BioLineRx Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 18, 2021

- Positive results from pharmacoeconomic cost effectiveness study of Motixafortide in stem cell mobilization support its use as standard of care in combination with G-CSF -

- Pre-NDA meeting with FDA set for mid-December; NDA submission planned for H1 2022 -

- Cash and cash equivalents at September 30, 2021 of $62.2 million -

- Management to hold conference call today, November 18, at 10:00 am EST -

TEL AVIV, Israel, Nov. 18, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended September 30, 2021 and provides a corporate update.

Significant events and achievements during the third quarter 2021 and subsequent period:

- Announced statistically significant positive results from a pharmacoeconomic cost effectiveness study supporting Motixafortide's use as the new standard-of-care and primary mobilization agent (in combination with G-CSF) in stem cell mobilization (SCM). The study demonstrated substantial clinical benefits and cost savings in favor of Motixafortide from a significantly higher number of mobilized cells, reduced numbers of apheresis sessions and reduced doses of G-CSF;
- Announced acceptance of an oral presentation, as well as three poster presentations, at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, which is taking place December 11-14. The presentations, which include an oral presentation describing the highly significant and clinically meaningful results from the Company's GENESIS Phase 3 clinical trial in stem cell mobilization (SCM), reflect the versatility of Motixafortide as the backbone of promising new treatments for both hematological and solid tumor cancers;
- Finalized preparations for a pre-NDA meeting with FDA, which is set for mid-December;
- Proceeded with activities in support of a New Drug Application (NDA) submission in stem cell mobilization planned for the first half of 2022;
- Ended the third quarter on a solid financial footing, with cash and cash equivalents of $62.2 million.

"The key highlight since our last quarterly update was the statistically significant positive results from a pharmacoeconomic study of Motixafortide in stem cell mobilization for multiple myeloma patients," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The study demonstrated that use of Motixafortide on top of G-CSF resulted in a net cost savings of $17,000 per patient, not including the cost of Motixafortide, driven by fewer doses of G-CSF and a reduction in the number of apheresis sessions and related costs, versus G-CSF alone. These cost savings should leave substantial room in the future to optimize our pricing strategy for Motixafortide at product launch and thereafter, if approved.

"These results, together with the overwhelmingly positive results from our GENESIS Phase 3 study, which showed that almost 90% of patients collected an optimal number of cells for transplantation following a single administration of Motixafortide and in only one apheresis session, strongly support our view that Motixafortide, in combination with G-CSF, can become the new standard of care in SCM as an upfront, or primary, therapy for all multiple myeloma patients. If approved, this represents a significant advancement in SCM to the benefit of patients and payers alike and, to that end, we plan to submit an NDA to the FDA in the first half of next year.

"Our significant progress in SCM, together with the encouraging results we have seen in trials to date in metastatic pancreatic cancer, reflect the versatility of Motixafortide in both hematological and solid tumor cancers, which we have an opportunity to highlight at this year's ASH meeting next month. Our notable presence at such an important medical conference reflects the excellent progress that we have made to date across these core programs and underscores the momentum that we have entering 2022.

"With over $62 million in cash, we believe we are well financed to achieve our upcoming important and potentially value creating milestones," Mr. Serlin concluded.

Upcoming Expected Milestones:

- Complete pre-NDA meeting with the FDA for SCM, scheduled for mid-December 2021;
- Complete recruitment of part 2 of ongoing Phase 1/2a trial of AGI-134 in solid tumors by end of 2021;
- Announce initial results for Part 2 of Phase 1/2a trial of AGI-134 in solid tumors in first half of 2022;
- Submit NDA for Motixafortide in SCM in first half of 2022.

Financial Results for the Quarter Ended September 30, 2021

Research and development expenses for the three months ended September 30, 2021 were $4.9 million, an increase of $1.4 million, or 41.3%, compared to $3.5 million for the three months ended September 30, 2020. The increase resulted primarily from an increase in expenses associated with the AGI-134 study and a timing difference related to a tax credit received in respect of AGI-134, as well as an increase in payroll and related-expenses due to a company-wide salary reduction related to the COVID-19 pandemic in the comparable 2020 period. Research and development expenses for the nine months ended September 30, 2021 were $14.3 million, an increase of $0.8 million, or 5.9%, compared to $13.5 million for the nine months ended September 30, 2020. The increase resulted primarily from an increase in expenses associated with the AGI-134 study, as well as an increase in payroll and related-expenses due to a company-wide salary reduction related to the COVID-19 pandemic in the comparable 2020

period, offset by lower expenses associated with the completed Motixafortide GENESIS and COMBAT clinical trials.

Sales and marketing expenses for the three months ended September 30, 2021 were $0.2 million, a decrease of $0.1 million, or 20.1%, compared to $0.3 million for the three months ended September 30, 2020. The decrease resulted primarily from lower consultancy services related to Motixafortide. Sales and marketing expenses for the nine months ended September 30, 2021 were $0.7 million, similar to the comparable period in 2020.

General and administrative expenses for the three months ended September 30, 2021 were $1.1 million, an increase of $0.2 million, or 22.3%, compared to $0.9 million for the three months ended September 30, 2020. The increase resulted primarily from an increase in directors' and officers' insurance. General and administrative expenses for the nine months ended September 30, 2021 were $3.1 million, an increase of $0.3 million, or 9.3%, compared to $2.8 million for the nine months ended September 30, 2020. The reason for the increase is similar to the aforementioned increase in the three-month period.

The Company's operating loss for the three months ended September 30, 2021 amounted to $6.2 million, compared to an operating loss of $4.6 million for the quarter ended September 30, 2020. The Company's operating loss for the nine months ended September 30, 2021 was $18.2 million, compared to $17.1 million for the comparable period in 2020.

Non-operating income (expenses) for the three and nine months ended September 30, 2021 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet and issuance expenses of the ATM. Non-operating income (expenses) for the three and nine months ended September 30, 2020 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses and issuance expenses of the ATM.

Net financial expenses for the three months ended September 30, 2021 amounted to $0.2 million compared to net financial expenses of $0.3 million for the three months ended September 30, 2020. Net financial expenses for the nine months ended September 30, 2021 amounted to $0.5 million compared to net financial expenses of $0.9 million for the nine months ended September 30, 2020. Net financial expenses for all periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits.

The Company's net loss for the three months ended September 30, 2021 amounted to $5.7 million, compared with a net loss of $4.6 million for the comparable period in 2020. The Company's net loss for the nine months ended September 30, 2021 amounted to $22.8 million, compared with a net loss of $18.0 million for the comparable period in 2020.

The Company held $62.2 million in cash, cash equivalents and short-term bank deposits as of September 30, 2021.

Net cash used in operating activities was $18.1 million for the nine months ended September 30, 2021, compared with net cash used in operating activities of $17.8 million for the nine months ended September 30, 2020. The $0.3 million increase in net cash used in operating activities in 2021 was primarily the result of an increase in research and development expenses.

Net cash used in investing activities was $42.2 million for the nine months ended September 30, 2021, compared to net cash provided by investing activities of $8.1 million for the nine months ended September 30, 2020. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was $57.6 million for the nine months ended September 30, 2021, compared to net cash provided by financing activities of $10.9 million for the nine months ended September 30, 2020. The cash flows in 2021 primarily reflect the underwritten public offering of our ADSs in January 2021, warrant exercises, and net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital. The cash flows in 2020 primarily reflect two registered direct offerings to institutional investors, net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Thursday, November 18, 2021, at 10:00 a.m. EST. To access the conference call, please dial +1-866-744-5399 from the US or +972-3-918-0644 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 21, 2021; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

(Tables follow)

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

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.

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. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 February 23, 2021. 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)

	December 31, 2020	September 30, 2021
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	16,831	14,077
Short-term bank deposits	5,756	48,128
Prepaid expenses	152	449
Other receivables	141	192
Total current assets	22,880	62,846
NON-CURRENT ASSETS		
Property and equipment, net	1,341	1,016
Right-of-use assets, net	1,355	1,338
Intangible assets, net	21,714	21,705
Total non-current assets	24,410	24,059
Total assets	47,290	86,905
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	3,092	3,575
Accounts payable and accruals:		
Trade	5,918	5,441
Other	1,440	1,128
Lease liabilities	191	169
Total current liabilities	10,641	10,313
NON-CURRENT LIABILITIES		
Warrants	10,218	4,013
Long-term loans, net of current maturities	2,740	-
Lease liabilities	1,661	1,678
Total non-current liabilities	14,619	5,691
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,260	16,004

EQUITY		
Ordinary shares	9,870	20,874
Share premium	279,241	338,051
Warrants	-	975
Capital reserve	12,322	13,154
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(277,987)	(300,737)
Total equity	22,030	70,901
Total liabilities and equity	47,290	86,905

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2021	2020	2021
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(3,484)	(4,923)	(13,546)	(14,340)
SALES AND MARKETING EXPENSES	(309)	(247)	(666)	(731)
GENERAL AND ADMINISTRATIVE EXPENSES	(856)	(1,047)	(2,843)	(3,108)
OPERATING LOSS	(4,649)	(6,217)	(17,055)	(18,179)
NON-OPERATING INCOME (EXPENSES), NET	294	710	(80)	(4,068)
FINANCIAL INCOME	39	52	214	299
FINANCIAL EXPENSES	(302)	(261)	(1,112)	(802)
NET LOSS AND COMPREHENSIVE LOSS	(4,618)	(5,716)	(18,033)	(22,750)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.01)	(0.08)	(0.04)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	296,508,550	708,473,164	231,380,969	646,427,790

BioLineRx Ltd.

CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

	Ordinary Shares	Share premium	Warrants	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2020	4,692	265,938	-	12,132	(1,416)	(247,966)	33,380
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2020:							
Issuance of share capital, net	3,581	4,754	-	-	-	-	8,335
Employee stock options exercised	8	224	-	(224)	-	-	8
Employee stock options forfeited and expired	-	191	-	(191)	-	-	-
Share-based compensation	-	-	-	1,118	-	-	1,118
Comprehensive loss for the period	-	-	-	-	-	(18,033)	(18,033)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	-	12,835	(1,416)	(265,999)	24,808

	Ordinary Shares	Share premium	Warrants	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2021	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2021:							
Issuance of share capital and warrants, net	8,764	39,569	975	-	-	-	49,308
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options forfeited and expired	-	233	-	(233)	-	-	-
Share-based compensation	-	-	-	1,104	-	-	1,104

Comprehensive loss for the period	-	-	-	-	-	(22,750)	(22,750)
BALANCE AT SEPTEMBER 30, 2021	20,874	338,051	975	13,154	(1,416)	(300,737)	70,901

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

	Ordinary Shares	Share premium	Warrants	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JULY 1, 2020	8,281	271,107	-	12,639	(1,416)	(261,381)	29,230
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2020:							
Share-based compensation	-	-	-	196	-	-	196
Comprehensive loss for the period	-	-	-	-	-	(4,618)	(4,618)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	-	12,835	(1,416)	(265,999)	24,808

	Ordinary Shares	Share premium	Warrants	Capital Reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JULY 1, 2021	20,496	335,887	975	12,972	(1,416)	(295,021)	73,893
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2021:							
Issuance of share capital, net	378	2,074	-	-	-	-	2,452
Employee stock options forfeited and expired	-	90	-	(90)	-	-	-
Share-based compensation	-	-	-	272	-	-	272
Comprehensive loss for the period	-	-	-	-	-	(5,716)	(5,716)
BALANCE AT SEPTEMBER 30, 2021	20,874	338,051	975	13,154	(1,416)	(300,737)	70,901

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

	Nine months ended September 30,	
	2020	2021
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(18,033)	(22,750)
Adjustments required to reflect net cash used in operating activities (see appendix below)	259	4,680
Net cash used in operating activities	(17,774)	(18,070)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(28,500)	(70,000)
Maturities of short-term deposits	36,626	27,813
Purchase of property and equipment	(1)	(35)
Net cash provided by (used in) investing activities	8,125	(42,222)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	13,411	49,308
Exercise of warrants	-	10,907
Employee stock options exercised	8	7
Repayments of loans	(2,338)	(2,502)
Repayments of lease liabilities	(162)	(145)
Net cash provided by financing activities	10,919	57,575
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,270	(2,717)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(15)	(37)

CASH AND CASH EQUIVALENTS - END OF PERIOD	6,552	14,077

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

	Nine months ended September 30,	
	2020	**2021**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	737	529
Exchange differences on cash and cash equivalents	15	37
Fair value adjustments of warrants	(727)	4,090
Share-based compensation	1,118	1,104
Warrant issuance costs	593	-
Interest and exchange differences on short-term deposits	(209)	(185)
Interest on loans	370	245
Exchange differences on lease liability	4	(3)
	1,901	5,817
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses and other receivables	125	(348)
Decrease in accounts payable and accruals	(1,767)	(789)
	(1,642)	(1,137)
	259	4,680
Supplemental information on interest received in cash	342	77
Supplemental information on interest paid in cash	671	541
Supplemental information on non-cash transactions:		
Changes in right-of-use asset	-	143
Exercise of warrants (portion related to accumulated fair value adjustments)	-	10,295

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