BioLineRx Reports Second Quarter 2015 Financial Results

August 20, 2015

TEL AVIV, Israel--(BUSINESS WIRE)--Aug. 20, 2015-- BioLineRx Ltd. (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, 2015.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, “We expect some very exciting milestones for our BL-8040 oncology platform in the coming few months. First, we expect to report top-line data, including response rates, from our Phase 2 clinical study for treating relapsed/refractory AML in the fourth quarter of 2015, following the highly encouraging results to date we reported from the dose escalation stage of this study. Additionally, we presented positive safety and efficacy results from our Phase 1 study of BL-8040 as a novel stem cell mobilization treatment at the European Hematology Association conference in June, which supported the use of BL-8040 as a single-agent, single-injection, one-day regimen for the collection and transplantation of stem cells. This is a major improvement over currently available procedures, and the superior composition of the collected cells may offer the potential for better quality grafts and improved transplant outcomes. We look forward to meeting with the FDA in October to discuss the next steps in the clinical development of this program. Based on the outcome of the meeting, we would expect to initiate a Phase 2 study as early as the first quarter of 2016.”

“We are also expanding our BL-8040 platform into multiple hematological indications beyond our primary AML program, which allows us to pursue additional high-potential, unmet medical needs, while at the same time reducing the overall development risk of our platform. In this regard, we have just announced the initiation of a Phase 2 study as a novel consolidation treatment for AML. The Phase 2b study, which is conducted in collaboration with the German Study Alliance Leukemia Group, will examine BL-8040 as part of a second-stage treatment, termed consolidation therapy, to improve outcomes for AML patients who have achieved remission after the standard first-line treatment regimen, called induction therapy. The consolidation therapy is aimed at eliminating the minimal residual disease left in the bone marrow that can lead to relapse. In addition, we are in the final planning stages for additional studies in AML patients with the FLT3-ITD mutation, and for hypoplastic myelodysplastic syndrome and aplastic anemia, which we expect to initiate by the end of this year.”

Dr. Savitsky continued, “In parallel, we have continued our ongoing dialogue with the EU regulatory authorities to confirm that our novel polymer BL-7010 for treating celiac disease can be developed on the medical device pathway in Europe. Following confirmation of the device pathway, we expect to initiate a pivotal CE Mark registration study for BL-7010 in the fourth quarter of 2015 or beginning of 2016. Currently, we are completing additional non-clinical studies and formulation work to further support advancing and potential approval of BL-7010 in Europe.”

“In addition to our core programs, we were proud to publish the results of our clinical trial for BL-5010, a novel formulation for the non-surgical removal of skin lesions, in *The British Journal of Dermatology*. Our partner Omega Pharma, now part of Perrigo, plans to submit an application for CE marking for BL-5010 in the third quarter of 2015. Upon potential CE Marking, we would expect the first sales of BL-5010 in Europe to start in 2016.”

Dr. Savitsky concluded, “We continue to pursue various collaboration agreements to maximize the value of our current pipeline assets, including discussions with additional partners for the purpose of monetizing some of our non-core programs. In parallel to our internal pipeline development, we continue to screen potential assets to develop under our strategic partnership with Novartis, and we will provide timely updates on therapeutic candidates selected by Novartis when these promising candidates emerge. Finally, we remain well capitalized to execute on our development program and to achieve significant milestones across our expanded therapeutic pipeline and we look forward to demonstrating our enhanced value proposition over the coming months.”

Financial Results for Quarter Ended June 30, 2015

Research and development expenses for the three months ended June 30, 2015 were $2.9 million, an increase of $0.1 million, or 4%, compared to $2.8 million for the three months ended June 30, 2014. The small 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. Research and development expenses for the six months ended June 30, 2015 were $6.1 million, an increase of $0.6 million, or 11%, compared to $5.5 million for the six months ended June 30, 2014. The reason for the increase is similar to the one discussed above in the three-month comparison.

Sales and marketing expenses for the three months ended June 30, 2015 were $0.3 million, substantially similar to the comparable period in 2014. Sales and marketing expenses for the six months ended June 30, 2015 were $0.6 million, a decrease of $0.1 million, or 14%, compared to $0.7 million for the six months ended June 30, 2014. The decrease resulted primarily from professional fees related to a number of significant business development activities carried out during the six-month period in 2014, which resulted in collaboration and outlicensing agreements later in the year.

General and administrative expenses for the three months ended June 30, 2015 were $1.0 million, an increase of $0.1 million, or 17%, compared to $0.8 million for the three months ended June 30, 2014. The small increase resulted primarily from an increase in salary-related payments. General and administrative expenses for the six months ended June 30, 2015 were $1.8 million, substantially similar to the comparable period in 2014.

The Company’s operating loss for the three months ended June 30, 2015 amounted to $4.2 million, compared with an operating loss of $3.9 million for the corresponding 2014 period. The Company’s operating loss for the six months ended June 30, 2015 amounted to $8.5 million, compared with an operating loss of $8.0 million for the corresponding 2014 period.

Net non-operating expenses amounted to $0.9 million for the three months ended June 30, 2015, a change of $1.1 million, compared to net non-operating income of $0.3 million for the three months ended June 30, 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). Net non-operating expenses amounted to $0.9 million for the six months ended June 30, 2015, a change of $2.9 million, compared to net non-operating income of $2.0 million for the corresponding 2014 period. The reason for the decrease is similar to the one discussed above in the three-month comparison.

Net financial income amounted to $0.2 million for the three months ended June 30, 2015, compared to net financial expense of $0.4 million for the corresponding 2014 period. Net financial income amounted to $0.3 million for the six months ended June 30, 2015, compared to net financial expense of $0.2 million for the corresponding 2014 period. Net financial income (expenses) for the 2015 period primarily relates to investment income earned on our 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 June 30, 2015 amounted to $4.8 million, compared with a net loss of $4.1 million for the corresponding 2014 period. The Company's net loss for the six months ended June 30, 2015 amounted to $9.1 million, compared with a net loss of $6.2 million for the corresponding 2014 period.

The Company held $54.8 million in cash, cash equivalents and short-term bank deposits as of June 30, 2015.

Net cash used in operating activities was $7.2 million for the six months ended June 30, 2015, compared to net cash used in operating activities of $7.7 million for the corresponding 2014 period. The $0.5 million decrease in net cash used in operating activities during the six-month period in 2015, compared to the six-month period in 2014, was primarily the result of an increase in trade payables and accruals.

Net cash used in investing activities for the six months ended June 30, 2015 was $17.9 million, compared to net cash used in investing activities of $15.5 million for the corresponding 2014 period. 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, 2015 was $28.6 million, compared to net cash provided by financing activities of $22.6 million for the corresponding 2014 period. The cash flows from financing activities primarily reflect the 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 second-quarter end June 30, 2015 results today, August 20, 2015, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-668-9141 from the U.S. or +972-3-918-0610 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 1-888-782-4291 from the U.S. or +972-3-925-5925 internationally. The replay will be available through August 23, 2015.

(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-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; BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study; and BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria).

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	June 30, 2015
	in USD thousands	

Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,790	9,404
Short-term bank deposits	28,890	45,385
Prepaid expenses	221	250
Other receivables	257	653
Total current assets	35,158	55,692
NON-CURRENT ASSETS		
Restricted deposits	166	-
Long-term prepaid expenses	49	57
Property and equipment, net	721	2,489
Intangible assets, net	117	117
Total non-current assets	1,053	2,663
Total assets	36,211	58,355
Liabilities and equity		
CURRENT LIABILITIES		
Accounts payable and accruals:		
Trade	1,654	2,959
Other	1,252	1,193
Total current liabilities	2,906	4,152
NON-CURRENT LIABILITIES		
Warrants	1,500	2,387
Total non-current liabilities	1,500	2,387
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	4,406	6,539
EQUITY		
Ordinary shares	1,055	1,448
Share premium	167,331	195,583
Other reserves	(1,416)	(1,416)
Capital reserve	9,800	10,287
Accumulated deficit	(144,965)	(154,086)
Total equity	31,805	51,816
Total liabilities and equity	36,211	58,355

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CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended June 30,		**Six months ended June 30,**	
	2014	**2015**	**2014**	**2015**
	in USD thousands		**in USD thousands**	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,792)	(2,891)	(5,511)	(6,102)
SALES AND MARKETING EXPENSES	(285)	(299)	(652)	(559)
GENERAL AND ADMINISTRATIVE EXPENSES	(834)	(976)	(1,824)	(1,832)
OPERATING LOSS	(3,911)	(4,166)	(7,987)	(8,493)
NON-OPERATING INCOME (EXPENSES), NET	279	(847)	1,966	(887)
FINANCIAL INCOME	-	205	306	278
FINANCIAL EXPENSES	(435)	(2)	(467)	(19)
NET LOSS	(4,067)	(4,810)	(6,182)	(9,121)
OTHER COMPREHENSIVE LOSS:				
CURRENCY TRANSLATION DIFFERENCES	424	-	288	-
COMPREHENSIVE LOSS	(3,643)	(4,810)	(5,894)	(9,121)

	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.12)	(0.09)	(0.20)	(0.19)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	34,005,072	53,562,019	30,503,968	48,095,879

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2014	**2015**
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,182)	(9,121)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,551)	1,976
Net cash used in operating activities	(7,733)	(7,145)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(30,825)	(39,184)
Maturities of short-term deposits	15,446	22,738
Maturities of restricted deposits	-	166
Purchase of property and equipment	(88)	(1,586)
Purchase of intangible assets	(3)	(7)
Net cash used in investing activities	(15,470)	(17,873)
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	22,612	28,645
Net cash provided by financing activities	22,612	28,645
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(591)	3,627
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	8,899	5,790
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	116	(13)
CASH AND CASH EQUIVALENTS - END OF PERIOD	8,424	9,404

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	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	139	195
Long-term prepaid expenses	2	(8)
Interest on restricted deposits	1	-
Interest and exchange rate differences on short-term deposits	238	(49)
Share-based compensation	498	487

Exchange differences on cash and cash equivalents	(63)	13
Loss (gain) on adjustment of warrants to fair value	(2,314)	887
Commitment fee paid by issuance of share capital	303	-
	(1,196)	1,525
Changes in operating asset and liability items:		
Increase in trade accounts receivable and other receivables	(71)	(425)
Increase (decrease) in accounts payable and accruals	(284)	876
	(355)	451
	(1,551)	1,976
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	-	512
Supplementary information on interest received in cash	28	30

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