BioLineRx Reports Third Quarter 2013 Financial Results

November 13, 2013

JERUSALEM, Nov. 13, 2013 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, today reported its results for the third quarter ending September 30, 2013.

(Logo: http://photos.prnewswire.com/prnh/20130730/630769)

Kinneret Savitsky, Ph.D., Chief Executive Officer of BioLineRx, stated, "As we approach the end of 2013, we see the Company's continued progress towards several significant catalysts over the next several quarters. For instance, one of our most advanced assets, BL-1040 for the prevention of ventricular remodeling post AMI, is progressing as scheduled at full steam in the PRESERVATION I CE-Mark registration trial. Fifty-five sites are currently open, including 14 in the U.S., and final results are expected in 2014."

Other highlights

BL-8040 (AML and other hematological indications):

- Granted orphan drug designation by the FDA, allowing a faster clinical path toward commercialization
- Added Memorial Sloan Kettering Cancer Center in New York to join the Phase 2 multi-center study, bringing the total number of sites to eight
- Received patent allowance through 2029 from the USPTO for method of obtaining stem cells

"During the third quarter, we made significant progress in our Phase 2 clinical trial for BL-8040, a best-in-class CXCR4 antagonist for the treatment of hematological cancers such as AML. In September, we received orphan drug status from the FDA, a designation with significant positive implications for BL-8040 as it advances through the clinic, including a seven-year market exclusivity period, clinical protocol assistance with the FDA, and federal grants and tax credits. We remain on track to deliver partial results from the trial by the end of this year, with final results expected in the second half of 2014. In addition, during the first half of 2014, we expect to commence additional clinical trials for BL-8040 in stem cell mobilization and chronic myeloid leukemia (CML)."

BL-5010 (skin lesions):

- Pivotal CE-Mark registration trial in Germany expected to commence by end of 2013, following receipt of regulatory approval
- Finalized CRO and all other study vendor contracts in anticipation of study commencement

"We look forward to commencing the CE-Mark registration trial for BL-5010, our novel composition for the non-surgical removal of skin lesions, by the end of 2013, once we receive regulatory approval from the German regulatory authorities. We expect to announce results from the study around mid-2014. Positive results could potentially allow BL-5010 to enter the European market by the end of next year. During 2014, we also plan to expand BL-5010 into additional therapeutic indications, such as actinic keratosis, a pre-cancerous skin condition. In parallel with completing preparations for the pivotal study, we continue to engage in meaningful discussions with potential partners."

BL-7010 (celiac disease):

- Received approval to commence Phase 1/2 clinical trial from regulatory authorities in Finland
- Finalized CRO and all other study vendor contracts in anticipation of study commencement by end of 2013

"Our unique therapeutic candidate for celiac disease, BL-7010, continues to generate a lot of excitement from notable scientists and physicians. Despite the unmet medical need and enormous size of the celiac market, there is no available treatment for the disease, and only a few clinical-stage products in development. We recently received approval from the Finnish regulatory authorities to commence a Phase 1/2 safety trial for BL-7010 at a world-leading site for celiac disease in Finland. We expect to begin this study by the end of 2013, and receive results by mid-2014. Assuming the study produces positive results, we hope to commence a Phase 2 efficacy study for BL-7010 by the end of next year."

New Board member:

- Appointed BJ Bormann, Ph.D., to Board of Directors

"As we look forward to a year full of significant milestones for our Company, we are excited to welcome Dr. BJ Bormann to our Board of Directors. We expect her vast experience and knowledge in the healthcare space to assist us in reaching new heights in our discovery and partnering initiatives. Her most recent position as Senior Vice President and Worldwide Head of Therapeutic Alliances and Strategic Partnerships at Boehringer Ingelheim Pharmaceuticals, as well as her former role as Vice President, Strategic Alliances, at Pfizer, Inc., are testaments to her extensive credentials. We are confident that she will be an essential addition to our Board."

Upcoming Analyst and Investor Day

- Thursday, November 21, 2013 in New York City

"Later this month, Dr. Bormann, as well as our entire management team, will join several other distinguished speakers to discuss selected programs from our broad pipeline at our annual Analyst and Investor Day in New York. We are looking forward to this event, as it is a wonderful opportunity for

our management team to engage directly with the investment community and provide detailed updates on our operational and developmental progress. As our programs advance through the clinic, we will continue to keep our loyal shareholders and potential investors fully updated of our progress," concluded Dr. Savitsky.

Financial Results

During the three-month and nine-month periods ended September 30, 2013 and 2012, no revenues were recorded.

Research and development expenses for the three months ended September 30, 2013 were NIS 8.2 million ($2.3 million), a decrease of NIS 7.7 million ($2.2 million), or 48%, compared to NIS 15.9 million ($4.5 million) for the three months ended September 30, 2012. The decrease resulted primarily from lower expenses in 2013 associated with the CLARITY clinical trial in respect of BL-1020, due to termination of the trial in March 2013, partially offset by a ramp-up in spending on other clinical-stage projects introduced during 2012. Research and development expenses for the nine months ended September 30, 2013 were NIS 39.7 million ($11.3 million), a decrease of NIS 6.8 million ($1.9 million), or 15%, compared to NIS 46.5 million ($13.2 million) for the comparable period in 2012. Without regard to the NIS 6.0 million one-time reversal of amounts previously accrued to the OCS in respect of BL-1020, research and development expenses in the nine-month period decreased by NIS 0.8 million ($0.2 million). The reason for the decrease is similar to the one discussed above in the three-month comparison.

Sales and marketing expenses for the three months ended September 30, 2013 were NIS 0.7 million ($0.2 million), compared to NIS 0.9 million ($0.3 million) for the three months ended September 30, 2012. The small decrease relates to lower professional fees and market research expenses as compared to the third quarter of last year. Sales and marketing expenses for the nine months ended September 30, 2013 were NIS 2.6 million ($0.7 million), substantially similar to the comparable period in 2012.

General and administrative expenses for the three months ended September 30, 2013 were NIS 2.7 million ($0.8 million), an insignificant decrease compared to NIS 2.8 million ($0.8 million) for the three months ended September 30, 2012. General and administrative expenses for the nine months ended September 30, 2013 were NIS 9.8 million ($2.8 million), an increase of NIS 0.5 million ($0.2 million), or 5%, compared to NIS 9.3 million ($2.6 million) for the comparable period in 2012. The increase resulted primarily from a one-time expense for professional services incurred in the 2013 period.

The Company's operating loss for the three months ended September 30, 2013 amounted to NIS 11.6 million ($3.3 million), compared with an operating loss of NIS 19.6 million ($5.5 million) for the comparable period in 2012. The Company's operating loss for the nine months ended September 30, 2013 amounted to NIS 52.1 million ($14.7 million), compared with an operating loss of NIS 58.5 million ($16.5 million) for the comparable period in 2012.

The Company's net non-operating expenses amounted to NIS 4.6 million ($1.3 million) for the three months ended September 30, 2013, an increase of NIS 1.4 million ($0.4 million), compared to net non-operating expenses of NIS 3.2 million ($0.9 million) for the three months ended September 30, 2012. Non-operating expenses primarily relate to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements completed in February 2012 and 2013. Net non-operating income amounted to NIS 9.2 million ($2.6 million) for the nine months ended September 30, 2013, an increase of NIS 6.9 million ($1.9 million), compared to net non-operating income of NIS 2.4 million ($0.7 million) for the comparable 2012 period. Non-operating income for both periods primarily relate to fair-value adjustments of liabilities on account of warrants, as discussed above in the three-month comparison.

Net financial expenses amounted to NIS 1.5 million ($0.4 million) for the three months ended September 30, 2013, a change of NIS 1.6 million ($0.5 million), compared to net financial income of NIS 0.2 million ($0.1 million) for the three months ended September 30, 2012. Net financial income and expenses result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on net assets denominated in dollars. Net financial expenses amounted to NIS 3.2 million ($0.9 million) for the nine months ended September 30, 2013, a change of NIS 7.5 million ($2.1 million), compared to net financial income of NIS 4.3 million ($1.2 million) for the comparable 2012 period. The reason for the change is similar to the one discussed above in the three-month comparison.

The Company's net loss for the three months ended September 30, 2013 amounted to NIS 17.7 million ($5.0 million), compared with a net loss of NIS 22.6 million ($6.4 million) for the comparable period in 2012. The Company's net loss for the nine months ended September 30, 2013 amounted to NIS 46.1 million ($13.0 million), compared with a net loss of NIS 51.8 million ($14.7 million) for the comparable period in 2012.

The Company held NIS 71.6 million ($20.3 million) in cash, cash equivalents and short-term bank deposits as of September 30, 2013.

Net cash used in operating activities was NIS 55.9 million ($15.8 million) for the nine months ended September 30, 2013, compared with net cash used in operating activities of NIS 52.6 million ($14.9 million) for the nine months ended September 30, 2012. The NIS 3.3 million ($0.9 million) increase in net cash used in operating activities during the nine-month period in 2013, compared to the nine-month period in 2012, was primarily the result of a reduction in net trade payables and accruals during the 2013 period.

Net cash used in investing activities for the nine months ended September 30, 2013 was NIS 17.5 million ($4.9 million), compared to net cash provided by investing activities of NIS 15.2 million ($4.3 million) for the nine months ended September 2012. The cash flows related to investing activities primarily stem from investments in, and maturities of, short-term bank deposits during the respective periods.

Net cash provided by financing activities for the nine months ended September 30, 2013 was NIS 50.0 million ($14.1 million), compared to net cash provided by financing activities of NIS 52.2 million ($14.7 million) for the nine months ended September 2012. The cash flows from financing activities in the 2012 period reflect the private placement completed in February 2012. The cash flows from financing activities in the 2013 period reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the share purchase agreement with Lincoln Park Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its third quarter 2013 results today, November 13, 2013, at 10:00 a.m. EST. The conference call will be available via webcast and can be accessed through the Investor Relations section of BioLineRx's website, www.biolinerx.com, and through www.kcsa.com. A presentation will be provided on BioLineRx's website to accompany management's remarks during the conference call. To dial into the conference call, please dial 1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. A replay of the conference call will be available approximately two hours after completion of the live conference call at www.biolinerx.com or www.kcsa.com. A dial-in replay of the call will also be

available until November 16, 2013. To access the replay, please dial 1-888-254-7270 from the U.S. or +972-3-925-5927 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a publicly-traded biopharmaceutical development company dedicated to building a portfolio of products for unmet medical needs, as well as those with advantages over currently available therapies. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in late 2013; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which is expected to commence a Phase 1/2 study in late 2013.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

Various statements in this release concerning BioLineRx's future expectations 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 most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 12, 2013. 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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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2012	September 30, 2013	Convenience translation into USD September 30, 2013
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	68,339	42,961	12,146
Short-term bank deposits	11,459	28,688	8,111
Prepaid expenses	804	809	229
Other receivables	2,254	875	247
Total current assets	82,856	73,333	20,733
		,	
NON-CURRENT ASSETS			
Restricted deposits	3,513	1,933	547
Long-term prepaid expenses	204	144	41
Property and equipment, net	3,172	2,681	758
Intangible assets, net	1,063	911	257
Total non-current assets	7,952	5,669	1,603
Total assets	90,808	79,002	22,336

Liabilities and equity

CURRENT LIABILITIES			
Current maturities of long-term bank loan	137	-	-
Accounts payable and accruals:			
Trade	12,283	12,564	3,552
OCS	6,148	-	-
Other	5,443	2,896	819
Total current liabilities	24,011	15,460	4,371
NON-CURRENT LIABILITIES			
Retirement benefit obligations	143	143	41
Warrants	10,725	13,165	3,722
Total non-current liabilities	10,868	13,308	3,763
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	34,879	28,768	8,134
EQUITY			
Ordinary shares	1,837	2,357	666
Share premium	464,629	504,309	142,581
Capital reserve	33,802	33,981	9,607
Accumulated deficit	(444,339)	(490,413)	(138,652)
Total equity	55,929	50,234	14,202
Total liabilities and equity	90,808	79,002	22,336

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE 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,**
	2012	**2013**	**2012**	**2013**	**2013**	**2013**
	NIS in thousands				**In thousands**	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(15,848)	(8,190)	(46,523)	(39,720)	(2,316)	(11,230)
SALES AND MARKETING EXPENSES	(912)	(731)	(2,626)	(2,565)	(207)	(725)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,834)	(2,663)	(9,315)	(9,789)	(752)	(2,767)
OPERATING LOSS	(19,594)	(11,584)	(58,464)	(52,074)	(3,275)	(14,722)
NON-OPERATING INCOME (EXPENSES), NET	(3,180)	(4,627)	2,351	9,214	(1,308)	2,605
FINANCIAL INCOME	1,827	501	8,323	2,484	142	702
FINANCIAL EXPENSES	(1,649)	(1,956)	(4,052)	(5,698)	(553)	(1,611)
COMPREHENSIVE LOSS FOR THE PERIOD	(22,596)	(17,666)	(51,842)	(46,074)	(4,994)	(13,026)
	NIS				**USD**	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.13)	(0.08)	(0.31)	(0.21)	(0.02)	(0.06)

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Nine months ended September 30,		**Nine months ended September 30,**
	2012	**2013**	**2013**
	NIS in thousands		**In thousands**
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(51,842)	(46,074)	(13,026)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(724)	(9,837)	(2,782)

Net cash used in operating activities	(52,566)	(55,911)	(15,808)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(48,992)	(104,127)	(29,439)
Maturities of short-term deposits	64,801	85,377	24,138
Maturities of restricted deposits	-	1,550	438
Purchase of property and equipment	(545)	(196)	(55)
Purchase of intangible assets	(21)	(96)	(27)
Net cash provided by (used in) investing activities	15,243	(17,492)	(4,945)
CASH FLOWS - FINANCING ACTIVITIES			
Repayments of bank loan	(224)	(127)	(36)
Issuance of share capital and warrants, net of issuance expenses	52,453	50,140	14,176
Proceeds from exercise of employee stock options	*	*	*
Net cash provided by financing activities	52,229	50,013	14,140
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14,906	(23,390)	(6,613)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	33,061	68,339	19,321
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	4,931	(1,988)	(562)
CASH AND CASH EQUIVALENTS - END OF PERIOD	52,898	42,961	12,146

* Less than 1,000

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Nine months ended September 30,		Nine months ended September 30,
	2012	2013	2013
	NIS in thousands		In thousands
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	1,188	870	246
Impairment of intangible assets	-	138	39
Long-term prepaid expenses	(17)	60	17
Exchange differences on cash and cash equivalents	(4,931)	1,988	562
Share-based compensation	2,358	2,400	678
Warrant issuance costs	1,204	470	133
Gain on adjustment of warrants to fair value	(5,528)	(10,191)	(2,881)
Interest and exchange differences on short-term deposits	1,726	1,521	431
Interest and linkage on bank loan	(21)	(10)	(3)
Interest and exchange differences on restricted deposits	(31)	30	8
	(4,052)	(2,724)	(770)
Changes in operating asset and liability items:			
Decrease in trade accounts receivable and other receivables	2,193	1,374	388
Increase (decrease) in accounts payable and accruals	1,135	(8,487)	(2,400)
	3,328	(7,113)	(2,012)
	(724)	(9,837)	(2,782)
Supplementary information on interest received in cash	1,439	449	127

SOURCE BioLineRx Ltd.