BioLineRx Reports Third Quarter 2017 Financial Results

November 21, 2017

TEL AVIV, Israel, Nov. 21, 2017 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the third quarter ended September 30, 2017.

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

Continued execution on multiple clinical development studies for BL-8040, the Company's lead oncology program:

- Initiation of two additional Phase 1b/2 studies under collaboration with Genentech, following the first study which was initiated in July 2017. All studies are exploring the combination of BL-8040 with Tecentriq (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy agent.
    - Phase 1b/2 trial for the maintenance treatment of patients with intermediate- and high-risk acute myeloid leukemia (AML) who have achieved complete response (CR) following induction and consolidation therapy.
    - Phase 1b/2 trial for the treatment of gastric cancer. This study is conducted as part of MORPHEUS, Roche's Novel Cancer Immunotherapy Development Platform.
- Completion of enrollment to the COMBAT study, which is investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda, in the treatment of pancreatic cancer patients.
- Regulatory submission to initiate Phase 3 pivotal study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation, expected to commence by the end of 2017, following receipt of regulatory approvals; and

- Several abstracts accepted to key scientific conferences:
    - Oral presentation at the American Society of Hematology (ASH) in December 2017 of pre-clinical data supporting BL-8040 as a robust mobilizer of hematopoietic stem cells associated with long-term engraftment.
    - Poster presentation at the ASCO GI conference of partial results from the monotherapy portion of the Phase 2a COMBAT study in pancreatic cancer. The abstract for this presentation will be published prior to the conference in January 2018.

Expected significant upcoming milestones for 2017 and 2018:

- Partial results from immuno-oncology Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA®, expected to be announced at ASCO GI conference in January 2018; top line results expected in H2 2018;
- Initiation of Phase 3 pivotal study for BL-8040 in stem-cell mobilization for autologous transplantation, expected by the end of 2017;
- Initiation of Phase 1b/2 immuno-oncology study for BL-8040 in combination with Genentech's atezolizumab for non-small cell lung cancer, expected by early 2018. Partial results in Phase 1b/2 solid tumors and AML trials in collaboration with Genentech are expected in H2 2018;
- Initiation of Phase 1 immuno-oncology study for AGI-134 in several solid tumor indications expected in H1 2018;
- Top-line results of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by mid-2018.

Philip A. Serlin, Chief Executive Officer of BioLineRx, remarked, "We are pleased to report third quarter-to-date activities that continue to demonstrate clinical and regulatory execution on our multiple programs. This included timely initiation of the studies under our cancer immunotherapy collaboration with Genentech for gastric cancer and AML, as well as finalization of all preparations for initiation of our Phase 3 GENESIS study in stem cell mobilization. We are also very excited about the completion of enrollment to the COMBAT study, which will allow us to report topline results as planned in H2 2018. By year-end 2017, we remain on track to have one Phase 3 and seven Phase 2 or 1b/2 clinical trials up and running, and in January 2018 we plan to announce partial results from our Phase 2 study in pancreatic cancer under our immunotherapy collaboration with Merck."

Financial Results for the Third Quarter Ended September 30, 2017

Research and development expenses for the three months ended September 30, 2017 were $5.7 million, an increase of $2.7 million, or 91.4%, compared to $3.0 million for the three months ended September 30, 2016. The increase resulted primarily from spending on the recently acquired AGI-134 near-clinical project and from higher expenses in 2017 associated with new BL-8040 studies commenced during the third quarter of 2016 and during 2017. Research and development expenses for the nine months ended September 30, 2017 were $13.3 million, an increase of $5.1 million, or 61.6%, compared to $8.2 million for the nine months ended September 30, 2016. The reason for the increase is the same as that presented in the three-month comparison above.

Sales and marketing expenses for the three months ended September 30, 2017 were $0.2 million, a decrease of $0.2 million, or 39.1%, compared to $0.4 million for the three months ended September 30, 2016. The decrease resulted primarily from market research activities related to BL-8040, as well as legal expenses related to business development collaborations and in-licensing activities, in the 2016 period. Sales and marketing expenses for the nine months ended September 30, 2017 were $1.2 million, an increase of $0.3 million, or 31.2%, compared to $0.9 million for the nine months ended September 30, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

General and administrative expenses for the three months ended September 30, 2017 were $1.1 million, similar to the comparable period in 2016. General and administrative expenses for the nine months ended September 30, 2017 were $3.0 million, similar to the comparable period in 2016.

The Company's operating loss for the three months ended September 30, 2017 amounted to $7.1 million, compared with an operating loss of $4.5 million for the corresponding 2016 period. The Company's operating loss for the nine months ended September 30, 2017 amounted to $17.6 million, compared with an operating loss of $12.1 million for the corresponding 2016 period. The increase in operating loss reflects a significant increase in research and development expenses for the respective periods.

Non-operating income (expenses) for the three and nine months ended September 30, 2017 and 2016 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. Non-operating expenses for the three-month and nine-month periods ended September 30, 2017 primarily result from a $0.3 million fair-value adjustment of derivative liabilities on account of the warrants issued in the direct placement conducted in July 2017. These fair-value adjustments are highly influenced by the Company's share price at each period end (revaluation date).

Net financial income amounted to $0.2 million for the three months ended September 30, 2017, similar to the comparable period in 2016. Net financial income amounted to $0.9 million for the nine months ended September 30, 2017 compared to net financial income of $0.4 million for the nine months ended September 30, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

The Company's net loss for the three months ended September 30, 2017 amounted to $7.2 million, compared with a net loss of $4.3 million for the corresponding 2016 period. The Company's net loss for the nine months ended September 30, 2017 amounted to $17.0 million, compared with a net loss of $11.6 million for the corresponding 2016 period.

The Company held $55.0 million in cash, cash equivalents and short-term bank deposits as of September 30, 2017.

Net cash used in operating activities was $14.2 million for the nine months ended September 30, 2017, compared with net cash used in operating activities of $10.4 million for the nine months ended September 30, 2016. The $3.8 million increase in net cash used in operating activities during the nine-month period in 2017, compared to the nine-month period in 2016, was primarily the result of increased research and development expenses in the 2017 period.

Net cash used in investing activities for the nine months ended September 30, 2017 was $19.5 million, compared to net cash provided by investing activities of $7.3 million for the nine months ended September 30, 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 acquisition of Agalimmune and investment in iPharma.

Net cash provided by financing activities for the nine months ended September 30, 2017 was $37.7 million, compared to net cash provided by financing activities of $1.5 million for the nine months ended September 30, 2016. The increase in cash flows from financing activities primarily reflects our public offering completed in April 2017 and the registered direct placement completed in July 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 21, 2017, at 10:00 a.m. EST. To access the conference call, please dial 1-888-407-2553 from the U.S. or +972-3-918-0664 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 November 24, 2017; please dial 1-866-500-4953 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/2 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.

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

	December 31, 2016	September 30, 2017
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	6,712
Short-term bank deposits	33,154	48,295
Prepaid expenses	255	282
Other receivables	223	558
Total current assets	36,101	55,847
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	60
Long-term investment	-	1,000
Property and equipment, net	2,605	2,365
Intangible assets, net	181	6,855
Total non-current assets	2,838	10,280
Total assets	38,939	66,127
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	4,349
Other	978	1,084
Total current liabilities	3,661	5,526
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	180
Warrants	1	1,396
Total non-current liabilities	251	1,576
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,912	7,102
EQUITY		
Ordinary shares	1,513	2,809
Share premium	199,567	239,606
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,569	10,227
Accumulated deficit	(175,206)	(192,201)
Total equity	35,027	59,025
Total liabilities and equity	38,939	66,127

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2017	2016	2017
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,954)	(5,654)	(8,233)	(13,306)
SALES AND MARKETING EXPENSES	(409)	(249)	(928)	(1,218)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,125)	(1,154)	(2,968)	(3,028)
OPERATING LOSS	(4,488)	(7,057)	(12,129)	(17,552)
NON-OPERATING INCOME (EXPENSES), NET	(14)	(333)	182	(342)
FINANCIAL INCOME	172	153	403	914
FINANCIAL EXPENSES	(4)	(6)	(12)	(15)
NET LOSS AND COMPREHENSIVE LOSS	(4,334)	(7,243)	(11,556)	(16,995)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.08)	(0.07)	(0.21)	(0.20)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	56,426,202	101,874,372	55,912,486	85,106,723

BioLineRx Ltd.

CONDENSED CONSOLIDATED 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, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options exercised	1	128	-	(128)	-	1
Employee stock options forfeited and expired	-	460	-	(460)	-	-
Share-based compensation				959		959
Comprehensive loss for the period	-	-	-	-	(11,556)	(11,556)
BALANCE AT SEPTEMBER 30, 2016	1,460	198,380	(1,416)	11,106	(170,921)	38,609

	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2017	1,513	199,567	(1,416)	10,569	(175,206)	35,027
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2017:						
Issuance of share capital, net	1,295	38,388	-	-	-	39,683
Employee stock options exercised	1	326	-	(326)	-	1
Employee stock options forfeited and expired	-	1,325	-	(1,325)	-	-
Share-based compensation	-	-	-	1,309	-	1,309
Comprehensive loss for the period	-	-	-	-	(16,995)	(16,995)
BALANCE AT SEPTEMBER 30, 2017	2,809	239,606	(1,416)	10,227	(192,201)	59,025

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

	Nine months ended September 30,	
	2016	2017
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(11,556)	(16,995)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,128	2,772
Net cash used in operating activities	(10,428)	(14,223)
CASH FLOWS - INVESTING ACTIVITIES		
Long-term investment	-	(1,000)
Investments in short-term deposits	(28,978)	(48,029)
Maturities of short-term deposits	36,480	33,327
Purchase of property and equipment	(164)	(109)
Purchase of intangible assets	(24)	(3,721)
Net cash provided by (used in) investing activities	7,314	(19,532)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,595	37,761
Repayments of bank loan	(72)	(70)
Proceeds from exercise of employee stock options	1	-
Net cash provided by financing activities	1,524	37,691
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,590)	3,936
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,544	2,469
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	60	307
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,014	6,712

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

	Nine months ended September 30,	
	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	368	381
Long-term prepaid expenses	4	(8)
Interest and exchange rate differences on short-term deposits	(277)	(439)
Share-based compensation	959	1,309
Warrant issuance costs	-	17
Exchange differences on cash and cash equivalents	(60)	(307)
Loss (gain) on adjustment of warrants to fair value	(179)	316
	815	1,269
Changes in operating asset and liability items:		
Decrease (Increase) in prepaid expenses and other receivables	14	(362)
Increase in accounts payable and accruals	299	1,865
	313	1,503
	1,128	2,772
Supplementary information on interest received in cash	310	378
Supplementary non-cash investment (see Note 4b)	-	2,985

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