BioLineRx Reports Second Quarter 2014 Financial Results

August 6, 2014

JERUSALEM--(BUSINESS WIRE)--Aug. 6, 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 the second quarter ended June 30, 2014.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, “In the second quarter of 2014 we continued to make headway in our clinical and pre-clinical programs, focusing primarily on our lead products in oncology and immunology - 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.

“BL-8040 is currently in the midst of the dose-escalation part of a Phase 2 trial for the treatment of AML, which is being conducted at several world-leading cancer research centers in the U.S. and Israel. The study is progressing nicely and we continue to expect final Phase 2 data in early 2015. Additionally, after receiving approval from the Israeli Ministry of Health, we expect to commence a Phase 1 trial for BL-8040 as a novel stem cell mobilization agent during the next 4-6 weeks, with results expected in late 2014 or early 2015. We also anticipate an investigator-initiated Phase 1/2 trial for BL-8040 as a treatment for chronic myeloid leukemia (CML) to commence by the end of the year, to be performed by Prof. Arnon Nagler at Sheba Medical Center in Israel. We look forward to providing updates on these important clinical milestones over the next several months, as well as reporting the final results from both the AML and stem cell mobilization trials within the next six to nine months.

“We also announced unblinded results of our Phase 1/2 safety study for BL-7010, our novel, non-absorbable, orally available, co-polymer intended for the treatment of celiac disease. BL-7010 showed no serious or dose-limiting adverse events after the 14-day repeated administration stage of the study, and pharmacokinetic analyses confirmed that there was no systemic exposure to BL-7010. This is significant, as the lack of systemic absorption may allow BL-7010 to be regulated as a medical device in Europe, accelerating its pathway to commercialization. Based on the anticipated therapeutic window for BL-7010, we are currently investigating lower repeated doses of BL-7010 as a continuation of this study, in order to potentially mitigate the minor gastrointestinal events observed at higher doses, as well in the placebo group, and to select the optimal dose to carry forward into the upcoming efficacy study, which we expect to commence in early 2015.

“As for BL-1040, our novel resorbable polymer solution for the prevention of ventricular remodeling following an acute myocardial infarction (AMI), PRESERVATION I, the ongoing CE Mark registration trial, continues to advance towards completion in the hands of our out-licensing partner, Bellerophon. Over 200 patients have been enrolled in the study, which is designed to enroll a total of approximately 300 patients. We continue to expect Bellerophon to complete enrollment by the end of the year, with study completion anticipated around mid-2015.

“Finally, as part of our ongoing efforts to investigate novel pipeline assets, we announced the in-licensing of BL-1110 for the treatment of neuropathic pain. While we remain focused primarily on the clinical development of our lead oncology and immunology programs, BioLineRx will continue to look at earlier-stage opportunities, based on our proven ability to identify such compounds, in order to enhance and maintain our development pipeline.”

Financial Results for Quarter and Six Months Ended June 30, 2014

Research and development expenses for the three months ended June 30, 2014 were NIS 9.7 million ($2.8 million), a decrease of NIS 2.4 million ($0.7 million), or 20%, compared to NIS 12.1 million ($3.5 million) for the three months ended June 30, 2013. The decrease resulted primarily from certain one-time costs associated with several clinical-stage projects in 2013, partially offset by increased spending on BL-7010 in the 2014 period. Research and development expenses for the six months ended June 30, 2014 were NIS 19.2 million ($5.6 million), a decrease of NIS 18.3 million ($5.3 million), or 49%, compared to NIS 37.5 million ($10.9 million) for the six months ended June 30, 2013, after taking into account the NIS 6.0 million ($1.7 million) one-time reversal of a liability to the OCS in respect of BL-1020. The decrease resulted primarily from termination of the BL-1020 CLARITY clinical trial in March 2013 and certain one-time costs associated with several clinical-stage projects in 2013, partially offset by increased spending on BL-7010 in the 2014 period as mentioned above.

Sales and marketing expenses for the three months ended June 30, 2014 were NIS 1.0 million ($0.3 million), substantially similar to the comparable period in 2013. Sales and marketing expenses for the six months ended June 30, 2014 were NIS 2.3 million ($0.7 million), an increase of NIS 0.5 million ($0.2 million), or 24%, compared to NIS 1.8 million ($0.5 million) for the six months ended June 30, 2013. The increase resulted primarily from professional fees related to increased business development activities.

General and administrative expenses for the three months ended June 30, 2014 were NIS 2.9 million ($0.8 million), a decrease of NIS 0.7 million ($0.2 million), or 20%, compared to NIS 3.6 million ($1.0 million) for the three months ended June 30, 2013. The decrease resulted primarily from a one-time expense for professional services incurred in the 2013 period. General and administrative expenses for the six months ended June 30, 2014 were NIS 6.3 million ($1.9 million), a decrease of NIS 0.8 million ($0.2 million), or 11%, compared to NIS 7.1 million ($2.1 million) for the six months ended June 30, 2013. The reason for the decrease is similar to the one discussed above in the three-month comparison.

The Company’s operating loss for the three months ended June 30, 2014 amounted to NIS 13.6 million ($3.9 million), compared with an operating loss of NIS 16.8 million ($4.9 million) for the comparable period in 2013. The Company’s operating loss for the six months ended June 30, 2014 amounted to NIS 27.8 million ($8.1 million), compared with an operating loss of NIS 40.5 million ($11.8 million) for the comparable period in 2013.

The Company’s net non-operating income amounted to NIS 1.0 million ($0.3 million) for the three months ended June 30, 2014, a decrease of NIS 0.6 million ($0.2 million), compared to net non-operating income of NIS 1.6 million ($0.5 million) for the three months ended June 30, 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 conducted in February 2012 and 2013. The Company’s net non-operating income amounted to NIS 6.8 million ($2.0 million) for the six months ended June 30, 2014, a decrease of NIS 7.0 million ($2.0 million), compared to net non-operating income of NIS 13.8 million ($4.0 million) for the comparable 2013 period. The reason for the decrease is similar to the one discussed above in the three-month comparison.

The Company’s net financial expense amounted to NIS 1.5 million ($0.4 million) for the three months ended June 30, 2014, compared to net financial

expense of NIS 0.4 million ($0.1 million) for the three months ended June 30, 2013. Net financial income and expense 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 financial expense amounted to NIS 0.6 million ($0.2 million) for the six months ended June 30, 2014, compared to net financial expense of NIS 1.8 million ($0.5 million) for the comparable 2013 period. The reason for the decrease is similar to the one discussed above in the three-month comparison.

The Company's net loss for the three months ended June 30, 2014 amounted to NIS 14.1 million ($4.1 million), compared with a net loss of NIS 15.6 million ($4.5 million) for the comparable period in 2013. The Company's net loss for the six months ended June 30, 2014 amounted to NIS 21.5 million ($6.3 million), compared with a net loss of NIS 28.4 million ($8.3 million) for the comparable period in 2013.

The Company held NIS 114.0 million ($33.1 million) in cash, cash equivalents and short-term bank deposits as of June 30, 2014.

Net cash used in operating activities was NIS 26.9 million ($7.8 million) for the six months ended June 30, 2014, compared with net cash used in operating activities of NIS 41.5 million ($12.1 million) for the six months ended June 30, 2013. The NIS 14.6 million ($4.3 million) decrease in net cash used in operating activities during the six-month period in 2014, compared to the six-month period in 2013, was primarily the result of decreased research and development spending.

Net cash used in investing activities for the six months ended June 30, 2014 was NIS 53.8 million ($15.6 million), compared to net cash used in investing activities of NIS 21.4 million ($6.2 million) for the six months ended June 30, 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 six months ended June 30, 2014 was NIS 78.6 million ($22.9 million), compared to net cash provided by financing activities of NIS 46.0 million ($13.4 million) for the six months ended June 30, 2013. The cash flows from financing activities in 2014 primarily reflect the Company's underwritten public offering of ADSs in March 2014. The cash flows from financing activities in 2013 primarily reflect the Company's 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 second quarter 2014 results today, August 6, 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 1-888-407-2553 from the U.S. 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 1-888-295-2634 from the U.S. or +972-3-925-5929 internationally. The replay will be available through August 9, 2014.

(Tables follow)

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)

	December 31, 2013	June 30, 2014	Convenience translation into USD June 30, 2014
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	30,888	28,963	8,424
Short-term bank deposits	32,345	84,994	24,722
Prepaid expenses	896	970	282
Other receivables	1,249	1,422	414
Total current assets	65,378	116,349	33,842
NON-CURRENT ASSETS			
Restricted deposits	573	568	165
Long-term prepaid expenses	169	162	47
Property and equipment, net	2,471	2,333	678
Intangible assets, net	878	853	248
Total non-current assets	4,091	3,916	1,138
Total assets	69,469	120,265	34,980
Liabilities and equity			
CURRENT LIABILITIES			
Accounts payable and accruals:			
Trade	7,945	6,397	1,860
Other	2,499	3,057	889
Total current liabilities	10,444	9,454	2,749
NON-CURRENT LIABILITIES			
Retirement benefit obligations	152	152	44
Warrants	18,187	10,130	2,947
Total non-current liabilities	18,339	10,282	2,991
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	28,783	19,736	5,740
EQUITY			
Ordinary shares	2,414	3,411	992
Share premium	509,857	588,622	171,210
Capital reserve	34,192	35,794	10,411
Accumulated deficit	(505,777)	(527,298)	(153,373)
Total equity	40,686	100,529	29,240
Total liabilities and equity	69,469	120,265	34,980

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CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended June 30,	Six months ended June 30,	Convenience translation into USD Three months ended June 30,	Six months ended June 30,

	2013	2014	2013	2014	2014	2014
	NIS in thousands				USD in thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(12,087)	(9,677)	(31,530)	(19,187)	(2,815)	(5,581)
SALES AND MARKETING EXPENSES	(1,063)	(987)	(1,834)	(2,270)	(287)	(660)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,604)	(2,888)	(7,126)	(6,351)	(840)	(1,847)
OPERATING LOSS	(16,754)	(13,552)	(40,490)	(27,808)	(3,942)	(8,088)
NON-OPERATING INCOME, NET	1,579	962	13,841	6,845	280	1,991
FINANCIAL INCOME	1,320	121	1,983	1,067	35	310
FINANCIAL EXPENSES	(1,713)	(1,653)	(3,742)	(1,625)	(480)	(473)
COMPREHENSIVE LOSS FOR THE PERIOD	(15,568)	(14,122)	(28,408)	(21,521)	(4,107)	(6,260)
	NIS				**USD**	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.069)	(0.042)	(0.132)	(0.071)	(0.012)	(0.021)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	226,191,857	340,050,724	215,502,443	305,039,680	340,050,724	305,039,680

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Six months ended June 30,		Six months ended June 30,
	2013	2014	2014
	NIS in thousands		In thousands
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(28,408)	(21,521)	(6,260)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(13,133)	(5,414)	(1,575)
Net cash used in operating activities	(41,541)	(26,935)	(7,835)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(75,008)	(107,211)	(31,184)
Maturities of short-term deposits	52,257	53,732	15,629
Maturities of restricted deposits	1,550	-	-
Additions to property and equipment	(132)	(311)	(90)
Additions to intangible assets	(79)	(10)	(3)
Net cash used in investing activities	(21,412)	(53,800)	(15,648)
CASH FLOWS - FINANCING ACTIVITIES			
Repayments of bank loan	(127)	-	-
Issuance of share capital and warrants, net	46,101	78,590	22,859
Proceeds from exercise of employee stock options	*	*	*
Net cash provided by financing activities	45,974	78,590	22,859
DECREASE IN CASH AND CASH EQUIVALENTS	(16,979)	(2,145)	(624)

CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	68,339	30,888	8,984
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(1,128)	220	64
CASH AND CASH EQUIVALENTS - END OF PERIOD	50,232	28,963	8,424

* Less than 1,000

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

			Convenience translation into USD
	Six months ended June 30,		**Six months ended June 30,**
	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	578	484	141
Impairment of intangible assets	138	-	-
Long-term prepaid expenses	34	7	2
Exchange differences on cash and cash equivalents	1,128	(220)	(64)
Share-based compensation	1,626	1,733	504
Warrant issuance costs	470	-	-
Gain on adjustment of warrants to fair value	(14,498)	(8,057)	(2,344)
Commitment fee paid by issuance of share capital	-	1,041	303
Interest and exchange differences on short-term deposits	972	830	241
Interest and linkage on bank loan	(10)	-	-
Interest and exchange differences on restricted deposits	17	5	2
	(9,545)	(4,177)	(1,215)
Changes in operating asset and liability items:			
Decrease (increase) in trade accounts receivable and other receivables	1,405	(247)	(72)
Decrease in accounts payable and accruals	(4,993)	(990)	(288)
	(3,588)	(1,237)	(360)
	(13,133)	(5,414)	(1,575)
Supplementary information on interest received in cash	323	96	28

Source: BioLineRx

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