



BioLineRx Reports Year End 2015 Financial Results

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TEL AVIV, Israel, March 10, 2016 /PRNewswire/ -- 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 year ended December 31, 2015.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "2015 was a year of significant progress for BioLineRx on several fronts, as we advanced our lead therapeutic clinical programs both from a development and regulatory perspective, and entered into an exciting new collaboration in the immuno-oncology space."

"During the past year, we enhanced and expanded the development strategy for our BL-8040 cancer therapy platform, which is currently being investigated for multiple cancer and hematological indications. These include a Phase 2 study for treating relapsed and refractory AML patients, top line results of which are expected by the end of this month. Results from the first part of this trial continue to demonstrate substantial mobilization of leukemic cells from the bone marrow to the peripheral blood and robust induction of cancer cell apoptosis, which, combined with the reported 38% composite remission rate, strongly suggest that BL-8040 has potent anti-leukemic activity. In addition, we are also assessing BL-8040 as an AML consolidation treatment in a large Phase 2b study that is currently up and running at full steam. Successful top-line safety and efficacy results were also reported from a Phase 1 study in stem cell mobilization, supporting BL-8040 as one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care. We now await receipt of regulatory approval in order to begin, by the end of the month, a Phase 2 trial for BL-8040 as a stem cell mobilizer for allogeneic transplantation. Finally, we are advancing an ongoing Phase 1/2 study for BL-8040 as a novel treatment for hMDS and AA, two bone marrow failure conditions."

"We recently entered the exciting field of immuno-oncology through our collaboration with Merck, a pioneer and world leader in cancer immunotherapy. A Phase 2 study is planned to commence by mid-year investigating BL-8040 in combination with KEYTRUDA[®], Merck's anti-PD-1 immunotherapy, in patients with metastatic pancreatic cancer. Although there have been significant advances in the immuno-oncology field, many cancer types, such as pancreatic cancer, remain resistant to immunotherapy, and combination treatments appear to offer a better chance to treat these cancers. We are therefore enthusiastic about this opportunity to evaluate the potential of our lead drug candidate as a combination therapy with immune checkpoint inhibitors. We are also planning to commence a Phase 2a trial for BL-8040 in the second half of 2016, for the treatment of AML patients with the FLT3-ITD mutation. With the guidance and insight of our newly established Oncology Scientific Advisory Board, consisting of world-renowned key opinion leaders, we look forward to realizing the potential of this promising oncology platform and to reaching several meaningful development milestones during 2016."

"BL-7010, for the treatment of celiac disease and gluten sensitivity, which was found to be safe and well tolerated in a Phase 1/2 trial in celiac patients, has recently received confirmation for the medical device designation pathway in Europe. Over the past year, we have invested considerable efforts in examining the potential of BL-7010 as a food supplement, in order to address the multi-billion dollar market for gluten sensitivity, which we believe has a significantly shorter time to market than drug or device pathways, especially in the US market. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a GRAS designation submission, and preparations for a relatively small clinical trial to support future marketing efforts. We expect to complete these activities by mid-2017, in order to support future expected partnering discussions for the food supplement market in the US and other relevant territories. We also plan to continue to evaluate the pathway in Europe for celiac disease and intend to make a decision about the timing and scope of the next efficacy study for European registration over the next few months."

"Regarding BL-5010, our partner Omega Pharma, now part of Perrigo, is swiftly progressing with its development as an OTC solution for the non-surgical removal of benign skin lesions. Omega Pharma submitted a CE Mark application for BL-5010 during the third quarter of 2015, and has completed the initial manufacturing process automation to support the product's commercial launch, expected during 2016. We also look forward to the potential expansion of this product to other markets and to non-OTC indications."

"During 2015, we invested significant efforts in our new strategic collaboration with Novartis and have been jointly evaluating promising therapeutic candidates to be developed under the collaboration. In addition, we continue to explore other collaboration possibilities for maximizing the value of our current pipeline assets, including some of our non-core programs."

Dr. Savitsky concluded, "Yesterday, we announced the appointment of Dr. Merrill Gersten as our new Chief Scientific Officer. Merrill brings with her many years of leadership in both academia and the pharma industry in the US. I am confident that she will bring great value to BioLineRx and I am very excited to begin working with her. Finally, with almost \$48 million on our balance sheet, we remain well capitalized to execute on our development programs and achieve significant milestones across our expanded therapeutic pipeline well into 2018."

Financial Results for Year Ended December 31, 2015

Research and development expenses for the year ended December 31, 2015 were \$11.5 million, a decrease of \$0.4 million, or 3.4%, compared to \$11.9 million for the year ended December 31, 2014. The decrease resulted primarily from a decrease in spending on BL-7010 and various other projects, partially offset by increased spending on BL-8040.

Sales and marketing expenses for the year ended December 31, 2015 were \$1.0 million, a decrease of \$0.6 million, or 37.5%, compared to \$1.6 million for the year ended December 31, 2014. The decrease resulted primarily from professional fees related to business development activities carried out in 2014, including professional services related to the strategic collaboration agreement with Novartis and the out-licensing agreement with Omega Pharma regarding BL-5010.

General and administrative expenses for the year ended December 31, 2015 were \$3.7 million, a decrease of \$0.1 million, or 2.6%, compared to \$3.8 million for the year ended December 31, 2014. The decrease primarily resulted from a decrease in salary-related payments, partially offset by a small increase in professional fees.

The Company's operating loss for the year ended December 31, 2015 amounted to \$16.2 million, compared with an operating loss of \$17.3 million for the year ended December 31, 2014.

The Company recognized net non-operating income of \$1.4 million for the year ended December, 2015, compared to net non-operating income of \$3.1 million for the year ended December 31, 2014. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of 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 (i.e., warrant revaluation date).

Net financial income amounted to \$0.4 million for the year ended December 31, 2015, compared to net financial income of \$3.1 million for the year ended December 31, 2014. Net financial income for 2015 primarily relates to investment income earned on bank deposits, partially offset by banking fees. The 2014 period also includes significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate prior to adoption of the dollar as the Company's functional and reporting currency, effective as of January 1, 2015.

The Company's net loss for the year ended December 31, 2015 amounted to \$14.4 million, compared with a net loss of \$11.1 million for the year ended December 31, 2014.

The Company held \$47.7 million in cash, cash equivalents and short-term bank deposits as of December 31, 2015.

Net cash used in operating activities for the year ended December 31, 2015 was \$14.2 million, compared to \$15.8 million for the year ended December 31, 2014. The decrease in net cash used in operating activities in 2015 was primarily the result of a decrease in the Company's operating loss.

Net cash used in investing activities for the year ended December 31, 2015 was \$15.6 million, compared to \$19.7 million for the year ended December 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 year ended December 31, 2015 was \$29.5 million, compared to \$32.6 million for the year ended December 31, 2014. The cash flows in 2015 primarily reflect the underwritten public offering of the Company's ADSs in March 2015. The cash flows in 2014 primarily reflect the underwritten public offering of the Company's ADSs in March 2014, as well as the investment made by Novartis pursuant to the strategic collaboration agreement with them signed in December 2014.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its year-end 2015 results today, March 10, 2016, at 10:00 a.m. EST. 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 1-888-254-7270 from the US or +972-3-925-5945 internationally. The replay will be available through March 13, 2016.

(Tables follow)

About BioLineRx

BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2 study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For more information on BioLineRx, please visit www.bioplinerx.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 10, 2016. 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.

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BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,		
	2013	2014	2015
	in USD thousands		
Assets			
CURRENT ASSETS			
Cash and cash equivalents	8,899	5,790	5,544
Short-term bank deposits	9,319	28,890	42,119
Prepaid expenses	258	221	229
Other receivables	360	257	291
Total current assets	<u>18,836</u>	<u>35,158</u>	<u>48,183</u>
NON-CURRENT ASSETS			
Restricted deposits	165	166	-
Long-term prepaid expenses	49	49	58
Property and equipment, net	712	721	2,909
Intangible assets, net	253	117	152
Total non-current assets	<u>1,179</u>	<u>1,053</u>	<u>3,119</u>
Total assets	<u>20,015</u>	<u>36,211</u>	<u>51,302</u>
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term bank loan	-	-	93
Accounts payable and accruals:			
Trade	2,289	1,654	1,910
Other	764	1,252	1,137
Total current liabilities	<u>3,053</u>	<u>2,906</u>	<u>3,140</u>
NON-CURRENT LIABILITIES			
Long-term bank loan, net of current maturities	-	-	344
Warrants	5,240	1,500	208
Total non-current liabilities	<u>5,240</u>	<u>1,500</u>	<u>552</u>
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	<u>8,293</u>	<u>4,406</u>	<u>3,692</u>
EQUITY			
Ordinary shares	640	1,055	1,455
Share premium	134,390	167,331	196,201
Other comprehensive income (loss)	1,418	(1,416)	(1,416)
Capital reserve	9,163	9,800	10,735
Accumulated deficit	<u>(133,889)</u>	<u>(144,965)</u>	<u>(159,365)</u>
Total equity	<u>11,722</u>	<u>31,805</u>	<u>47,610</u>
Total liabilities and equity	<u>20,015</u>	<u>36,211</u>	<u>51,302</u>

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2013	2014	2015
	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES, NET	(12,208)	(11,866)	(11,489)
SALES AND MARKETING EXPENSES	(1,136)	(1,589)	(1,003)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,664)	(3,800)	(3,704)
OPERATING LOSS	<u>(17,008)</u>	<u>(17,255)</u>	<u>(16,196)</u>
NON-OPERATING INCOME, NET	1,161	3,061	1,445
FINANCIAL INCOME	720	3,566	457
FINANCIAL EXPENSES	(1,897)	(448)	(106)
NET LOSS	<u>(17,024)</u>	<u>(11,076)</u>	<u>(14,400)</u>
OTHER COMPREHENSIVE INCOME (LOSS):			
CURRENCY TRANSLATION DIFFERENCES	1,097	(2,834)	-
COMPREHENSIVE LOSS	<u>(15,927)</u>	<u>(13,910)</u>	<u>(14,400)</u>
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	<u>(0.76)</u>	<u>(0.34)</u>	<u>(0.28)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>22,488,516</u>	<u>32,433,883</u>	<u>51,406,434</u>

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	<u>Year ended December 31,</u>		
	<u>2013</u>	<u>2014</u>	<u>2015</u>
	<u>in USD thousands</u>		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(17,024)	(11,076)	(14,400)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(2,501)	(4,674)	232
Net cash used in operating activities	<u>(19,525)</u>	<u>(15,750)</u>	<u>(14,168)</u>
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(35,665)	(57,186)	(63,130)
Maturities of short-term deposits	29,669	37,650	50,083
Maturities of restricted deposits	795	-	166
Purchase of property and equipment	(85)	(187)	(2,683)
Purchase of intangible assets	<u>(32)</u>	<u>(6)</u>	<u>(36)</u>
Net cash used in investing activities	<u>(5,318)</u>	<u>(19,729)</u>	<u>(15,600)</u>
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	15,108	32,635	29,053
Proceeds of bank loan	-	-	467
Repayments of bank loan	(37)	-	(31)
Proceeds from exercise of employee stock options	<u>3</u>	<u>-</u>	<u>-</u>
Net cash provided by financing activities	<u>15,074</u>	<u>32,635</u>	<u>29,489</u>
DECREASE IN CASH AND CASH EQUIVALENTS	(9,769)	(2,844)	(279)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	18,307	8,899	5,790
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	361	(265)	33
CASH AND CASH EQUIVALENTS - END OF YEAR	<u>8,899</u>	<u>5,790</u>	<u>5,544</u>

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	<u>Year ended December 31,</u>		
	<u>2013</u>	<u>2014</u>	<u>2015</u>
	<u>in USD thousands</u>		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	318	269	441
Write-off of intangible assets	38	105	-
Retirement benefit obligations	2	(42)	-
Long-term prepaid expenses	10	(6)	(9)
Exchange differences on cash and cash equivalents	653	(261)	(33)
Warrant issuance costs	130	-	-
Gain on adjustment of warrants to fair value	(1,432)	(3,454)	(1,292)

Commitment fee paid by issuance of share capital	-	303	-
Share-based compensation	842	1,055	1,152
Interest and exchange differences on short-term deposits	395	(2,787)	(182)
Interest and linkage differences on bank loan	(3)	-	1
Interest and exchange differences on restricted deposits	11	(20)	-
	<u>964</u>	<u>(4,838)</u>	<u>78</u>

Changes in operating asset and liability items:

Decrease (increase) in trade accounts receivable and other receivables	253	80	(42)
Increase (decrease) in accounts payable and accruals	<u>(3,718)</u>	<u>84</u>	<u>196</u>
	<u>(3,465)</u>	<u>164</u>	<u>154</u>
	<u>(2,501)</u>	<u>(4,674)</u>	<u>232</u>

Supplementary information on investing and financing activities not involving cash flows:

Credit received in connection with purchase of property and equipment	-	143	87
	<u>-</u>	<u>143</u>	<u>87</u>

Supplementary information on interest received in cash	<u>139</u>	<u>97</u>	<u>173</u>
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