931)	(4,750)	(5)	(1,279)
COMPREHENSIVE PROFIT (LOSS) FOR THE PERIOD	73,149	(7,938)	29,525	(35,986)	(2,138)	(9,694)
_	NIS				USD	
PROFIT (LOSS) PER ORDINARY SHARE - BASIC	0.59	(0.06)	0.24	(0.29)	(0.02)	(0.08)