BioLineRx Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 23, 2020

- Phase 3 GENESIS study in SCM showed statistically significant positive results for primary endpoint in interim analysis; enrollment halted early; topline data in H1 2021 -

- Interim analysis for Phase 2b BLAST study in consolidation AML did not demonstrate statistically significant effect in primary endpoint; study will not continue; Company exploring alternative development options in AML -

- Phase 2a COMBAT/KEYNOTE-202 study in PDAC on track to report full results, including progression free survival and overall survival data, by year end -

- Management to hold conference call today, November 23, at 10:00 am EST -

TEL AVIV, Israel, Nov. 23, 2020 /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, 2020 and provides a corporate update.

Significant events and achievements during the third quarter 2020 and subsequent period:

- Reported positive results from a pre-planned interim analysis of GENESIS Phase 3 trial of motixafortide for stem cell mobilization (SCM) in multiple myeloma patients. The Data Monitoring Committee (DMC) found statistically significant evidence favoring treatment with motixafortide in the primary endpoint, and subsequently issued a recommendation to cease patient enrollment immediately. In accordance with the DMC's recommendation, study enrollment was completed at 122 patients (instead of 177 as originally planned). SCM is the Company's most efficient path to registration;
- Announced initiation of Phase 2 investigator-initiated study of motixafortide in combination with LIBTAYO® and chemotherapy in first-line PDAC. The study is being run by Columbia University;
- Announced initiation of investigator-initiated Phase 1b study, led by Wolfson Medical Center in Holon, Israel, to evaluate motixafortide in patients hospitalized with acute respiratory distress syndrome (ARDS) secondary to COVID-19 and other respiratory viral infections;
- Renewed study enrollment in Part of Phase 1/2a trial for AGI-134, which had been temporarily suspended in the second quarter of 2020 due to clinical operating risks associated with the COVID-19 pandemic;
- Conducted interim analysis for Phase 2b BLAST study in consolidation AML; analysis did not demonstrate statistically significant effect in primary endpoint; DMC recommended not to continue the study.

"The past several months have been very exciting for BioLineRx, highlighted by the very positive result of the interim analysis of our Phase 3 GENESIS study in stem cell mobilization" stated Philip Serlin, Chief Executive Officer of BioLineRx. "A statistically significant benefit in the primary endpoint was observed by combining motixafortide with the standard of care, G-CSF, leading the DMC to recommend that we cease study enrollment at 122 patients, instead of the 177 originally planned. We look forward to publishing final results of the study in the first half of next year, as we continue to advance motixafortide toward registration.

"With regard to the Phase 2b BLAST study in consolidation AML, based on the results of the interim analysis, the DMC recommended not to continue the study. Although we are disappointed by this outcome, particularly following the positive results that we previously observed in our Phase 1/2a study of motixafortide with cytarabine in relapsed/refractory AML, we continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment. We will decide on next steps in AML once we've had a chance to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from this study. I would also like to express our gratitude to the University of Halle, as study sponsor, and Dr. Carsten Müller-Tidow, as principal study investigator, as well as the other investigators and the patients who made this important trial possible.

"Finally, in the coming weeks, we plan to announce full results, including progression free survival (PFS) and overall survival (OS) data, on all study patients from the triple combination arm of our Phase 2a COMBAT/KEYNOTE-202 study in second-line PDAC. We previously shared preliminary positive overall response rate and disease control rate data, on approximately half of the patients enrolled in this study arm, at last year's ESMO IO conference, and we remain optimistic that the combination of motixafortide and KEYTRUDA®, together with chemotherapy, will prove beneficial to survival as well.

"The significant and growing body of data that we are compiling on motixafortide, including the strikingly positive results of the interim analysis in the GENESIS phase 3 study reported last month, reassure us about the unique characteristics of motixafortide as the best-in-class CXCR4 antagonist, and confirm our belief that this promising compound can potentially serve as the backbone of combination therapies to treat a broad range of solid tumor and hematological cancers," Mr. Serlin concluded.

Upcoming Expected Milestones

- Overall final results, including PFS and OS data, from the COMBAT/KEYNOTE-202 Phase 2a triple combination study in second-line PDAC by the end of 2020;
- Final results from the Phase 3 GENESIS trial in SCM in the first half of 2021;

- Preliminary results of the Phase 1b study in ARDS in the first half of 2021;
- Initial results from Part 2 of the Phase 1/2a trial of AGI-134 in solid tumors in the second half of 2021;
- Data from the Columbia University-initiated study of motixafortide in combination with LIBTAYO® and chemotherapy in first-line PDAC in mid-2022;

Financial Results for the Quarter Ended September 30, 2020

Research and development expenses for the three months ended September 30, 2020 were $3.5 million, a decrease of $2.1 million compared to $5.6 million for the comparable period in 2019. The decrease resulted primarily from termination of the BATTLE clinical study for motixafortide in 2019 and from lower expenses associated with the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second and third quarters of 2020. Research and development expenses for the nine months ended September 30, 2020 were $13.5 million, a decrease of $1.7 million, compared to $15.2 million for the nine months ended September 30, 2019. The decrease resulted primarily from lower expenses associated with the motixafortide COMBAT clinical trial and the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic mentioned above.

Sales and marketing expenses for three months ended September 30, 2020 were $0.3 million, an increase of $0.1 million compared to $0.2 million for the comparable period in 2019. The increase resulted primarily from consultancy services and market research for motixafortide offset by a decrease in payroll and related expenses related to a reduction in headcount. Sales and marketing expenses for the nine months ended September 30, 2020 were $0.7 million, similar to the comparable period in 2019**.**

General and administrative expenses for the three months ended September 30, 2020 were $0.9, similar to the comparable period in 2019. General and administrative expenses for the nine months ended September 30, 2020 were $2.8 million, similar to the comparable period in 2019.

The Company's operating loss for the three months ended September 30, 2020 amounted to $4.6 million, compared to an operating loss of $6.6 million for the comparable period in 2019. The Company's operating loss for the nine months ended September 30, 2020 was $17.1 million, compared to $18.7 million for the comparable period in 2019**.**

Non-operating income (expenses) for the three- and nine-month periods ended September 30, 2020 and 2019 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 Company's ATM program.

Net financial expenses for the three months ended September 30, 2020 amounted to $0.3 million compared to net financial expenses of $0.4 million for the comparable period in 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial expenses for the nine months ended September 30, 2020 amounted to $0.9 million, similar to the comparable period in 2019. Net financial expenses for both 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, 2020 amounted to $4.6 million, compared with a net loss of $3.9 million for the comparable period in 2019. The Company's net loss for the nine months ended September 30, 2020 amounted to $18.0 million, compared with a net loss of $15.6 million for the comparable period in 2019.

The Company held $20.8 million in cash, cash equivalents and short-term bank deposits as of September 30, 2020.

Net cash used in operating activities was $17.8 million for the nine months ended September 30, 2020, compared with net cash used in operating activities of $17.2 million for the nine months ended September 30, 2019. The $0.6 million increase in net cash used in operating activities during the nine-month period in 2020 was primarily the result of the decrease in accounts payable and accruals in the 2020 period.

Net cash provided by investing activities was $8.1 million for the nine months ended September 30, 2020, compared to net cash provided by investing activities of $2.1 million for the nine months ended September 30, 2019. 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 $10.9 million for the nine months ended September 30, 2020, compared to net cash provided by financing activities of $16.6 million for the nine months ended September 30, 2019. The cash flows in 2020 primarily reflect the May and June financings and the net proceeds from the Company's ATM program, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering of our ADSs in February 2019, as well as net proceeds from the ATM facility.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 23, 2020 at 10:00 a.m. EST. To access the conference call, please dial +1-866-744-5399 from the US 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 on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until November 25, 2020; please dial +1-877-456-0009 from the US or +972-3-925-5929 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 currently being evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, and for which positive data in respect of the study's primary endpoint was recently

announced from an interim analysis, resulting in early cessation of recruitment. Motixafortide is also being evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD.

BioLineRx is 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. 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. 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 coronavirus outbreak; 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 March 12, 2020. 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, 2019	September 30, 2020
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	6,552
Short-term bank deposits	22,192	14,275
Prepaid expenses	108	269
Other receivables	613	327
Total current assets	28,210	21,423
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,462
Right-of-use assets, net	1,650	1,423
Intangible assets, net	21,891	21,731
Total non-current assets	25,357	24,616
Total assets	53,567	46,039
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	2,969
Accounts payable and accruals:		
Trade	7,794	5,933
Other	1,280	1,374
Lease liabilities	202	200
Total current liabilities	11,968	10,476
NON-CURRENT LIABILITIES		

Warrants	658	5,600
Long-term loans, net of current maturities	5,799	3,554
Lease liabilities	1,762	1,601
Total non-current liabilities	8,219	10,755
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	20,187	21,231
EQUITY		
Ordinary shares	4,692	8,281
Share premium	265,938	271,107
Capital reserve	12,132	12,835
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(265,999)
Total equity	33,380	24,808
Total liabilities and equity	53,567	46,039

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2020	2019	2020
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,558)	(3,484)	(15,252)	(13,546)
SALES AND MARKETING EXPENSES	(201)	(309)	(683)	(666)
GENERAL AND ADMINISTRATIVE EXPENSES	(884)	(856)	(2,763)	(2,843)
OPERATING LOSS	(6,643)	(4,649)	(18,698)	(17,055)
NON-OPERATING INCOME (EXPENSES), NET	3,055	294	3,976	(80)
FINANCIAL INCOME	247	39	628	214
FINANCIAL EXPENSES	(597)	(302)	(1,484)	(1,112)
NET LOSS AND COMPREHENSIVE LOSS	(3,938)	(4,618)	(15,578)	(18,033)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.03)	(0.02)	(0.11)	(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	148,920,707	296,508,550	142,527,942	231,380,969

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

	Ordinary Shares	Share premium	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
			in USD thousands			
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	1,018	11,266	-	-	-	12,284
Employee stock options exercised	1	53	(53)	-	-	1
Employee stock options forfeited and expired	-	919	(919)	-	-	-
Share-based compensation	-	-	1,170	-	-	1,170
Comprehensive loss for the period	-	-	-	-	(15,578)	(15,578)
BALANCE AT SEPTEMBER 30, 2019	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	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

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

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JULY 1, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	128	829	-	-	-	957
Employee stock options exercised	-	26	(26)	-	-	-
Employee stock options forfeited and expired	-	53	(53)	-	-	-
Share-based compensation	-	-	397	-	-	397
Comprehensive loss for the period	-	-	-	-	(3,938)	(3,938)
BALANCE AT SEPTEMBER 30, 2019	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	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:						
Issuance of share capital, net	-	-	-	-	-	-
Employee stock options exercised	-	-	-	-	-	-
Employee stock options forfeited and expired	-	-	-	-	-	-
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

BioLineRx Ltd
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Nine months ended September 30,	
	2019	2020
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(15,578)	(18,033)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,658)	259
Net cash used in operating activities	(17,236)	(17,774)

CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(34,517)	(28,500)
Maturities of short-term deposits	36,637	36,626
Purchase of property and equipment	(54)	(1)
Net cash provided by investing activities	2,066	8,125
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	16,836	13,411
Employee stock options exercised	1	8
Repayments of loans	(70)	(2,338)
Repayments of lease liabilities	(165)	(162)
Net cash provided by financing activities	16,602	10,919
INCREASE IN CASH AND CASH EQUIVALENTS	1,432	1,270
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	49	(15)
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,885	6,552

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

	Nine months ended September 30,	
	2019	**2020**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	667	737
Long-term prepaid expenses	(3)	-
Exchange differences on cash and cash equivalents	(49)	15
Fair value adjustments of warrants	(4,429)	(727)
Share-based compensation	1,170	1,118
Warrant issuance costs	417	593
Interest and exchange differences on short-term deposits	(628)	(209)
Interest on loans	512	370
Exchange differences on lease liability	-	4
	(2,343)	1,901
Changes in operating asset and liability items:		
Decrease in prepaid expenses and other receivables	265	125
Increase (decrease) in accounts payable and accruals	420	(1,767)
	685	(1,642)
	(1,658)	259
Supplemental information on interest received in cash	628	342
Supplemental information on interest paid in cash	782	671

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