BioLineRx Reports Second Quarter 2016 Financial Results

August 11, 2016

TEL AVIV, Israel, Aug. 11, 2016 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reports its financial results for the second quarter ended June 30, 2016.

Highlights and achievements during second quarter of 2016 and to date:

- Submission of regulatory filings to initiate Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA®, under immuno-oncology collaboration with Merck announced earlier this year
- Signing of additional immuno-oncology collaboration, this time with MD Anderson Cancer Center, for second Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA
- Continued enrollment in large (n=194), randomized Phase 2b study for BL-8040 as consolidation treatment for AML patients following standard induction treatment
- Commercial launch of BL-5010 as OTC treatment for non-surgical removal of skin lesions by Omega Pharma (a division of Perrigo), following CE Mark approval in March
- In-licensing of liver fibrosis project under Novartis collaboration
- Philip A. Serlin appointed Chief Executive Officer, effective October 2016

Expected upcoming significant milestones for remainder of 2016:

- Initiation of Phase 2a study in pancreatic cancer, under immuno-oncology collaboration with Merck, following expected regulatory approval in Q3 2016
- Second Phase 2a immuno-oncology study in pancreatic cancer, under collaboration with MD Anderson Cancer Center, expected to commence by end of 2016
- Full set of data from Phase 2a study for BL-8040 in r/r AML to be presented at the Society of Hematologic Oncology (SOHO) annual meeting, September 7-10, 2016, in Houston, Texas
- Partial results from Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by end of 2016
- Regulatory submission for BL-7010 clinical efficacy study, for marketing purposes as food supplement
- Expansion of commercial rollout of BL-5010 by Omega to additional countries and development of 2nd OTC indication for the product

Philip A. Serlin, Chief Financial and Operating Officer of BioLineRx, remarked, "The second quarter of 2016 highlighted the continued execution of our plans as we advance and expand our lead oncology platform, BL-8040; see the initial market penetration of BL-5010; continue the development of BL-7010 as a food supplement, and maintain active asset screening and in-licensing activities with Novartis.

"We are pleased to have entered into an immuno-oncology collaboration with MD Anderson for a second Phase 2a study of BL-8040 with Merck's KEYTRUDA in pancreatic cancer, which provides additional validation of the potential of our lead oncology drug platform in the cancer immunotherapy space. We continue to examine other potential collaborations in this space. In addition, we are looking forward to announcing full results from our successful Phase 2a study for relapsed and refractory AML at the upcoming Society of Hematology Oncology Meeting in September 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 look forward to initiating our Phase 2a study in pancreatic cancer under our collaboration with Merck, expected by the end of this quarter," added Mr. Serlin.

"BL-5010, our first product in the market, is already being sold in a number of countries in Europe. Omega Pharma plans to continue to gradually launch the product in additional European countries over the next 6-9 months, and beyond that time frame, to additional territories. To date, we have not recorded material revenues from this collaboration, but we expect revenues to gradually increase as the first product launch expands and the second product launch commences. In addition, we have in-licensed a drug candidate for the treatment of liver fibrosis, specifically nonalcoholic steatohepatitis (NASH), under our strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and we expect to in-license additional promising projects to the collaboration in the next few months," continued Mr. Serlin.

"In closing, we ended the second quarter with $41.8 million of cash on our balance sheet. With our focus on achieving our expected milestones, we remain well positioned to carry out our strategic and operational plans," Mr. Serlin concluded.

Financial Results for Second Quarter Ended June 30, 2016

Research and development expenses for the three months ended June 30, 2016 were $2.7 million, a decrease of $0.2 million, or 5.2%, compared to $2.9 million for the comparable period in 2015. The small decrease resulted primarily from lower spending on BL-7010 in the 2016 period, partially offset by increased spending related to clinical trial preparations for BL-8040. Research and development expenses for the six months ended June 30, 2016 were $5.3 million, a decrease of $0.8 million, or 13.5%, compared to $6.1 million for the comparable period in 2015. The decrease resulted primarily from lower expenditures for BL-7010 during the 2016 period, as well as the conclusion of one of the clinical trials for BL-8040 in 2015.

Sales and marketing expenses for the three months ended June 30, 2016 were $0.3 million, similar to the comparable period in 2015. Sales and marketing expenses for the six months ended June 30, 2016 were $0.5 million, similar to the comparable period in 2015.

General and administrative expenses for the three months ended June 30, 2016 were $0.9 million, a decrease of $0.1 million, or 12.5%, compared to $1.0 million for the comparable period in 2015. The small decrease resulted primarily from a decrease in salary-related payments and depreciation. General and administrative expenses for the six months ended June 30, 2016 were $1.8 million, similar to the comparable period in 2015.

The Company's operating loss for the three months ended June 30, 2016 amounted to $3.8 million, compared with an operating loss of $4.2 million for the corresponding 2015 period. The Company's operating loss for the six months ended June 30, 2016 amounted to $7.6 million, compared with an operating loss of $8.5 million for the corresponding 2015 period.

Non-operating income (expenses) for the three and six months ended June 30, 2016 and 2015 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. These fair-value adjustments, which were not material in the 2016 periods, are highly influenced by the Company's share price at each period end (revaluation date).

Financial income (expenses), net for the three and six months ended June 30, 2016 and 2015 primarily relate to investment income earned on bank deposits, as well as banking fees. The decrease from 2015 to 2016 reflects a lower cash balance and a continued reduction in global investment yields.

The Company's net loss for the three months ended June 30, 2016 amounted to $3.7 million, compared with a net loss of $4.8 million for the corresponding 2015 period. The Company's net loss for the six months ended June 30, 2016 amounted to $7.2 million, compared with a net loss of $9.1 million for the corresponding 2015 period.

The Company held $41.8 million in cash, cash equivalents and short-term bank deposits as of June 30, 2016.

Net cash used in operating activities was $7.4 million for the six months ended June 30, 2016, compared with net cash used in operating activities of $7.1 million for the comparable period in 2015. The $0.3 million increase in net cash used was primarily the result of a decrease in trade payables and accruals.

Net cash provided by investing activities for the six months ended June 30, 2016 was $4.2 million, compared to net cash used in investing activities of $17.9 million for the comparable period in 2015. 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, 2016 was $1.5 million, compared to net cash provided by financing activities of $28.6 million for the comparable period in 2015. The decrease in cash flows from financing activities reflects the underwritten public offering which was completed in March 2015.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its second quarter end June 30, 2016 results today, August 11, 2016, at 10:00 a.m. EDT. To access the conference call, please dial 1-866-652-8972 from the US, or +972-3-918-0687 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 1-888-326-9310 from the US or +972-3-925-5904 internationally. The replay will be available through August 14, 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.biolinerx.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.

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2015	June 30, 2016
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,544	3,877
Short-term bank deposits	42,119	37,945
Prepaid expenses	229	324
Other receivables	291	548
Total current assets	48,183	42,694
NON-CURRENT ASSETS		
Long-term prepaid expenses	58	54
Property and equipment, net	2,909	2,770
Intangible assets, net	152	162
Total non-current assets	3,119	2,986
Total assets	51,302	45,680
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	1,910	1,732
Other	1,137	980
Total current liabilities	3,140	2,805
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	344	296
Warrants	208	15
Total non-current liabilities	552	311
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,692	3,116
EQUITY		
Ordinary shares	1,455	1,459
Share premium	196,201	197,858
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,735	11,251
Accumulated deficit	(159,365)	(166,588)
Total equity	47,610	42,564
Total liabilities and equity	51,302	45,680

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2016	2015	2016
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,891)	(2,740)	(6,102)	(5,279)
SALES AND MARKETING EXPENSES	(299)	(272)	(559)	(520)
GENERAL AND ADMINISTRATIVE EXPENSES	(976)	(854)	(1,832)	(1,843)
OPERATING LOSS	(4,166)	(3,866)	(8,493)	(7,642)
NON-OPERATING INCOME (EXPENSES), NET	(847)	48	(887)	196
FINANCIAL INCOME	205	88	278	232
FINANCIAL EXPENSES	(2)	(5)	(19)	(9)
NET LOSS AND COMPREHENSIVE LOSS	(4,810)	(3,735)	(9,121)	(7,223)

	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.09)	(0.07)	(0.19)	(0.13)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	53,562,019	56,423,601	48,095,879	55,651,371

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

	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2015	1,055	167,331	(1,416)	9,800	(144,965)	31,805
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2015:						
Issuance of share capital, net	393	28,252	-	-	-	28,645
Share-based compensation	-	-	-	487	-	487
Comprehensive loss for the period	-	-	-	-	(9,121)	(9,121)
BALANCE AT JUNE 30, 2015	1,448	195,583	(1,416)	10,287	(154,086)	51,816

	Ordinary shares	Share premium	Other comprehensive 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 SIX MONTHS ENDED JUNE 30, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options forfeited and expired	-	66	-	(66)	-	-
Share-based compensation	-	-	-	582	-	582
Comprehensive loss for the period	-	-	-	-	(7,223)	(7,223)
BALANCE AT JUNE 30, 2016	1,459	197,858	(1,416)	11,251	(166,588)	42,564

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

	Six months ended June 30,	
	2015	2016
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(9,121)	(7,223)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,976	(223)
Net cash used in operating activities	(7,145)	(7,446)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(39,184)	(19,804)
Maturities of short-term deposits	22,738	24,182

Maturities of restricted deposits	166	-
Purchase of property and equipment	(1,586)	(164)
Purchase of intangible assets	(7)	(24)
Net cash provided by (used in) investing activities	(17,873)	4,190
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	28,645	1,595
Repayments of bank loan	-	(48)
Net cash provided by financing activities	28,645	1,547
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,627	(1,709)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,790	5,544
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(13)	42
CASH AND CASH EQUIVALENTS - END OF PERIOD	9,404	3,877

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

	Six months ended June 30,	
	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	195	245
Long-term prepaid expenses	(8)	4
Interest and exchange rate differences on short-term deposits	(49)	(204)
Share-based compensation	487	582
Exchange differences on cash and cash equivalents	13	(42)
Loss (gain) on adjustment of warrants to fair value	887	(193)
	1,525	392
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(425)	(352)
Increase (decrease) in accounts payable and accruals	876	(263)

	451	(615)
	1,976	(223)
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	30	192

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