BioLineRx Reports First Quarter 2013 Results

May 7, 2013

JERUSALEM--(BUSINESS WIRE)--May. 7, 2013-- BioLineRx Ltd. (NASDAQ: BLRX)(TASE: BLRX), a biopharmaceutical development company, today reported its results for the quarter ended March 31, 2013.

Recent Highlights:

- **BL-7040 (IBD)** – Received positive results from a Phase 2 proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of inflammatory bowel disease (IBD)

  Immediate next steps include evaluating the most advantageous ways to progress with this therapeutic candidate from a clinical and business perspective, including examining potential additional indications. Plans also include accelerating discussions with potential co-development and licensing partners.

- **BL-8040 (AML)** – Received U.S. regulatory approvals to commence a Phase 2a trial for the treatment of relapsed/refractory acute myeloid leukemia (AML); trial to be conducted at three sites in the U.S. and five sites in Israel, with initial patient enrollment expected in Q2 2013; partial results expected in Q4 2013 and final results expected in the second half of 2014

- **BL-1040 (ventricular remodeling)** – Recruitment commenced at U.S. sites for the PRESERVATION I clinical trial, a CE Mark registration trial for BL-1040 (BCM), a novel medical device for the prevention of ventricular remodeling following an acute myocardial infarction; there are currently multiple active sites recruiting in six countries

- **BL-5010 (skin lesions)** – Reached final stages of development for proprietary pen-like applicator for BL-5010, a novel formulation of two acids being developed for the non-surgical removal of skin lesions; planning to commence pivotal CE-Mark registration trial for European approval in the second half of 2013

- **BL-8020 (HCV)** – Commenced a Phase 1/2 clinical trial to evaluate the effectiveness of an orally-available, interferon-free treatment for Hepatitis C (HCV) at two sites in France, following approval from the French regulatory authorities; partial results expected in Q4 2013; final results expected in the first half of 2014

- **BL-1020 (schizophrenia)** – Disappointing results of interim analysis for the Phase 2/3 CLARITY trial led to termination of the trial; full unblinded study data is expected during Q3 2013

- **BL-9010 (severe asthma)** – Added a novel, bi-specific antibody for the treatment of severe and persistent asthma to the main therapeutic pipeline, following promising pre-clinical data

- **Capital Raise** – $8 million direct equity placement to the OrbiMed Group was completed in February 2013

“In the past few months, we have seen major progress on a number of clinical and pre-clinical programs in our pipeline, which offer exciting opportunities to address unmet medical needs in a wide range of therapeutic areas. We believe our active programs offer significant potential for patients around the world, as well as for the future success of our Company and its shareholders,” stated Kinneret Savitsky, Ph.D, Chief Executive Officer of BioLineRx. “In the third quarter of this year, we expect to receive a full analysis of the unblinded study data for all participants in the CLARITY Phase 2/3 trial for BL-1020. While we discontinued this clinical trial in mid-March based on disappointing results of the interim analysis, we will not decide the future of the overall BL-1020 program until we have carried out a more thorough review of the full unblinded results.”

“The PRESERVATION I study being conducted by our partner, Ikaria, for BL-1040, for the treatment of ventricular remodeling post-AMI, is moving forward at full steam, with multiple sites in six countries around the world actively recruiting, including a number of sites in the U.S. BL-1040 remains one of our leading compounds, with significant clinical data expected to be reported next year, and we hope that it will eventually offer a great benefit to heart attack patients,” continued Dr. Savitsky.

“We continue to accelerate development of our clinical pipeline, with three of our compounds completing significant milestones since the beginning of the year. Our BL-7040 compound for IBD completed a Phase 2a open-label, proof-of-concept study with very encouraging and positive results. We are

now evaluating next steps for BL-7040 in order to identify the best way to move forward from both a clinical and business perspective, including examining potential additional indications. In parallel, we are also planning to accelerate discussions with potential co-development and licensing partners for this asset."

"In addition, BL-8040, for hematological cancers, one of our most exciting programs, just received FDA approval to commence a Phase 2a trial for the treatment of relapsed/refractory AML. We are excited to initiate this multicenter, open-label study under an IND, which will be conducted in the U.S. and Israel, and will enroll up to 50 patients. MD Anderson Cancer Center in Houston will be the initial site for this trial, with two additional premier sites in the US and five other well-known sites in Israel expected to participate. We believe the excitement surrounding the trial, especially at these particular sites, is a testament to the need for an AML therapy, as well as the potential of BL-8040 shown in the previous pre-clinical and clinical data."

"Finally, we recently reported enrollment of the first patient in our Phase 1/2 trial for BL-8020, an oral treatment for HCV, at a leading hospital in Paris, France. We look forward to partial results from the trial in the fourth quarter of 2013, as well as final results in the first half of 2014. I would also like to point out that as our pipeline evolves, we continue to replenish our pre-clinical pipeline with the addition of promising assets, such as BL-9010 for the treatment of severe and persistent asthma, which recently graduated from our Early Development Program," concluded Dr. Savitsky

Financial Results for Q1 2013:

During the three months ended March 31, 2013 and 2012, no revenues were recorded.

Research and development expenses for the three months ended March 31, 2013 were NIS 19.4 million ($5.3 million), an increase of NIS 4.7 million ($1.3 million) or 32% compared to NIS 14.7 million ($4.0 million) for the three months ended March 31, 2012. In March 2013, due to the BL-1020 CLARITY study termination, the Company reversed the remaining liability to repay grants previously received from the OCS in respect of BL-1020, as it became more likely than not that such liability would not be repaid. As a result, a one-time credit to research and development expenses in the amount of NIS 6.0 million was recorded during the quarter. Without regard to this one-time credit, research and development expenses increased by NIS 10.8 million compared to the first quarter of 2012. The primary reason for this increase is significantly higher expenses in 2013 associated with the CLARITY clinical trial, as well as a ramp-up in spending on other clinical-stage projects introduced during 2012.

Sales and marketing expenses for the three months ended March 31, 2013 were NIS 0.8 million ($0.2 million), similar to the three months ended March 31, 2012.

General and administrative expenses for the three months ended March 31, 2013 were NIS 3.5 million ($1.0 million), similar to the three months ended March 31, 2012.

The Company's operating loss the three months ended March 31, 2013 amounted to NIS 23.7 million ($6.5 million), compared with an operating loss of NIS 19.0 million ($5.2 million) for the comparable period in 2012.

Non-operating income for the three months ended March 31, 2013 amounted to NIS million 12.3 ($3.4 million), an increase of NIS 9.4 million ($2.6 million), compared to net non-operating income of NIS 2.8 million ($0.8 million) for the three months ended March 31, 2012. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which were completed in February 2012 and 2013. These fair-value adjustments were highly influenced by the Company's share price at each period end (revaluation date).

Net financial expenses for the three months ended March 31, 2013 amounted to NIS million 1.4 ($0.4 million), a decrease of NIS 0.4 million ($0.1 million), compared to net financial expenses of NIS 1.8 million ($0.5 million) for the three months ended March 31, 2012. Net financial expenses for both periods result primarily from changes in the average exchange rate of the dollar in relation to the NIS, which had a negative effect on the Company's net assets denominated in dollars.

Net loss for the three months ended March 31, 2013 amounted to NIS 12.8 million ($3.5 million), compared with a net loss of NIS 17.9 million ($4.9 million) for the comparable period in 2012.

As of March 31, 2013, BioLineRx had NIS 102.4 million ($28.1 million) in cash, cash equivalents and short-term bank deposits.

Net cash used in operating activities was NIS 19.2 million ($5.3 million) for the three months ended March 31, 2013, compared with net cash used in operating activities of NIS 12.9 million ($3.5 million) for the three months ended March 31, 2012. The NIS 6.3 million ($1.8 million) increase in net cash used in operating activities during the three-month period in 2013, compared to the three-month period in 2012, was primarily the result of increased research and development spending.

Net cash used in investing activities for the three months ended March 31, 2013 was NIS 43.8 million ($12.0 million), compared to net cash provided by investing activities of NIS 22.1 million ($6.1 million) for the three months ended March 2012. The cash flows related to investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective quarters.

Net cash provided by financing activities for the three months ended March 31, 2013 was NIS 42.0 million ($11.5 million), compared to net cash provided by financing activities of NIS 52.4 million ($14.4 million) for the three months ended March 2012. The cash flows from financing activities primarily reflect the direct and private placements that were completed in February 2013 and 2012.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its first quarter 2013 results today, May 7, 2013, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-668-9141 from the U.S. or +972-3-918-0609 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 +972-3-925-5921 internationally. The replay will be available through May 10, 2013.

(Tables follow)

About BioLineRx

BioLineRx 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 seven clinical stage candidates: 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-7040 for treating inflammatory bowel disease (IBD) has completed a Phase 2a trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase 2 study; BL-1021 for neuropathic pain is in Phase 1 development; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; and BL-1020 for schizophrenia. In addition, BioLineRx has five 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, the content of which does not form a part of this press release.

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.

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

			Convenience translation into USD
	December 31, 2012	**March 31, 2013**	**March 31, 2013**
	NIS in thousands		**In thousands**
Assets			
CURRENT ASSETS			
Cash and cash equivalents	68,339	46,638	12,785
Short-term bank deposits	11,459	55,805	15,297
Prepaid expenses	804	843	231
Other receivables	2,254	2,581	707
Total current assets	82,856	105,867	29,020
NON-CURRENT ASSETS			
Restricted deposits	3,513	1,950	535
Long-term prepaid expenses	204	192	53
Property and equipment, net	3,172	2,947	807
Intangible assets, net	1,063	1,056	290
Total non-current assets	7,952	6,145	1,685
Total assets	90,808	112,012	30,705
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term bank loan	137	54	15
Accounts payable and accruals:			
Trade	12,283	21,873	5,996
OCS	6,148	-	-
Other	5,443	5,300	1,453
Total current liabilities	24,011	27,227	7,464
NON-CURRENT LIABILITIES			
Retirement benefit obligations	143	143	39
Warrants	10,725	10,625	2,913

Total non-current liabilities	10,868	10,768	2,952
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	34,879	37,995	10,416
EQUITY			
Ordinary shares	1,837	2,225	610
Share premium	464,629	494,749	135,622
Capital reserve	33,802	34,222	9,381
Accumulated deficit	(444,339)	(457,179)	(125,324)
Total equity	55,929	74,017	20,289
Total liabilities and equity	90,808	112,012	30,705

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CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(UNAUDITED)

			Convenience translation into USD
	Three months ended March 31,		**Three months ended March 31,**
	2012	**2013**	**2013**
	NIS in thousands		**In thousands**
RESEARCH AND DEVELOPMENT EXPENSES, NET	(14,675)	(19,443)	(5,330)
SALES AND MARKETING EXPENSES	(766)	(771)	(211)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,525)	(3,522)	(965)
OPERATING LOSS	(18,966)	(23,736)	(6,506)
NON-OPERATING INCOME, NET	2,819	12,262	3,361
FINANCIAL INCOME	446	663	182
FINANCIAL EXPENSES	(2,231)	(2,029)	(556)
NET LOSS AND COMPREHENSIVE LOSS	(17,932)	(12,840)	(3,519)
	NIS		**USD**
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.12)	(0.06)	(0.02)

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Three months ended March 31,		**Three months ended March 31,**
	2012	**2013**	**2013**
	NIS in thousands		**In thousands**
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(17,932)	(12,840)	(3,519)

Adjustments required to reflect net cash used in operating activities (see appendix below)	5,012	(6,353)	(1,741)
Net cash used in operating activities	(12,920)	(19,193)	(5,260)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(22,872)	(56,695)	(15,542)
Maturities of short-term deposits	45,338	11,412	3,128
Maturities of restricted deposits	-	1,550	425
Purchase of property and equipment	(382)	(42)	(11)
Purchase of intangible assets	(16)	(30)	(8)
Net cash provided by (used in) investing activities	22,068	(43,805)	(12,008)
CASH FLOWS - FINANCING ACTIVITIES			
Repayments of bank loan	(77)	(76)	(21)
Issuance of share capital and warrants, net of issuance expenses	52,453	42,091	11,538
Proceeds from exercise of employee stock options	*	*	*
Net cash provided by financing activities	52,376	42,015	11,517
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	61,524	(20,983)	(5,751)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	33,061	68,339	18,733
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(836)	(718)	(197)
CASH AND CASH EQUIVALENTS - END OF PERIOD	93,749	46,638	12,785

* Represents an amount less than 1,000.

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Three months ended March 31,		**Three months ended March 31,**
	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	406	304	83
Long-term prepaid expenses	(1)	12	3
Exchange differences on cash and cash equivalents	836	718	197
Interest and exchange differences on short-term deposits	1,904	937	257
Interest and linkage on bank loan	(5)	(7)	(2)
Share-based compensation	965	999	273
Warrant issuance costs	1,204	470	130
Gain on adjustment of warrants to fair value	(4,023)	(12,732)	(3,490)
Interest and exchange differences on restricted deposits	4	13	4
	1,290	(9,286)	(2,545)
Changes in operating asset and liability items:			

Decrease (increase) in trade accounts receivable and other receivables	1,673	(366)	(100)
Increase in accounts payable and accruals	2,049	3,299	904
	3,722	2,933	804
	5,012	(6,353)	(1,741)
Supplementary information on interest received in cash	601	316	87

Source: BioLineRx Ltd.

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