



BioLineRx Reports First Quarter 2016 Financial Results

May 17, 2016

TEL AVIV, Israel, May 17, 2016 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/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, 2016.

Highlights and achievements during the first quarter of 2016, and to date:

- Signing of immuno-oncology collaboration with Merck for BL-8040 Phase 2a study in pancreatic cancer
- Successful top-line results from Phase 2a study for BL-8040 in r/r AML
- Continued ramp-up of Phase 2b study for BL-8040 as consolidation treatment for AML patients following standard induction treatment
- Initiation of Phase 2 study for BL-8040 in allogeneic stem-cell transplantation
- Receipt of medical device classification for BL-7010 for celiac disease in Europe
- BL-5010 for non-surgical removal of skin lesions receives CE mark and begins initial product launch in Europe

Expected upcoming significant milestones for the remainder of 2016:

- Initiation of Phase 2a study for BL-8040 in combination with KEYTRUDA®, in patients with metastatic pancreatic cancer, expected mid-year
- Full set of data from Phase 2a study for BL-8040 in r/r AML to be provided at an upcoming US-based scientific conference
- Partial results from Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by end of 2016
- Initiation of efficacy study in gluten sensitivity for BL-7010
- Roll-out of BL-5010 product launch by Omega to additional countries and selection of 2nd OTC indication for development

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "During the first quarter of 2016, we made significant progress in advancing BL-8040, our lead oncology platform. We announced successful results in our Phase 2a study for relapsed and refractory AML and we continue to push forward in our Phase 2b trial in an earlier treatment line for AML - as a consolidation treatment following standard induction treatment. We also announced our entering into the exciting field of immuno-oncology, through our collaboration with Merck on a Phase 2a study to investigate BL-8040 in combination with KEYTRUDA® for the treatment of pancreatic cancer. In addition, we are progressing with our strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. Novartis has flagged several pre-clinical projects, which we intend to bring into our pipeline over the next few months. With \$45 million of cash on our balance sheet as of the end of the first quarter, we are well positioned to carry out our strategic and operational plans through the end of 2018, and look forward to achieving our expected milestones during the second half of 2016."

Financial Results for First Quarter Ended March 31, 2016

Research and development expenses for the three months ended March 31, 2016 were \$2.5 million, a decrease of \$0.7 million, or 20.9%, compared to \$3.2 million for the three months ended March 31, 2015. The decrease resulted primarily from the conclusion of one of the clinical trials for BL-8040 in 2015, and the wind-down of a second clinical trial for BL-8040 during the 2016 period.

Sales and marketing expenses for the three months ended March 31, 2016 were \$0.2 million, substantially similar to the comparable period in 2015.

General and administrative expenses for the three months ended March 31, 2016 were \$1.0 million, an increase of \$0.1 million, or 15.5%, compared to \$0.9 million for the three months ended March 31, 2015. The small increase was the cumulative effect of an increase in several categories of expenses, none of which individually was material.

The Company's operating loss for the three months ended March 31, 2016 amounted to \$3.8 million, compared with an operating loss of \$4.3 million for the corresponding 2015 period.

Non-operating income (expenses) for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Financial income (expenses), net for the three months ended March 31, 2016 and 2015 were not material, and primarily relate to investment income earned on bank deposits, as well as banking fees.

The Company's net loss for the three months ended March 31, 2016 amounted to \$3.5 million, compared with a net loss of \$4.3 million for the corresponding 2015 period.

The Company held \$45.0 million in cash, cash equivalents and short-term bank deposits as of March 31, 2016

Net cash used in operating activities was \$4.2 million for the three months ended March 31, 2016, compared with net cash used in operating activities of \$3.5 million for the 2015 period. The \$0.7 million increase in net cash used in operating activities was primarily the result of a decrease in trade payables and accruals.

Net cash provided by investing activities for the three months ended March 31, 2016 was \$1.7 million, compared to net cash used in investing activities of \$20.7 million for the corresponding 2015 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 three months ended March 31, 2016 was \$1.6 million, compared to net cash provided by financing activities of \$26.5 million for the corresponding 2015 period. The decrease in cash flows from financing activities reflects the underwritten public offering completed by the Company in March 2015.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its first-quarter end March 31, 2016 results today, May 17, 2016, 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 1-888-295-2634 from the US or +972-3-925-5945 internationally. The replay will be available through May 20, 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 has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment, and has recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; 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 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For additional information on BioLineRx, please visit the Company's website at www.bioplinrx.com, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).

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.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

	<u>December 31,</u>	<u>March 31,</u>
	<u>2015</u>	<u>2016</u>
	<u>in USD thousands</u>	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,544	4,584
Short-term bank deposits	42,119	40,423
Prepaid expenses	229	466
Other receivables	291	396
Total current assets	<u>48,183</u>	<u>45,869</u>

NON-CURRENT ASSETS		
Long-term prepaid expenses	58	56
Property and equipment, net	2,909	2,859
Intangible assets, net	152	157
Total non-current assets	<u>3,119</u>	<u>3,072</u>
Total assets	<u><u>51,302</u></u>	<u><u>48,941</u></u>

Liabilities and equity

CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	1,910	1,465
Other	1,137	1,001
Total current liabilities	<u>3,140</u>	<u>2,559</u>

NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	344	320
Warrants	208	60
Total non-current liabilities	<u>552</u>	<u>380</u>

COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>3,692</u>	<u>2,939</u>

EQUITY		
Ordinary shares	1,455	1,459
Share premium	196,201	197,792
Other comprehensive income (loss)	(1,416)	(1,416)
Capital reserve	10,735	11,021
Accumulated deficit	(159,365)	(162,854)
Total equity	<u>47,610</u>	<u>46,002</u>
Total liabilities and equity	<u><u>51,302</u></u>	<u><u>48,941</u></u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended	
	March 31,	
	2015	2016
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(3,211)	(2,539)
SALES AND MARKETING EXPENSES	(260)	(248)
GENERAL AND ADMINISTRATIVE EXPENSES	(856)	(989)
OPERATING LOSS	(4,327)	(3,776)
NON-OPERATING INCOME (EXPENSES), NET	(40)	148
FINANCIAL INCOME	73	143
FINANCIAL EXPENSES	(17)	(4)
NET LOSS AND COMPREHENSIVE LOSS	<u>(4,311)</u>	<u>(3,489)</u>
	in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.101)</u>	<u>(0.064)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>42,506,905</u>	<u>54,870,561</u>

BioLineRx Ltd.
CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

Ordinary	Share	Other	Capital	Accumulated	Total
shares	premium	comprehensive	reserve	deficit	Total
		income (loss)			
in USD thousands					

BALANCE AT JANUARY 1, 2015	1,055	167,331	(1,416)	9,800	(144,965)	31,805
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2015:						
Issuance of share capital, net	365	26,095	-	-	-	26,460
Share-based compensation	-	-	-	234	-	234
Comprehensive loss for the period	-	-	-	-	(4,311)	(4,311)
BALANCE AT MARCH 31, 2015	1,420	193,426	(1,416)	10,034	(149,276)	54,188

	Ordinary shares	Share premium	Other comprehensive income (loss)	Capital reserve	Accumulated Deficit	Total
in USD thousands						
BALANCE AT JANUARY 1, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Share-based compensation	-	-	-	286	-	286
Comprehensive loss for the period	-	-	-	-	(3,489)	(3,489)
BALANCE AT MARCH 31, 2016	1,459	197,792	(1,416)	11,021	(162,854)	46,002

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Three months ended March 31,	
	2015	2016
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(4,311)	(3,489)
Adjustments required to reflect net cash used in operating activities (see appendix below)	843	(695)
Net cash used in operating activities	<u>(3,468)</u>	<u>(4,184)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(31,153)	(10,300)
Maturities of short-term deposits	10,634	12,102
Purchase of property and equipment	(149)	(137)
Purchase of intangible assets	(2)	(11)
Net cash provided by (used in) investing activities	<u>(20,670)</u>	<u>1,654</u>
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	26,460	1,595
Repayments of bank loan	-	(23)
Net cash provided by financing activities	<u>26,460</u>	<u>1,572</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,322	(958)

CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,790	5,544
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(37)	(2)
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>8,075</u>	<u>4,584</u>

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Three months ended	
	March 31,	
	2015	2016
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	102	122
Long-term prepaid expenses	(1)	2
Interest on short-term deposits	(9)	(106)
Share-based compensation	234	286
Exchange differences on cash and cash equivalents	37	2
Interest and linkage differences on bank loan	-	(1)
Loss (gain) on adjustment of warrants to fair value	40	(148)
	<u>403</u>	<u>157</u>
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(459)	(342)
Increase (decrease) in accounts payable and accruals	899	(510)
	<u>440</u>	<u>(852)</u>
	<u>843</u>	<u>(695)</u>
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	<u>30</u>	<u>103</u>

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