BioLineRx Reports First Quarter 2014 Financial Results

May 20, 2014

Company Poised to Execute on Multiple Clinical Milestones

JERUSALEM--(BUSINESS WIRE)--May 20, 2014-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reported its financial results for first quarter ended March 31, 2014.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, “In the first quarter of 2014 we have generated significant progress in several of our clinical and pre-clinical programs. We continue to focus our efforts in the therapeutic areas of oncology and immunology, and have succeeded in rapidly advancing our two lead clinical programs - BL-8040 for the treatment of acute myeloid leukemia (AML), stem cell mobilization and other hematological indications; and BL-7010 for the treatment of celiac disease. We anticipate reaching several key milestones for these programs in the coming months. We expect to commence a Phase 1 stem cell mobilization study for BL-8040 during the second quarter, with results expected during the second half of this year. We also expect Prof. Arnon Nagler, Director, Bone Marrow Transplantation Dept. and Cord Blood Bank, Sheba Medical Center, to initiate an investigator-led Phase 1/2 study in Chronic Myeloid Leukemia (CML) in 2014. In addition, we expect to report final Phase 2 data from our AML study for BL-8040 in early 2015. For BL-7010, we anticipate final results from our ongoing Phase 1/2 study in the next few months, and pending positive results, would look to initiate a randomized efficacy study later in 2014. We view these milestones as the primary value drivers for BioLineRx, and we are committed to moving these programs along as expeditiously as possible.

“In addition, BL-1040, which is being developed by Bellerophon (f/k/a Ikaria) as the Bioabsorbable Cardiac Matrix (BCM) device, is in the midst of a CE Mark Registration trial at 80 sites worldwide, 14 of which are in the U.S. Over 200 patients have been enrolled in the trial to date, out of a total planned enrollment of approximately 300 patients. Due to a lower than expected enrollment rate that was recently communicated to us by Bellerophon, we anticipate an approximate six-month delay in the study, with study enrollment to be finalized by the end of 2014, and the study to be completed in mid-2015. Bellerophon has also informed us that it plans to file for a CE mark in the European Union in the second half of 2015.

“On a different note, we have recently been engaged in discussions with Bellerophon relating to its performance under the BL-1040 license agreement. We believe that Bellerophon has breached the agreement in several ways, and we also disagree with Bellerophon about the timing of a $12.5 million milestone payment that Bellerophon would owe to us in the future based upon progress in the BL-1040 clinical development program. We have had a number of discussions with Bellerophon on these issues and these discussions are continuing. Although we hope we can resolve the outstanding issues with Bellerophon amicably, if we are unable to reach agreement with Bellerophon on these issues, we would consider all other remedies available to us.

“Another one of our clinical programs, BL-5010P, for the non-surgical removal of benign skin lesions, is gaining interest in the industry. We are currently engaged in advanced discussions with several potential partners for the out-licensing of BL-5010P in a number of potential indications, such as actinic keratosis and warts, and the outcome of these discussions will determine the development plan for this promising product.

“We can also report progress on the commercialization front as we continue to explore earlier-stage partnering deals, as well as regional and co-development arrangements, in order to reduce the financial risk associated with the development of some of our non-core assets. During the past quarter we entered into a collaboration with JHL Biotech, a Taiwan-based rising star in the global biologics space backed by a consortium of top-tier venture capital firms, for the development and commercialization of BL-9020, a novel monoclonal antibody for the treatment of Type 1 diabetes. In addition to out-licensing the project for development and commercialization in China and Southeast Asia, this partnership provides us with a platform for the development and manufacturing of biologics. These types of arrangements enable us to focus our resources on our lead development assets, while maintaining substantial upside potential on the partnered programs. We also see significant potential for further enhancing our presence in the Asian pharmaceutical industry.

“Following our successful financing in March of this year, we have the necessary funding to executive our development and commercialization plans through 2016, and we look forward to sharing with our shareholders our continued progress as we anticipate a number of significant catalysts over the next several quarters,” concluded Dr. Savitsky.

Financial Results for Quarter Ended March 31, 2014

Research and development expenses for the three months ended March 31, 2014 were NIS 9.5 million ($2.7 million), a decrease of NIS 9.9 million ($2.8 million), or 51%, compared to NIS 19.4 million ($5.5 million) for the three months ended March 31, 2013. The decrease resulted primarily from termination of the BL-1020 CLARITY clinical trial in March 2013, which was partially offset by a ramp-up in spending on other clinical-stage projects, primarily BL-8040 and BL-7010.

Sales and marketing expenses for the three months ended March 31, 2014 were NIS 1.3 million ($0.4 million), an increase of NIS 0.5 million ($0.2 million), or 66%, compared to NIS 0.8 million ($0.2 million) for the three months ended March 31, 2013. The increase resulted primarily from professional fees in connection with increased business development activities.

General and administrative expenses for the three months ended March 31, 2014 and 2013 were NIS 3.5 million ($1.0 million).

The Company’s operating loss for the three months ended March 31, 2014 amounted to NIS 14.3 million ($4.1 million), compared with an operating loss of NIS 23.7 million ($6.8 million) for the comparable period in 2013.

The Company recognized net non-operating income of NIS 5.9 million ($1.7 million) for the three months ended March 31, 2014, a decrease of NIS 6.4 million ($1.8 million), compared to net non-operating income of NIS 12.3 million ($3.5 million) for the three months ended March 31, 2013. 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 completed in February 2012 and 2013. These fair-value adjustments are highly influenced by the Company’s share price at each

period end (revaluation date).

The Company recognized net financial income of NIS 1.0 million ($0.3 million) for the three months ended March 31, 2014, a change of NIS 2.4 million ($0.7 million), compared to net financial expenses of NIS 1.4 million ($0.4 million) for the three months ended March 31, 2013. 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 the Company's net assets denominated in dollars.

The Company's net loss for the three months ended March 31, 2014 amounted to NIS 7.4 million ($2.1 million), compared with a net loss of NIS 12.8 million ($3.7 million) for the comparable period in 2013.

The Company held NIS 130.7 million ($37.5 million) in cash, cash equivalents and short-term bank deposits as of March 31, 2014

Net cash used in operating activities was NIS 11.8 million ($3.4 million) for the three months ended March 31, 2014, compared with net cash used in operating activities of NIS 19.2 million ($5.5 million) for the three months ended March 31, 2013. The NIS 7.4 million ($2.1 million) decrease in net cash used in operating activities during the three-month period in 2014, compared to the three-month period in 2013, was primarily the result of decreased research and development spending.

Net cash used in investing activities for the three months ended March 31, 2014 was NIS 66.2 million ($19.0 million), compared to net cash used in investing activities of NIS 43.8 million ($12.6 million) for the three months ended March 31, 2013. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the three months ended March 31, 2014 was NIS 78.6 million ($22.5 million), compared to net cash provided by financing activities of NIS 42.0 million ($12.1 million) for the three months ended March 31, 2013. The cash flows from financing activities in 2014 primarily reflect the underwritten public offering completed in March 2014. The cash flows from financing activities in 2013 primarily reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the share purchase agreement with LPC.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its first quarter 2014 results today, May 20, 2014, at 10:00 a.m. EDT. A presentation will be available on BioLineRx's website to accompany management's remarks on the call. To access the conference call, please dial 1-888-860-9642 from the U.S., or +972-3-918-0691 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 1-888-276-1485 from the U.S. or +972-3-9255945 internationally. The replay will be available through May 23, 2014.

About BioLineRx

BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. 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 Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial; 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 in the midst of a Phase 1/2 study.

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 17, 2014. 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, 2013	March 31, 2014	March 31, 2014
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	30,888	31,947	9,162
Short-term bank deposits	32,345	98,791	28,331
Prepaid expenses	896	927	266
Other receivables	1,249	793	227
Total current assets	65,378	132,458	37,986
NON-CURRENT ASSETS			
Restricted deposits	573	576	165
Long-term prepaid expenses	169	191	55
Property and equipment, net	2,471	2,404	690
Intangible assets, net	878	859	246
Total non-current assets	4,091	4,030	1,156
Total assets	69,469	136,488	39,142
Liabilities and equity			
CURRENT LIABILITIES			
Accounts payable and accruals:			
Trade	7,945	6,899	1,979
Other	2,499	4,271	1,225
Total current liabilities	10,444	11,170	3,204
NON-CURRENT LIABILITIES			
Retirement benefit obligations	152	152	44
Warrants	18,187	12,304	3,528
Total non-current liabilities	18,339	12,456	3,572
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	28,783	23,626	6,776
EQUITY			
Ordinary shares	2,414	3,396	974
Share premium	509,857	587,451	168,468
Capital reserve	34,192	35,191	10,092
Accumulated deficit	(505,777)	(513,176)	(147,168)
Total equity	40,686	112,862	32,366
Total liabilities and equity	69,469	136,488	39,142

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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,
	2013	2014	2014
	NIS in thousands		In thousands
RESEARCH AND DEVELOPMENT EXPENSES, NET	(19,443)	(9,510)	(2,727)
SALES AND MARKETING EXPENSES	(771)	(1,283)	(368)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,522)	(3,463)	(993)
OPERATING LOSS	(23,736)	(14,256)	(4,088)
NON-OPERATING INCOME, NET	12,262	5,883	1,687

FINANCIAL INCOME	663	1,258	361
FINANCIAL EXPENSES	(2,029)	(284)	(81)
NET LOSS AND COMPREHENSIVE LOSS	(12,840)	(7,399)	(2,121)
	NIS		**USD**
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.06)	(0.03)	(0.01)

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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,**
	2013	**2014**	**2014**
	NIS in thousands		**In thousands**
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(12,840)	(7,399)	(2,121)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(6,353)	(4,448)	(1,275)
Net cash used in operating activities	(19,193)	(11,847)	(3,396)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(56,695)	(91,352)	(26,197)
Maturities of short-term deposits	11,412	25,317	7,260
Maturities of restricted deposits	1,550	-	-
Purchase of property and equipment	(42)	(163)	(47)
Purchase of intangible assets	(30)	-	-
Net cash used in investing activities	(43,805)	(66,198)	(18,984)
CASH FLOWS - FINANCING ACTIVITIES			
Repayments of bank loan	(76)	-	-
Issuances of share capital and warrants, net	42,091	78,576	22,533
Proceeds from exercise of employee stock options	*	-	-
Net cash provided by financing activities	42,015	78,576	22,533
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(20,983)	531	153
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	68,339	30,888	8,858
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(718)	528	151
CASH AND CASH EQUIVALENTS - END OF PERIOD	46,638	31,947	9,162

* Represents an amount less than 1,000.

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,		Convenience translation into USD Three months ended March 31,
	2013	2014	2014
	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	304	249	71
Long-term prepaid expenses	12	(22)	(6)
Exchange differences on cash and cash equivalents	718	(528)	(151)
Interest and exchange differences on short-term deposits	937	(411)	(118)
Interest and linkage on bank loan	(7)	-	-
Share-based compensation	999	999	286
Warrant issuance costs	470	-	-
Gain on adjustment of warrants to fair value	(12,732)	(5,883)	(1,687)
Interest and exchange differences on restricted deposits	13	(3)	(1)
	(9,286)	(5,599)	(1,606)
Changes in operating asset and liability items:			
Decrease (increase) in trade accounts receivable and other receivables	(366)	425	122
Increase in accounts payable and accruals	3,299	726	209
	2,933	1,151	331
	(6,353)	(4,448)	(1,275)
Supplementary information on interest received in cash	316	46	13

Source: BioLineRx

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