BioLineRx Reports Significant Progress Across Oncology Programs and Provides Third Quarter Financial Update

November 8, 2018

Management to hold conference call at 10:00 am EST

TEL AVIV, Israel, Nov. 8, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the third quarter ended September 30, 2018 and provided a corporate update.

Highlights and achievements during the third quarter 2018 and subsequent period:

- Reported positive results from lead-in period of Phase 3 GENESIS trial in stem-cell mobilization; data from first lead-in patient cohort prompted Data Monitoring Committee to recommend early continuation to randomized placebo-controlled part 2 of trial;
- Presented data from ongoing Phase 2a COMBAT/KEYNOTE-202 pancreatic cancer study in collaboration with Merck at the ESMO 2018 Congress demonstrating that BL-8040 in combination with KEYTRUDA® (pembrolizumab) showed encouraging disease control and overall survival in patients with metastatic pancreatic cancer; compelling pharmacodynamic data also demonstrated T-cell infiltration into tumors and a reduction of the tumor immuno-suppressive microenvironment;
- Based on COMBAT/KEYNOTE-202 results, announced expansion of immuno-oncology collaboration with Merck to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy;
- Entered into agreement with Biokine Therapeutics to increase the Company's economic stake in BL-8040 to 80% from the previous level of 60%;
- Initiated Phase 1/2a multicenter, open-label clinical study in the UK and Israel for AGI-134, a novel immunotherapy evoking a direct anti-tumor response and vaccine effect for the treatment of solid tumors;

"We made significant progress during the third quarter and subsequent period advancing clinical development of both of our oncology programs – BL-8040 and AGI-134," said Philip Serlin, Chief Executive Officer of BioLineRx. "The Phase 3 GENESIS study in stem-cell mobilization is now advancing in the randomized placebo-controlled part 2 of the trial. We are also rapidly moving forward in our expanded collaboration with Merck in pancreatic cancer, on the basis of the encouraging results recently presented at ESMO, with an additional cohort adding chemotherapy to the BL-8040/KEYTRUDA combination. Further, we are very pleased to have initiated the first-in-human clinical study for AGI-134, our unique immunotherapy cancer vaccine. These achievements follow BL-8040's very promising results in relapsed/refractory AML that were presented at the recent EHA Congress during the second quarter, showing significantly improved overall survival compared to historical data."

"BL-8040 is currently being evaluated in eight Phase 2 or Phase 3 clinical trials in multiple oncology indications, four of which are being run under collaborations with global pharma companies. In addition, based on the very promising data seen in relapsed/refractory AML, we intend to further pursue this indication and we continue to evaluate the optimal clinical development pathway going forward. The broad dataset from BL-8040's robust clinical development program was the motivation behind our recent decision to significantly increase our economics in BL-8040, and sets the stage for a catalyst-rich 2019," Mr. Serlin concluded.

Expected significant milestones through end of 2019:

- Initiation of Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under collaboration with Merck by the end of 2018;
- Potential interim results from Phase 2 AML consolidation study in mid-2019;
- Initial safety results from part 1 of Phase 1/2a trial for AGI-134 in second half of 2019;
- Top-line results from the Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under collaboration with Merck toward the end of 2019;
- Top-line results from one or more of the solid tumor trials under collaboration with Genentech during 2019.

Financial Results for the Third Quarter Ended September 30, 2018

Research and development expenses for the three months ended September 30, 2018 were $5.0 million, a decrease of $0.6 million, or 11.1 %, compared to $5.6 million for the three months ended September 30, 2017. The decrease resulted primarily from higher expenses associated with drug product development and manufacturing for AGI-134 in the 2017 period. Research and development expenses for the nine months ended September 30, 2018 were $14.6 million, an increase of $1.3 million, or 9.6 %, compared to $13.3 million for the nine months ended September 30, 2017. The increase in the 2018 period resulted primarily from higher expenses associated with BL-8040, including the GENESIS and COMBAT trials; preparations for initiation of the AGI-134 clinical trial; and BL-1230.

Sales and marketing expenses for the three months ended September 30, 2018 were $0.3 million, similar to the comparable period in 2017. Sales and marketing expenses for the nine months ended September 30, 2018 were $1.1 million, a decrease of $0.1 million, or 6.7%, compared to $1.2 million for the nine months ended September 30, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 paid in the 2017 period.

General and administrative expenses for the three months ended September 30, 2018 were $0.9 million, a decrease of $0.3 million, or 22.7%, compared to $1.2 million for the three months ended September 30, 2017. The decrease resulted from a decrease in fees paid for consulting services.

General and administrative expenses for the nine months ended September 30, 2018 were $2.9 million, a decrease of $0.2 million, or 5.9%, compared to $3.0 million for the nine months ended September 30, 2017. The decrease also resulted from a decrease in fees paid for consulting services.

The Company's operating loss for the three months ended September 30, 2018 amounted to $6.2 million, compared with an operating loss of $7.1 million for the corresponding 2017 period. The Company's operating loss for the nine months ended September 30, 2018 amounted to $18.6 million, compared with an operating loss of $17.6 million for the corresponding 2017 period.

Non-operating income (expenses) for the three and nine months ended September 30, 2018 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet and the capital gain from realization of the investment in iPharma. Non-operating income (expenses) for the three and nine months ended September 30, 2017 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial income amounted to $0.1 million for the three months ended September 30, 2018, similar to the comparable period in 2017. Net financial income for both periods relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits. Net financial income amounted to $0.4 million for the nine months ended September 30, 2018, compared to net financial income of $0.9 million for the nine months ended September 30, 2017. Net financial income for the 2018 period primarily relates to investment income earned on bank deposits, offset by losses recorded on foreign currency hedging transactions. Net financial income for the 2017 period relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits.

The Company's net loss for the three months ended September 30, 2018 amounted to $6.3 million, compared with a net loss of $7.2 million for the corresponding period. The Company's net loss for the nine months ended September 30, 2018 amounted to $17.3 million, compared with a net loss of $17.0 million for the corresponding 2017 period.

The Company held $35.0 million in cash, cash equivalents and short-term bank deposits as of September 30, 2018.

Net cash used in operating activities was $19.1 million for the nine months ended September 30, 2018, compared with net cash used in operating activities of $14.2 million for the nine months ended September 30, 2017. The $4.9 million increase in net cash used in operating activities during the nine-month period in 2018, compared to the nine-month period in 2017, was the result of increased research and development expenses in the 2018 period, as well as a decrease in accounts payable and increase in prepaid expenses and other receivables.

Net cash provided by investing activities was $16.0 million for the nine months ended September 30, 2018, compared to net cash used in investing activities of $19.5 million for the nine months ended September 30, 2017. The changes in cash flows from investing activities relate primarily relate primarily to investments in, and maturities of, short-term bank deposits, as well as the investment in Agalimmune in 2017 and the realization of the investment in iPharma in 2018.

Net cash provided by financing activities was $2.8 million for the nine months ended September 30, 2018, compared to net cash provided by financing activities of $37.7 million for the nine months ended September 30, 2017. The decrease in cash flows from financing activities reflects the public offering completed in April 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 8, 2018 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 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 on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until November 10, 2018; please dial +1-888-326-9310 from the U.S. or +972-3-925-5925 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 has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. 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, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), 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.

Forward Looking Statement

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 6, 2018. 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, 2017	September 30, 2018
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,110	4,703
Short-term bank deposits	44,373	30,300
Prepaid expenses	307	1,266
Other receivables	586	835
Total current assets	50,376	37,104
NON-CURRENT ASSETS		
Long-term prepaid expenses	61	66
Long-term investment	1,000	-
Property and equipment, net	2,505	2,197
Intangible assets, net	7,023	7,033
Total non-current assets	10,589	9,296
Total assets	60,965	46,400
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	3,804
Other	1,113	1,028
Total current liabilities	6,722	4,925
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	86
Warrants	1,205	804
Total non-current liabilities	1,362	890
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	5,815
EQUITY		
Ordinary shares	2,836	2,922
Share premium	240,682	244,058
Other comprehensive loss	10,337	11,889
Capital reserve	(1,416)	(1,416)
Accumulated deficit	(199,558)	(216,868)
Total equity	52,881	40,585
Total liabilities and equity	60,965	46,400

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2018	2017	2018
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,654)	(5,027)	(13,306)	(14,581)
SALES AND MARKETING EXPENSES	(249)	(293)	(1,218)	(1,137)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,154)	(892)	(3,028)	(2,850)
OPERATING LOSS	(7,057)	(6,212)	(17,552)	(18,568)
NON-OPERATING INCOME (EXPENSES), NET	(333)	(255)	(342)	870
FINANCIAL INCOME	153	154	914	534
FINANCIAL EXPENSES	(6)	(11)	(15)	(146)

NET LOSS AND COMPREHENSIVE LOSS	(7,243)	(6,324)	(16,995)	(17,310)
	in USD		**in USD**	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.07)	(0.06)	(0.20)	(0.16)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	101,874,372	107,110,585	85,106,723	107,040,191

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, 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

	Ordinary shares	**Share premium**	**Other comprehensive loss**	**Capital reserve**	**Accumulated deficit**	**Total**
			in USD thousands			
BALANCE AT JANUARY 1, 2018	2,836	240,682	(1,416)	10,337	(199,558)	52,881
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	85	2,803	-	-	-	2,888
Employee stock options exercised	1	46	-	(47)	-	-
Employee stock options forfeited and expired	-	527	-	(527)	-	-
Share-based compensation	-	-	-	2,126	-	2,126
Comprehensive loss for the period	-	-	-	-	(17,310)	(17,310)
BALANCE AT SEPTEMBER 30, 2018	2,922	244,058	(1,416)	11,889	(216,868)	40,585

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

	Nine months ended September 30,	
	2017	**2018**
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(16,995)	(17,310)
Adjustments required to reflect net cash used in operating activities (see appendix below)	2,772	(1,741)
Net cash used in operating activities	(14,223)	(19,051)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(48,029)	(22,000)
Maturities of short-term deposits	33,327	36,613
Long-term investment	(1,000)	-
Proceeds from realization of long-term investment	-	1,500
Purchase of property and equipment	(109)	(76)
Purchase of intangible assets	(3,721)	(40)
Net cash provided by (used in) investing activities	(19,532)	15,997
CASH FLOWS - FINANCING ACTIVITIES		

Issuance of share capital and warrants, net of issuance costs	37,761	2,888
Repayments of bank loan	(70)	(70)
Net cash provided by financing activities	37,691	2,818
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,936	(236)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	307	(171)
CASH AND CASH EQUIVALENTS - END OF PERIOD	6,712	4,703

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

	Nine months ended September 30,	
	2017	**2018**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	381	414
Long-term prepaid expenses	(8)	(5)
Interest and exchange rate differences on short-term deposits	(439)	(540)
Share-based compensation	1,309	2,126
Warrant issuance costs	17	-
Gain on realization of long-term investment	-	(500)
Interest and linkage differences on bank loan	-	(1)
Exchange differences on cash and cash equivalents	(307)	171
Loss (gain) on adjustment of warrants to fair value	316	(401)
	1,269	1,264
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(362)	(1,208)
Increase (decrease) in accounts payable and accruals	1,865	(1,797)
	1,503	(3,005)
	2,772	(1,741)
Supplementary information on interest received in cash	378	598
Supplementary non-cash investment	2,985	-

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