BioLineRx Reports First Quarter 2015 Financial Results

May 18, 2015

JERUSALEM--(BUSINESS WIRE)--May 18, 2015-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reports its financial results for the first quarter ended March 31, 2015.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, “During the first quarter of 2015, we continued to focus on advancing our lead programs through value-driving clinical and regulatory milestones. We recently completed the dose escalation stage of our ongoing BL-8040 Phase 2 clinical study for treating relapsed and refractory acute myeloid leukemia (AML), which continues to show excellent safety and tolerability, as well as robust mobilization and apoptosis of the cancer cells. We have begun to enroll patients in the expansion stage of the study at the optimal chosen dose of 1.5 mg/kg. In addition, we announced successful top-line safety and efficacy results from our Phase 1 study of BL-8040 as a novel, single-agent stem cell mobilization treatment, where we met all safety and efficacy endpoints. We plan to meet with the FDA as soon as possible to discuss the results of the study and obtain more clarity on the next steps in clinical development for this indication. We intend to present the full Phase 1 study results at the European Hematology Association Conference in June, which we expect will garner significant interest from the transplant community.”

Dr. Savitsky continued, “BioLineRx has significant milestones upcoming in the near term and over the next twelve months. In the fourth quarter of 2015, we anticipate reporting top-line results from the complete Phase 2 AML study, including the current expansion phase. Over the next few months, we are also preparing to initiate several additional clinical studies for BL-8040 that will expand the potential indications for our lead platform. The required regulatory submissions have been made for the first of these studies, a large Phase 2b study to evaluate BL-8040 as a consolidation AML therapy. In addition, we plan to assess BL-8040 as a novel treatment for hypoplastic myelodysplastic syndrome and aplastic anemia with the initiation of a Phase 2 trial. Following that, we expect to initiate a third AML trial for BL-8040, a Phase 2 study in combination with a FLT3 inhibitor agent, for patients with FLT3-ITD-mutated AML. We are very excited to explore the expanded potential for BL-8040, which we believe is poised to become a market-leading hematological platform.”

“Beyond our BL-8040 platform, we are awaiting formal approval of the device regulatory pathway by the EU Notified Body with regard to BL-7010, our novel polymer for treating celiac disease. In addition, we are finalizing additional non-clinical studies and formulation work to support potential initiation of a pivotal CE Mark registration study in the fourth quarter of this year.”

“Finally, at the beginning of the year, we announced that our partner Bellerophon had completed enrollment for BL-1040, our most advanced partnered program, in the PRESERVATION 1 pivotal CE Mark registration study. The enrolled patients are completing the six-month follow up period and we expect to report top-line results in mid-2015. In parallel to the study in Europe, Bellerophon is preparing to commence a U.S. pivotal study in the first half of 2016.”

Dr. Savitsky concluded, “From a corporate perspective, we recently announced our intention to carry out a 1:10 reverse split of our ordinary shares traded in Tel Aviv. The purpose of this reverse share split is to provide for a 1:1 ratio of our ordinary shares traded in Tel Aviv with our American Depositary Shares traded on NASDAQ, thus preventing any confusion in the market due to the current 10:1 ratio. In addition, we would also like to emphasize our strong balance sheet following the successful completion of a $29 million secondary public offering of our ADSs this quarter, which allows us to aggressively progress the clinical development of BL-8040 and BL-7010, and continue to screen for opportunities we hope to realize under our strategic collaboration with Novartis. We believe we have a sufficient cash runway to pursue all planned clinical activities for the next three years.”

Financial Results for First Quarter Ended March 31, 2015

Research and development expenses for the three months ended March 31, 2015 were $3.2 million, an increase of $0.5 million, or 18%, compared to $2.7 million for the corresponding 2014 period. The increase resulted primarily from increased spending on BL-8040 in the 2015 period, partially offset by decreased spending on BL-7010, BL-9020 and BL-5010.

Sales and marketing expenses for the three months ended March 31, 2015 were $0.3 million, a decrease of $0.1 million, or 29%, compared to $0.4 million for the three months ended March 31, 2014. The decrease resulted primarily from professional fees related to a number of significant business development activities carried out during the 2014 period, which resulted in collaboration and outlicensing agreements later in the year.

General and administrative expenses for the three months ended March 31, 2015 were $0.9 million, a decrease of $0.1 million, or 14%, compared to $1.0 million for the three months ended March 31, 2014. The small decrease resulted primarily from exchange rate differences.

The Company’s operating loss for the three months ended March 31, 2015 amounted to $4.3 million, compared with an operating loss of $4.1 million for the corresponding 2014 period.

The Company recognized an immaterial amount of net non-operating expenses for the three months ended March 31, 2015, compared to net non-operating income of $1.7 million for the corresponding period in 2014. Non-operating income (expenses) for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by the Company’s share price at each period end (revaluation date).

The Company recognized an immaterial amount of net financial income for the three months ended March 31, 2015, compared to net financial income of $0.3 million for the corresponding period in 2014. Net financial income (expenses) for the 2015 period primarily relates to investment income earned on bank deposits, as well as banking fees. The 2014 period also includes exchange rate differences primarily relating to changes in the USD/NIS exchange rate.

The Company’s net loss for the three months ended March 31, 2015 amounted to $4.3 million, compared with a net loss of $2.1 million for the corresponding 2014 period.

The Company held $57.5 million in cash, cash equivalents and short-term bank deposits as of March 31, 2015.

Net cash used in operating activities was $3.5 million for the three months ended March 31, 2015, compared with net cash used in operating activities of $3.4 million for the three months ended March 31, 2014. The $0.1 million increase in net cash used in operating activities during the three-month period in 2015, compared to the three-month period in 2014, was primarily the result of increased research and development spending, partially offset by an increase in trade payables and accruals.

Net cash used in investing activities for the three months ended March 31, 2015 was $20.7 million, compared to net cash used in investing activities of $19.1 million for the three months ended March 31, 2014. 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, 2015 was $26.5 million, compared to net cash provided by financing activities of $22.6 million for the three months ended March 31, 2014. The cash flows from financing activities primarily reflect underwritten public offerings of our ADSs in March 2015 and 2014.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its first-quarter end March 31, 2015 results today, May 18, 2015, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-407-2553 from the US, or +972-3-918-0644 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 1-877-456-0009 from the US or +972-3-925-5944 internationally. The replay will be available through May 21, 2015.

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 scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

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 23, 2015. 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)

	December 31, 2014	**March 31, 2015**
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,790	8,075
Short-term bank deposits	28,890	49,418
Prepaid expenses	221	296
Other receivables	257	641

Total current assets	35,158	58,430
NON-CURRENT ASSETS		
Restricted deposits	166	166
Long-term prepaid expenses	49	50
Property and equipment, net	721	1,111
Intangible assets, net	117	116
Total non-current assets	1,053	1,443
Total assets	36,211	59,873
Liabilities and equity		
CURRENT LIABILITIES		
Accounts payable and accruals:		
Trade	1,654	2,614
Other	1,252	1,531
Total current liabilities	2,906	4,145
NON-CURRENT LIABILITIES		
Warrants	1,500	1,540
Total non-current liabilities	1,500	1,540
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	4,406	5,685
EQUITY		
Ordinary shares	1,055	1,420
Share premium	167,331	193,426
Other reserves	(1,416)	(1,416)
Capital reserve	9,800	10,034
Accumulated deficit	(144,965)	(149,276)
Total equity	31,805	54,188
Total liabilities and equity	36,211	59,873

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CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31,	
	2014	**2015**
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,719)	(3,211)
SALES AND MARKETING EXPENSES	(367)	(260)
GENERAL AND ADMINISTRATIVE EXPENSES	(990)	(856)
OPERATING LOSS	(4,076)	(4,327)
NON-OPERATING INCOME (EXPENSES), NET	1,687	(40)
FINANCIAL INCOME	355	73
FINANCIAL EXPENSES	(81)	(17)
NET LOSS	(2,115)	(4,311)
OTHER COMPREHENSIVE LOSS:		
CURRENCY TRANSLATION DIFFERENCES	(136)	-
COMPREHENSIVE LOSS	(2,251)	(4,311)
	in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.008)	(0.010)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	269,241,871	425,069,045

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2014	2015
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(2,115)	(4,311)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,276)	843
Net cash used in operating activities	(3,391)	(3,468)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(26,240)	(31,153)
Maturities of short-term deposits	7,231	10,634
Purchase of property and equipment	(47)	(149)
Purchase of intangible assets	-	(2)
Net cash used in investing activities	(19,056)	(20,670)
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital and warrants, net	22,610	26,460
Net cash provided by financing activities	22,610	26,460
INCREASE IN CASH AND CASH EQUIVALENTS	163	2,322
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	8,899	5,790
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	100	(37)
CASH AND CASH EQUIVALENTS - END OF PERIOD	9,162	8,075

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2014	2015
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	71	102
Long-term prepaid expenses	(6)	(1)
Interest on short-term deposits	(119)	(9)
Share-based compensation	286	234
Exchange differences on cash and cash equivalents	(151)	37
Loss (gain) on adjustment of warrants to fair value	(1,687)	40
	(1,606)	403
Changes in operating asset and liability items:		

Decrease (increase) in trade accounts receivable and other receivables	122	(459)
Increase in accounts payable and accruals	208	899
	330	440
	(1,276)	843
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	-	482
Supplementary information on interest received in cash	13	30

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