BioLineRx Reports Third Quarter 2015 Financial Results

November 16, 2015

TEL AVIV, Israel--(BUSINESS WIRE)--Nov. 16, 2015-- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reported its financial results for the third quarter ended September 30, 2015.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, “Our focus during the third quarter of 2015 was on continued clinical execution, primarily for BL-8040, our lead platform for the treatment of acute myeloid leukemia (AML) and other oncology and hematology indications. While we continued to advance the development of BL-8040 for the treatment of relapsed or refractory AML, as well as stem cell mobilization for transplantation purposes, in August we initiated a clinical study for BL-8040 as a novel consolidation treatment for AML, and we expect to initiate clinical studies in two additional indications in the upcoming months. We are also currently performing an extensive evaluation of BL-8040’s potential in the exciting immuno-oncology space, expanding upon our unique oncology platform. CXCR4 antagonists have been identified as potentially synergistic with immune checkpoint inhibitors. In this regard, we believe BL-8040’s best-in-class qualities make it a great candidate to explore such combinations.”

“Earlier this month we reported positive results from the dose-escalation part of BL-8040’s Phase 2 clinical trial in relapsed or refractory AML, including clinical response (remission) data. The encouraging composite response rate of 38%, which will be presented for the first time at the upcoming American Society of Hematology (ASH) Annual Meeting, together with continued robust mobilization and apoptotic effects, strongly suggest that BL-8040 has potent anti-leukemic activity and, in combination with Ara-C, may improve the response typically achieved in this advanced AML population. We are looking forward to reporting top-line results from this study in early 2016. With regard to BL-8040 as a novel stem cell mobilization treatment, last month we held a meeting with the FDA, which has provided us with substantial clarification regarding the future development plan for this indication. We are gearing up to start a Phase 2 study in stem cell mobilization in the first quarter of 2016.

Dr. Savitsky continued, “After successfully completing a Phase 1/2 study for BL-7010 for the treatment of celiac disease, we are waiting for a response from the EU regulatory authorities regarding classification of BL-7010 as a medical device in Europe. Contingent upon this decision, we are planning to start the next efficacy study in celiac disease in the first half of 2016. In parallel, we are investing considerable efforts in examining alternative development and commercialization pathways for this promising product, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity, which also has a significantly shorter time to market, especially in the US.

“Our partner Omega Pharma, now part of Perrigo, is swiftly progressing in the development of BL-5010 as an OTC solution for the non-surgical removal of benign skin lesions. In September, they submitted an application for CE Mark designation for this product. Assuming successful completion of the CE Mark registration process, we expect the first sales in Europe to begin 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 look forward to in-licensing promising therapeutic candidates for development under the collaboration in the near future. Finally, with over $50 million on our balance sheet, we remain well capitalized to execute on our development program and to achieve significant milestones across our expanded therapeutic pipeline well into 2018, and we look forward to demonstrating our enhanced value proposition over the coming months.”

Financial Results for Quarter and Nine Months Ended September 30, 2015

Research and development expenses for the three months ended September 30, 2015 were $2.6 million, a decrease of $0.4 million, or 13.4%, compared to $3.0 million for the three months ended September 30, 2014. The decrease resulted primarily from decreased spending on BL-1110, BL-7010 and BL-5010 in the 2015 period, partially offset by increased spending on BL-8040. Research and development expenses for the nine months ended September 30, 2015 were $8.7 million, an increase of $0.2 million, or 2.3%, compared to $8.5 million for the nine months ended September 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-7040, BL-5010 and BL-8020.

Sales and marketing expenses for the three months ended September 30, 2015 were $0.3 million, substantially similar to the comparable period in 2014. Sales and marketing expenses for the nine months ended September 30, 2015 were $0.8 million, a decrease of $0.1 million, or 13.9%, compared to $0.9 million for the nine months ended September 30, 2014. The decrease resulted primarily from significant professional fees related to a number of material business development activities carried out during the nine-month period in 2014, which resulted in collaboration and outlicensing agreements.

General and administrative expenses for the three months ended September 30, 2015 were $0.8 million, substantially similar to the comparable period in 2014. General and administrative expenses for the nine months ended September 30, 2015 were $2.6 million, substantially similar to the comparable period in 2014.

The Company’s operating loss for the three months ended September 30, 2015 amounted to $3.6 million, compared with an operating loss of $4.1 million for the corresponding 2014 period. The Company’s operating loss for the nine months ended September 30, 2015 amounted to $12.1 million, substantially similar to the corresponding 2014 period.

Net non-operating income amounted to $2.0 million for the three months ended September 30, 2015, an increase of $0.6 million, compared to net non-operating income of $1.4 million for the three months ended September 30, 2014. Net non-operating income amounted to $1.1 million for the nine months ended September 30, 2015, a decrease of $2.3 million, compared to net non-operating income of $3.4 million for the nine months ended September 30, 2014. Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

Net financial income was immaterial for the three months ended September 30, 2015, compared to net financial income of $2.0 million for the three months ended September 30, 2014. Net financial income amounted to $0.3 million for the nine months ended September 30, 2015, compared to net financial income of $1.8 million for the nine months ended September 30, 2014. 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 significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate.

The Company's net loss for the three months ended September 30, 2015 amounted to $1.6 million, compared with a net loss of $0.7 million for the corresponding 2014 period. The Company's net loss for the nine months ended September 30, 2015 amounted to $10.7 million, compared with a net loss of $6.9 million for the corresponding 2014 period.

The Company held $50.7 million in cash, cash equivalents and short-term bank deposits as of September 30, 2015.

Net cash used in operating activities was $11.0 million for the nine months ended September 30, 2015, substantially similar to the comparable period in 2014.

Net cash used in investing activities for the nine months ended September 30, 2015 was $18.7 million, compared to net cash used in investing activities of $15.6 million for the nine months ended September 30, 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 nine months ended September 30, 2015 was $29.3 million, compared to net cash provided by financing activities of $22.6 million for the nine months ended September 30, 2014. 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 third quarter 2015 results today, November 16, 2015, at 10:00 a.m. EST. 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 1-888-254-7270 from the U.S. or +972-3-925-5928 internationally. The replay will be available through November 19, 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 relapsed/refractory acute myeloid leukemia (AML), has recently initiated a Phase 2b study as an AML consolidation treatment, 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	September 30, 2015
	in USD thousands	
Assets		

CURRENT ASSETS		
Cash and cash equivalents	5,790	5,320
Short-term bank deposits	28,890	45,387
Prepaid expenses	221	186
Other receivables	257	992
Total current assets	35,158	51,885
NON-CURRENT ASSETS		
Restricted deposits	166	-
Long-term prepaid expenses	49	56
Property and equipment, net	721	2,962
Intangible assets, net	117	128
Total non-current assets	1,053	3,146
Total assets	36,211	55,031
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	-	93
Accounts payable and accruals:		
Trade	1,654	2,349
Other	1,252	1,148
Total current liabilities	2,906	3,590
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	-	366
Warrants	1,500	404
Total non-current liabilities	1,500	770
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	4,406	4,360
EQUITY		
Ordinary shares	1,055	1,450
Share premium	167,331	195,950
Other reserves	(1,416)	(1,416)
Capital reserve	9,800	10,400
Accumulated deficit	(144,965)	(155,713)
Total equity	31,805	50,671
Total liabilities and equity	36,211	55,031

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CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		**Nine months ended September 30,**	
	2014	**2015**	**2014**	**2015**
	in USD thousands		**in USD thousands**	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,975)	(2,576)	(8,486)	(8,678)
SALES AND MARKETING EXPENSES	(305)	(265)	(957)	(824)
GENERAL AND ADMINISTRATIVE EXPENSES	(791)	(762)	(2,615)	(2,594)
OPERATING LOSS	(4,071)	(3,603)	(12,058)	(12,096)
NON-OPERATING INCOME, NET	1,380	1,983	3,346	1,096
FINANCIAL INCOME	1,991	85	2,216	363
FINANCIAL EXPENSES	-	(91)	(386)	(111)
NET LOSS	(700)	(1,626)	(6,883)	(10,748)
OTHER COMPREHENSIVE LOSS:				
CURRENCY TRANSLATION DIFFERENCES	(2,027)	-	(1,739)	-
COMPREHENSIVE LOSS	(2,727)	(1,626)	(8,622)	(10,748)

	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.03)	(0.22)	(0.21)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	34,115,051	54,632,788	31,725,364	50,306,892

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 30,	
	2014	2015
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,883)	(10,748)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(4,094)	(232)
Net cash used in operating activities	(10,977)	(10,980)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(40,045)	(51,262)
Maturities of short-term deposits	24,584	34,878
Maturities of restricted deposits	-	166
Purchase of property and equipment	(156)	(2,466)
Purchase of intangible assets	(3)	(22)
Net cash used in investing activities	(15,620)	(18,706)
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	22,612	28,844
Proceeds of bank loan	-	467
Repayments of bank loan	-	(8)
Net cash provided by financing activities	22,612	29,303
DECREASE IN CASH AND CASH EQUIVALENTS	(3,985)	(383)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	8,899	5,790
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(211)	(87)
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,703	5,320

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 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	211	322
Long-term prepaid expenses	10	(7)
Interest on restricted deposits	(11)	-
Interest and exchange rate differences on short-term deposits	(1,609)	(113)
Share-based compensation	781	770
Exchange differences on cash and cash equivalents	(220)	87
Gain on adjustment of warrants to fair value	(3,693)	(1,096)
Commitment fee paid by issuance of share capital	303	-
	(4,228)	(37)
Changes in operating asset and liability items:		
Decrease (increase) in trade accounts receivable and other receivables	365	(700)
Increase (decrease) in accounts payable and accruals	(231)	505
	134	(195)
	(4,094)	(232)
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	-	228
Supplementary information on interest received in cash	51	105

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