BioLineRx Reports First Quarter 2017 Financial Results

May 25, 2017

TEL AVIV, Israel, May 25, 2017 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the first quarter ended March 31, 2017.

Highlights and achievements during the first quarter 2017 and to date:

Continued advancing the Company's lead project, BL-8040, in an extensive clinical development program:

- Announced plans to initiate Phase 3 pivotal study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation in H2 2017, following successful meeting with the FDA.
- Initiated Phase 2b immuno-oncology collaboration with MD Anderson Cancer Center for additional BL-8040 and KEYTRUDA combination study in pancreatic cancer, as part of strategic cancer immunotherapy collaboration between MSD and MD Anderson Cancer Center.
- Reported partial results on Phase 2 open label study for BL-8040 as novel stem cell mobilization treatment for allogeneic bone-marrow transplantation. Interim results support BL-8040 as a one-day dosing regimen for rapid mobilization of substantial amounts of stem cells, a significant improvement over the current standard-of-care which requires four-to-six daily injections of G-CSF; and
- Reported filing of regulatory submissions to commence a Phase 1b trial for BL-8040 in combination with Genentech's atezolizumab in acute myeloid leukemia (AML), which will be led by BioLineRx. This study is expected to commence in H2 2017.

In parallel, the Company made significant progress in expanding and accelerating its growth potential:

- Acquired Agalimmune Ltd., a UK-based biopharmaceutical company developing cancer immunotherapy treatments, thereby broadening and bolstering BioLineRx's position in immuno-oncology with a second novel lead compound, AGI-134;
- Completed underwritten public offering of American Depository Shares for net proceeds of $26.2 million, which will be used to fund a number of clinical trials, including a Phase 3 pivotal study for BL-8040 in autologous stem-cell mobilization, as well as the aggressive clinical development of both BL-8040 and AGI-134 in the immuno-oncology space.

Expected significant upcoming milestones for 2017 and 2018:

- Partial results from immuno-oncology Phase 2a study for pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA® expected in H2 2017; top line results expected in H2 2018;
- Initiation of Phase 3 pivotal study for BL-8040 in stem-cell mobilization for autologous transplantation in H2 2017;
- Initiation of Phase 1b immuno-oncology studies for BL-8040 in combination with Genentech's atezolizumab in pancreatic, gastric, and non-small cell lung cancer, as well as AML, expected in H2 2017; partial results expected in H2 2018;
- Completion of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation, top line results expected by year end 2017; and
- Initiation of Phase 1 immuno-oncology study for AGI-134 in several solid tumor indications expected in H1 2018.

Philip A. Serlin, Chief Executive Officer of BioLineRx, remarked, "Our 2017 activities have fueled significant excitement at BioLineRx, as we reinforced our position in the high value field of immuno-oncology following our acquisition of a second novel drug compound, AGI-134, and strengthened our balance sheet to fund our main development objectives with support from key fundamental investors. We ended the first quarter with pro forma cash of $57 million, including net proceeds of $26 million from our recent public offering, sufficient to fund – and accelerate - our clinical programs, including both BL-8040 and AGI-134, through late 2019."

"With important catalysts in the next 12-18 months, our team is driven and focused on advancing our asset pipeline. We look forward to providing updates as we execute on our plans," Mr. Serlin concluded.

Financial Results for the First Quarter Ended March 31, 2017

Research and development expenses for the three months ended March 31, 2017 were $3.6 million, an increase of $1.1 million, or 41%, compared to $2.5 million for the three months ended March 31, 2016. The increase resulted primarily from an increase in spending on BL-8040 and an increase in spending on new projects.

Sales and marketing expenses for the three months ended March 31, 2017 were $0.7 million, an increase of $0.4 million, or 175%, compared to $0.3 million for the three months ended March 31, 2016. The increase resulted primarily from market research activities and one-time professional fees related to business development activities.

General and administrative expenses for the three months ended March 31, 2017 were $1.0 million, similar to the comparable period in 2016.

The company's operating loss for the three months ended March 31, 2017 amounted to $5.3 million, compared with an operating loss of $3.8 million for the corresponding 2016 period.

Non-operating income (expenses) for the three months ended March 31, 2017 and 2016 were not material, and primarily related to fair-value adjustments of warrant liabilities.

Net financial income amounted to $0.5 million for the three months ended March 31, 2017, compared to net financial income of $0.1 million for the corresponding 2016 period. The increase in net financial income related primarily to gains recorded on foreign currency hedging transactions.

The Company's net loss for the three months ended March 31, 2017 amounted to $4.9 million, compared with a net loss of $3.5 million for the corresponding 2016 period.

The Company held $30.4 million in cash, cash equivalents and short-term bank deposits as of March 31, 2017. In April 2017, the Company completed an underwritten public offering of its American Depositary Shares for net proceeds of $26.2 million.

Net cash used in operating activities for the three months ended March 31, 2017 was $3.8 million, compared with net cash used in operating activities of $4.2 million for the three months ended March 31, 2016. The $0.4 million decrease in net cash used in operating activities was primarily the result of an increase in trade payables and accruals.

Net cash provided by investing activities for the three months ended March 31, 2017 was $1.4 million, compared to net cash provided by investing activities of $1.7 million for the three months ended March 31, 2016. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the investment in Agalimmune.

Net cash provided by financing activities for the three months ended March 31, 2017 was $2.1 million, compared to net cash provided by financing activities of $1.6 million for the three months ended March 31, 2016. The increase in cash flows from financing activities primarily reflects funding under the share purchase agreement with LPC.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, March 25, 2017, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-668-9141 from the U.S. or +972-3-918-0609 internationally. The call will also be available via webcast and can be accessed through the Investor Relations page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call at the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until May 28, 2017; please dial 1-877-456-0009 from the U.S. or +972-3-925-5946 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds, 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 is expected to initiate a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is expected to initiate a first-in-man study in the first half of 2018. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's Atezolizumab in several Phase 1b studies for multiple solid tumor indications and AML.

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 23, 2017. 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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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	December 31, 2016	March 31, 2017
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	2,201
Short-term bank deposits	33,154	28,167
Prepaid expenses	255	700
Other receivables	223	580
Total current assets	36,101	31,648
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	55
Property and equipment, net	2,605	2,540
Intangible assets, net	181	6,875
Total non-current assets	2,838	9,470
Total assets	38,939	41,118
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	3,450
Other	978	1,631
Total current liabilities	3,661	5,174
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	227
Warrants	1	1
Total non-current liabilities	251	228
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,912	5,402
EQUITY		
Ordinary shares	1,513	1,642
Share premium	199,567	205,892
Capital reserve	10,569	9,659
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(175,206)	(180,061)
Total equity	35,027	35,716
Total liabilities and equity	38,939	41,118

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

	Three months ended March 31,	
	2016	2017
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(2,539)	(3,590)
SALES AND MARKETING EXPENSES	(248)	(681)
GENERAL AND ADMINISTRATIVE EXPENSES	(989)	(1,030)
OPERATING LOSS	(3,776)	(5,301)
NON-OPERATING INCOME (EXPENSES)	148	(5)
FINANCIAL INCOME	143	457
FINANCIAL EXPENSES	(4)	(6)
NET LOSS AND COMPREHENSIVE LOSS	(3,489)	(4,855)
	in USD	

LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.06)	(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	54,870,561	58,620,094

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital Reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2016	1,455	196,201	10,735	(1,416)	(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	11,021	(1,416)	(162,854)	46,002

	Ordinary shares	Share premium	Capital Reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2017	1,513	199,567	10,569	(1,416)	(175,206)	35,027
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2017:						
Issuance of share capital, net	128	4,944	-	-	-	5,072
Employee stock options exercised	1	296	(297)	-	-	-
Employee stock options forfeited and expired	-	1,085	(1,085)	-	-	-
Share-based compensation	-	-	472	-	-	472
Comprehensive loss for the period	-	-	-	-	(4,855)	(4,855)
BALANCE AT MARCH 31, 2017	1,642	205,892	9,659	(1,416)	(180,061)	35,716

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

	Three months ended March 31,	
	2016	2017
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(3,489)	(4,855)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(695)	1,062
Net cash used in operating activities	(4,184)	(3,793)
CASH FLOWS - INVESTING ACTIVITIES		

Investments in short-term deposits	(10,300)	(7,013)
Maturities of short-term deposits	12,102	12,143
Purchase of property and equipment	(137)	(45)
Purchase of intangible assets	(11)	(3,718)
Net cash provided by investing activities	1,654	1,367
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,595	2,087
Repayments of bank loan	(23)	(23)
Net cash provided by financing activities	1,572	2,064
DECREASE IN CASH AND CASH EQUIVALENTS	(958)	(362)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,544	2,469
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(2)	94
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,584	2,201

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

	Three months ended March 31,	
	2016	2017
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	122	119
Long-term prepaid expenses	2	(3)
Exchange differences on cash and cash equivalents	2	(94)
Gain on adjustment of warrants to fair value	(148)	-
Share-based compensation	286	472
Interest and exchange differences on short-term deposits	(106)	(143)
Interest and linkage differences on bank loan	(1)	-
	157	351

Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(342)	(802)
Increase (Decrease) in accounts payable and accruals	(510)	1,513
	(852)	711
	(695)	1,062
Supplementary information on interest received in cash	103	137
Supplementary non-cash investment (see Note 4b)		2,985

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